Centers for Disease Control and Prevention

National Center for Emerging and Zoonotic Infectious Diseases

Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases (ELC)

CDC-RFA-CK-24-0002

Application Due Date: April 30, 2024, no later than 11:59pm ET.

2/15/2024: Updated to correct formatting. See pages 150-166.

2/23/2024: Updated (1) Page 24, *Evaluation Plan for 2024* sub-bullets; (2) *Program J: VPD & Respiratory Diseases*, Strategy/Activity numbering; and (3) *Project M: Mycotics*, Estimated Total Availability of Funds.

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Part I. Overview

Applicants must go to the synopsis page of this announcement at www.grants.gov and click on the "Subscribe" button link to ensure they receive notifications of any changes to CDC-RFA-CK-24-0002. Applicants also must provide an e-mail address to www.grants.gov to receive notifications of changes.

A. Federal Agency Name:

Centers for Disease Control and Prevention (CDC)

B. Notice of Funding Opportunity (NOFO) Title:

Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases (ELC)

C. Announcement Type: New - Type 1:

This announcement is only for non-research activities supported by CDC. If research is proposed, the application will not be considered. For purposes of this NOFO, research is defined as set forth in 45 CFR 75.2 and, for further clarity, as set forth in 42 CFR 52.2 (see eCFR :: 45 CFR 75.2 -- Definitions and *https://www.gpo.gov/fdsys/pkg/CFR-2007-title42-vol1/pdf/CFR-2007-title42-vol1-sec52-2.pdf*. In addition, for purposes of research involving human subjects and available exceptions for public health activities, please see 45 CFR 46.102(l) *(https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.102#p-46.102(l))*.

D. Agency Notice of Funding Opportunity Number:

CDC-RFA-CK-24-0002

E. Assistance Listings Number:

93.323

F. Dates:

1. Due Date for Letter of Intent (LOI):

The LOI date will generate once the Synopsis is published if Days or a Date are entered.
Not Applicable
Not applicable

2. Due Date for Applications:
April 30, 2024, no later than 11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov.

3. Due Date for Informational Conference Call
ELC will hold an information webinar.

Date: February 20, 2024
Time: 3:00 PM Eastern Time (US and Canada)
Topic: Informational Webinar for ELC Cooperative Agreement (CK24-0002)

Register in advance for this webinar:
https://cdc.zoomgov.com/webinar/register/WN_dzVsHPEJRBqOqZ7HxuttPA

Or an H.323/SIP room system: H.323: 161.199.138.10 (US West) or 161.199.136.10 (US East)
Meeting ID: 160 865 3428 Passcode: 74827076 SIP: 1608653428@sip.zoomgov.com Passcode: 74827076

After registering, you will receive a confirmation email containing information about joining the webinar.

F. Executive Summary:

Summary Paragraph
The Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases (ELC) Notice of Funding Opportunity (NOFO) builds upon the program that was initiated in 1995 as one of the key activities under CDC's plan to address emerging infectious disease threats. The purpose of this NOFO is to enhance the capacity of public health agencies to effectively detect, respond, prevent and control known and emerging (and re-emerging) infectious diseases. This is accomplished by providing financial and technical resources to (1) strengthen epidemiologic capacity; (2) enhance laboratory capacity; (3) improve information systems including public health informatics goals outlined in CDC's Data Modernization Initiative; and (4) enhance collaboration among epidemiology, laboratory, and information systems components of public health departments.

a. Eligible Applicants:
Open Competition

b. NOFO Type:
CA (Cooperative Agreement)

c. Approximate Number of Awards
65

d. Total Period of Performance Funding:
$1,150,000,000

e. Average One Year Award Amount:
$240,000,000
Figure is estimate only.

This amount is subject to the availability of funds.

f. Total Period of Performance Length:
5 year(s)

g. Estimated Award Date:
August 01, 2024

h. Cost Sharing and / or Matching Requirements:
No

Part II. Full Text

A. Funding Opportunity Description

1. Background

a. Overview
The goal of the Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases (ELC) program is to reduce illnesses, deaths, and related disparities caused by a wide range of infectious disease threats. The ELC Program provides annual funding, strategic direction and technical assistance to domestic jurisdictions for core capacities in epidemiology, laboratory, and health information technology activities. In addition to strengthening core infectious disease capacities nationwide, this cooperative agreement also supports a myriad of specific infectious disease programs.

b. Statutory Authorities
Patient Protection and Affordable Care Act (PL 111-148) (42 USC 300hh-31).

c. Healthy People 2030
The ELC supports the following activities aligned with Healthy People 2030 Topics and Objectives: Food Safety, Health Communication and Health Information Technology, Healthcare Associated Infections, Immunization and Infectious Diseases, Public Health Infrastructure, and Respiratory Diseases.

d. Other National Public Health Priorities and Strategies
Other national public health priorities and strategies are defined in individual program/project guidance.

e. Relevant Work
This ELC Competing Continuation builds upon the program that was initiated in 1995 as one of the first key activities under CDC's plan to address emerging infectious disease threats. The program has grown to become one of CDC's nationwide cooperative agreements for supporting state and local infectious disease capacity for 1) cross-cutting epidemiology, laboratory and health information systems, and 2) specific infectious disease-area Programs and Projects. This also builds upon special one-time funding allocations (e.g., COVID-19) that helped to enhance epidemiology, laboratory, and health information systems to specific disease and health threats.

2. CDC Project Description

a. Approach

Bold indicates period of performance outcome.

Abbreviated ELC Logic Model provided below. See Attachments for complete ELC Logic Model.

Strategies	**Short-Term Outcomes**	**Intermediate Outcomes**	**Long-Term Outcomes**
Enhance and sustain a highly skilled, diverse workforce	Assess public health workforce needs and build workforce capacity Conduct timely investigations	More effective and integrated public health workforce better prepared to respond to infectious disease threats	More timely, complete, and effective investigation efforts to: • Respond to outbreaks • Investigate outbreaks • Implement control measures
Improve surveillance, reporting, investigation, preparedness, and response	Conduct surveillance and analyze, compile, and disseminate data	Improved understanding of the epidemiology and incidence of infectious diseases, including for people who are at increased risk	Improved use of data to: • Inform public health response and control • Develop and implement public health best practices and/or guidelines • Inform program and policy development
Strengthen laboratory testing for surveillance, detection, preparedness, and response	Utilize modern laboratory techniques for surveillance, detection, and response	Improved surveillance resulting in: •Improved completeness, accuracy, and representativeness of data •Increased use of data and distribution to public health partners, communities, and other types of partners	Reduced morbidity, mortality, and health disparities of infectious diseases
Enhance coordination and collaboration among laboratory network partners	Improve AMD capacity in state and local health departments	Expanded and improved PHL core and surge testing capacity	
Sustain and enhance health information	Identify and assess gaps and inefficiencies	Improved efficiency of laboratory operations	

systems, electronic data exchange, and an enterprise infrastructure in line with data modernization efforts	in public health lab (PHL) operations		
Enhance coordination among epidemiology, laboratory, and health information systems	Improve coordination between PHLs and their partners	Improved operational efficiency between PHLs and their network partners	
Support collection, use, and reporting of actionable data, including data to advance health equity	Increase interoperability and data exchange between public health and key partners	Progression toward development of enterprise infrastructure and shared services	
Implement public health interventions and tools	Integrate surveillance information systems to meet public health needs		
Inform policies using a health equity lens	Develop and implement strong public health interventions, tools, and policies using a health equity lens	Increased awareness of protective actions	
Engage and sustain key partnerships	Engage and sustain multi-level and community partnerships		
Disseminate relevant public health information	Ensure timely, accessible communications and outreach tailored for diverse populations		

i. Purpose

The purpose of this NOFO is to protect the public health and safety of the American people by enhancing the capacity of public health agencies to effectively detect, respond, prevent and control known and emerging (or re-emerging) infectious diseases. ELC is CDC's national funding strategy to support state, local, and territorial health departments to address infectious disease threats in the U.S.

ii. Outcomes

As reflected in the ELC Logic Model, awardees are expected to show measurable progress, on an annual basis, made toward the outcomes for this five-year project period. Each of ELC's

Programs and Projects focuses on one or more of these outcomes; and are specified in the 'Outcomes' section of the respective guidance.

iii. Strategies and Activities

Note that each Program/Project has a separate guidance (identified below) which details strategies, activities, and other key criteria. The preparation of your response to this NOFO, and subsequent implementation and monitoring/evaluation of funded activities must be coordinated via and ELC Governance Team.

The framework of the ELC Cooperative Agreement is organized into three major sections of content:

Section I: Cross-cutting Emerging Infectious Disease Capacity, Systems and Leadership

A. Cross-Cutting Epidemiology and Laboratory Capacity

B. ELC Leadership, Management and Administration

C. Health Information Systems Capacity

D. Advanced Molecular Detection (AMD)

E. National Wastewater Surveillance System

F. Emerging Issues

Section II: Emerging Infectious Disease Programs

G. Enteric, Foodborne, Waterborne, and Zoonotic Diseases: Surveillance, Detection, Response, Reporting, and Prevention

H. Healthcare-associated Infections (HAI) and Antimicrobial Resistance (AR)

I. Antimicrobial Resistance Laboratory Network (AR Lab Network)

J. Enhanced Surveillance of Vaccine Preventable Disease (VPD) and Respiratory Diseases

K. Vector-borne Diseases and Tick-Associated Conditions: Building Comprehensive Programs to Identify, Diagnose, Report, Prevent, and Respond

Section III: Disease-Specific Projects

L. Prion Surveillance

M. Mycotics: Detecting and Preventing Fungal Infections

N. Binational Border Infectious Disease Surveillance (BIDS) Program

O. Global Migration, Border Interventions and Migrant Health

P. Parasitic Diseases Surveillance

Q. Combating Antimicrobial Resistant Gonorrhea and Other STIs (CARGOS)

R. Rabies Surveillance and Laboratory Capacity

S. Surveillance for Emerging Threats to Pregnant People and Infants Network (SET-NET)

T. Human Papillomavirus Surveillance Among Men

U. HIV Centers for Cluster and Outbreak Response Enhancement (HIV C-CORE)

As described above, ELC is a complex Cooperative Agreement with cross-cutting and large infectious disease programs, as well as a myriad of disease-specific projects. Within each program or project section, the activities will be grouped by key strategies that link back to the mid- and long-term outcomes (see below and Logic Model in Section 2.a). Programs and Projects will vary in the number of strategies applied, and specific activities associated with these strategies are described in the program and project attachments within this NOFO.

A. Surveillance, Detection and Response

1a: Enhance and sustain a highly skilled, diverse workforce

1b: Improve surveillance, reporting, investigation, preparedness, and response

1c: Strengthen laboratory testing for surveillance, detection, preparedness, and response

1d: Enhance coordination and collaboration among laboratory network partners

1e: Sustain and enhance health information systems, electronic data exchange, and an enterprise infrastructure in line with data modernization efforts

1f: Support collection, use, and reporting of actionable data, including data to advance health equity

B. Prevention and Intervention Strategies

2a: Implement public health interventions and tools

2b: Improve policies using a health equity lens

C. Coordination and Partnerships

3a: Engage and sustain key partnerships

3b: Disseminate relevant public health information

1. Collaborations

Internal coordination for effective ELC portfolio management

Since 2012, all ELC recipients have been required to operate under a governance structure for the management and oversight of the portfolio of ELC activities in their jurisdiction. All ELC recipients are required to maintain an active ELC Governance Team comprised of a Project Director (PD) and representatives from epidemiology, laboratory, health information systems, and fiscal (the PD may serve as a representative for one of these areas). Representatives on the Governance Team should be positioned within the organization such that they may make strategic recommendations and decisions about the activities supported with ELC resources. Members are expected to communicate with other staff regarding various aspects of ELC activities within the jurisdiction. Additionally, and for this new Project Period, there is an expectation that the Governance Team designate a member to work with the Senior Advisory Committee (described in next section).

The role of this Team is to work together to assure sufficient and appropriate oversight and integration of the ELC Cooperative Agreement planning and implementation.

a. With other CDC programs and CDC-funded organizations:
Funding to support the ELC portfolio should complement and be closely coordinated with other CDC programs (e.g., Emerging Infections Program (EIP), Public Health Emergency Preparedness (PHEP), and Public Health Infrastructure Grant (PHIG), etc.) which also provide resources for improving surveillance, preparedness, and response to infectious diseases.

Furthermore, ELC recipients must coordinate with their Senior Advisory Committee, which is described in the Public Health Emergency Preparedness (PHEP) NOFO and where recipients are required to "describe plans for establishing and maintaining a jurisdictional Senior Advisory Committee or an equivalent entity." This concept and requirement for collaboration is (or will be) referenced in other CDC "Infrastructure" Cooperative Agreements such as the Public Health Infrastructure Grant (PHIG) and Preventive Health and Health Services Block Grant. The Senior Advisory Committee should be comprised of senior officials from governmental and non-government organizations. The committee's purpose is to enhance the integration of disciplines involved in homeland security, health care, public health, behavioral health, environmental health, emergency management and emergency medical services, and to oversee resource coordination and alignment across federal resources. The advisory committee must include representatives who can facilitate collaboration on plans for key preparedness funding streams, including Public Health Emergency Preparedness (PHEP), Epidemiology and Laboratory Capacity (ELC), and Public Health Infrastructure Grant (PHIG). ELC is asking each recipients' Governance Team to designate a member of the Governance Team, or staff outside the Governance Team with appropriate authority, to coordinate and collaborate with this Senior Advisory Committee.

Each Program or Project has its own description of required or suggested collaborations if applicable. This information may be found in each of the specific attachments.

b. With organizations not funded by CDC:
The financial assistance provided under the ELC Cooperative Agreement is finite and frequently is inadequate to cover the health department capacity needs in a given budget period. Even when resources are made available, the ELC is aware that there is not a standard approach that can be used to implement activities at the local level (including Local Health Department (LHD)). In providing local support, direct funding is one option; however, considerations of overall management need to be considered. Another approach to local support can be through direct assistance such as having State Health Department staff dedicated to provide outbreak support or assistance with community outreach or partnership building at the local level. Regardless of the type of support (fiscal, direct, combination), the goal is for ELC recipients to actively provide leadership, support and collaborate with the LHDs within their jurisdictions. ELC recipients should be able to report on how this support is being provided and demonstrate the benefit to the LHD and populations they serve.

Where appropriate, ELC recipients are encouraged to coordinate with tribal nations while acknowledging and respecting tribal sovereignty. ELC recipients should describe how they support tribes in areas such as testing, data sharing, and providing technical assistance with surveillance or outbreaks. Coordination and collaboration with tribal nations and the federal

government should also aim to understand and address public health issues on tribal lands within the recipient geographic area.

Each program or project that appears in Part II of this NOFO has its own program guidance that provides collaboration (if applicable) information specific to that CDC program.

2. Population(s) of Focus

Each program or project that appears in Part II of this NOFO has its own program guidance that provides a population of focus (if applicable) specific to that CDC program.

This NOFO, including funding and eligibility, is not limited based on, and does not discriminate on the basis of race, color, national origin, disability, age, sex (including gender identity, sexual orientation, and pregnancy) or other constitutionally protected statuses.

a. Health Disparities

The goal of health equity is for everyone to have a fair and just opportunity to attain their highest level of health. Achieving this requires focused and ongoing societal efforts to address historical and contemporary injustices; overcome economic, social, and other obstacles to health and healthcare; and eliminate preventable health disparities.

Broadly defined, social determinants of health are non-medical factors that influence health outcomes. They are the conditions in which people are born, grow, work, live, and age, and the wider set of forces and systems shaping the conditions of daily life. These forces (e.g., racism, climate) and systems include economic policies and systems, development agendas, social norms, social policies, and political systems. See content below and in other sections (e.g., Approach, Collaborations, Populations of Focus) for information on how this specific NOFO affects social determinants of health.

A health disparity is a preventable difference in the burden of disease, injury, violence, or opportunities to achieve optimal health that are experienced by populations that have been socially, economically, geographically, and environmentally disadvantaged. Health disparities are inextricably linked to a complex blend of social determinants that influence which populations are most disproportionately affected by these diseases and conditions.

ELC strongly encourages recipients to prioritize understanding the drivers of health inequities in their jurisdictions, and recipients should use their funding to reduce inequities as they address existing and emerging infectious diseases within their respective jurisdictions. Recognizing there are many local strategies, activities, and approaches to advance health equity, ELC recipients have a unique role in advancing health equity within this body of work. ELC recipients are expected to coordinate and collaborate within and external to their agency to assess and understand health inequities and take action to reduce them.

The ELC-funded recipients, which are comprised of state, large local, and U.S. territory and affiliate health departments, serve as the foundation for our national public health infrastructure. Incorporating health equity-centered language, principles, and practices into ELC work is a fundamental step toward further strengthening the infrastructure necessary to protect the health of the overall population, including those in areas where the social vulnerability is high (e.g., rural areas, geographic locations experiencing inequities due to climate change or overall infectious disease).

iv. Funding Strategy (amounts and awards are per year averages)
Section I: Cross-cutting Emerging Infectious Disease Capacity, Systems and Leadership

A. Cross-Cutting Epidemiology and Laboratory Capacity; $24,000,000 ; 65 awards

B. ELC Leadership, Management and Administration; $5,800,000; 65 awards

C. Health Information Systems Capacity; $28,000,000; 65 awards

D. Advanced Molecular Detection (AMD); $4,000,000; 65 awards

E. National Wastewater Surveillance System; $6,000,000; 20 awards

F. Emerging Issues; $TBD; TBD awards

Section II: Emerging Infectious Disease Programs

G. Enteric, Foodborne, Waterborne, and Zoonotic Diseases: Surveillance, Detection, Response, Reporting, and Prevention; $33,000,000; 58 awards

H. Healthcare-associated Infections (HAI) and Antimicrobial Resistance (AR); $15,400,000; 65 awards

I. Antimicrobial Resistance Laboratory Network (AR Lab Network); $15,300,000; 65 awards

J. Enhanced Surveillance of Vaccine Preventable Disease (VPD) and Respiratory Diseases; $16,700,000; 60 awards

K. Vector-borne Diseases and Tick-Associated Conditions: Building Comprehensive Programs to Identify, Diagnose, Report, Prevent, and Respond; $14,000,000; 60 awards

Section III: Disease-Specific Projects

L. Prion Surveillance; $500,000; 6 awards

M. Mycotics: Detecting and Preventing Fungal Infections; $1,000,000; 40 awards

N. Binational Border Infectious Disease Surveillance (BIDS) Program; $1,200,000; 4 awards

O. Global Migration, Border Interventions and Migrant Health; $150,000; 2 awards

P. Parasitic Diseases Surveillance; $404,000; 11 awards

Q. Combating Antimicrobial Resistant Gonorrhea and Other STIs (CARGOS); $13,000,000; 20 awards

R. Rabies Surveillance and Laboratory Capacity; $200,000; 20 awards

S. Surveillance for Emerging Threats to Pregnant People and Infants Network (SET-NET); $8,000,000; 26 awards

T. Human Papillomavirus Surveillance Among Men; $375,000; 3 awards

U. HIV Centers for Cluster and Outbreak Response Enhancement (HIV C-CORE); $6,900,000; 9 awards

b. Evaluation and Performance Measurement

i. CDC Evaluation and Performance Strategy

ii. Applicant Evaluation and Performance Measurement Plan

Applicants must provide an evaluation and performance measurement plan that demonstrates how the recipient will fulfill the requirements described in the CDC Evaluation and Performance Measurement and Project Description sections of this NOFO. At a minimum, the plan must describe:

- How applicant will collect the performance measures, respond to the evaluation questions, and use evaluation findings for continuous program quality improvement, including, as applicable to the award, how findings will contribute to reducing or eliminating health disparities and inequities.
- How key program partners will participate in the evaluation and performance measurement planning processes.
- Available data sources, feasibility of collecting appropriate evaluation and performance data, and other relevant data information (e.g., performance measures proposed by the applicant).
- How evaluation findings will be disseminated to communities and populations of interest in a manner that is suitable to their needs.
- Plans for updating the Data Management Plan (DMP) as new pertinent information becomes available. If applicable, throughout the lifecycle of the project. Updates to DMP should be provided in annual progress reports. The DMP should provide a description of the data that will be produced using these NOFO funds; access to data; data standards ensuring released data have documentation describing methods of collection, what the data represent, and data limitations; and archival and long-term data preservation plans. For more information about CDC's policy on the DMP, see https://www.cdc.gov/grants/additional-requirements/ar-25.html.

Where the applicant chooses to, or is expected to, take on specific evaluation studies, the applicant should be directed to:

- Describe the type of evaluations (i.e., process, outcome, or both).
- Describe key evaluation questions to be addressed by these evaluations.
- Describe other information (e.g., measures, data sources).

Recipients will be required to submit a more detailed Evaluation and Performance Measurement plan, including a DMP, if applicable, within the first 6 months of award, as described in the Reporting Section of this NOFO.

Applicants must provide an evaluation and performance measurement plan that demonstrates how the recipient will fulfill the requirements described in the CDC Evaluation and Performance Measurement and Project Description sections of this NOFO. At a minimum, the plan must describe:

- How applicant will collect the performance measures, respond to the evaluation questions, and use evaluation findings for continuous program quality improvement.

- How key program partners will participate in the evaluation and performance measurement planning processes.
- Available data sources, feasibility of collecting appropriate evaluation and performance data, and other relevant data information (e.g., performance measures proposed by the applicant)

Where the applicant chooses to, or is expected to, take on specific evaluation studies, they should be directed to:

- Describe the type of evaluations (i.e., process, outcome, or both).
- Describe key evaluation questions to be addressed by these evaluations.
- Describe other information (e.g., measures, data sources).

Recipients will be required to submit a more detailed Evaluation and Performance Measurement plan within the first 6 months of award, as described in the Reporting Section of this NOFO.

If needed, ELC will work with recipients during the first six months of the project period to finalize an evaluation and performance measurement plan to monitor the progress of the activities implemented and outcomes achieved. Each ELC Program or Project attachment illustrates its specific requirements for the NOFO.

Performance measures included throughout this NOFO and guidance are representative and may not be final at the time of NOFO publication. Please see the CK24-0002 Performance Measure Guidance document for all final measures and descriptions.

d. Work Plan

Each Program or Project for which the applicant is applying (see Part III) must include a Work Plan. Work Plans should be detailed and should focus on the first year of the project period with only a high level plan for subsequent years. Work Plans should demonstrate alignment among the outcomes, strategies, activities, timelines, and staffing/collaborations. Additional information on performance measures, data sources, and population of focus can also be included. (Note: recipients will incorporate this Work Plan into their Approach for each ELC project they are applying for. See Program and Project Attachments).

c. Organizational Capacity of Recipients to Implement the Approach

The successful ELC recipient must have a demonstrated core organizational capacity in order to effectively conduct the activities for which awards are made. This organizational capacity includes skill sets such as program planning and performance management, partnership development, evaluation, performance monitoring, financial reporting, budget management and administration, and personnel management (including developing staffing plans, developing and training workforce and developing a sustainability plan). Applicants also must be fully capable of managing the required procurement efforts, including the ability to write and award contracts in accordance with 45 or 74 C.F.R.

<u>Additional information pertaining to eligibility:</u>

To maximize the impact of funding anticipated to be available, the ELC program is leveraging the legislative authorities associated with this funding to prioritize recipients to those meeting the population thresholds described below. Working with recipients of sizeable populations allows

ELC to take advantage of economies of scale in implementing programs and reducing the marginal cost of additional resources added per population served. This strategy allows ELC to reach the greatest number of people within the allotted budget while also balancing the need for direct support to some of the United States' largest cities and counties.

The health department or agency must:

A. have sufficient and timely access to public health data for the for which they have public health authority.
B. have independent authority to promote and protect health within their jurisdiction.
C. have the requisite legal, financial, and technical capabilities to receive and administer Federal funds.
D. be registered in the System for Award Management (SAM) database and maintain an active SAM registration with current information when it has an active federal award or an application.
E. must have functional infectious disease detection, prevention, and control programs, and already existing public health outbreak response infrastructure and capacity.

e. CDC Monitoring and Accountability Approach

Monitoring activities include routine and ongoing communication between CDC and recipients, site visits, and recipient reporting (including work plans, performance, and financial reporting). Consistent with applicable grants regulations and policies, CDC expects the following to be included in post-award monitoring for grants and cooperative agreements:

- Tracking recipient progress in achieving the desired outcomes.
- Ensuring the adequacy of recipient systems that underlie and generate data reports.
- Creating an environment that fosters integrity in program performance and results.

Monitoring may also include the following activities deemed necessary to monitor the award:

- Ensuring that work plans are feasible based on the budget and consistent with the intent of the award.
- Ensuring that recipients are performing at a sufficient level to achieve outcomes within stated timeframes.
- Working with recipients on adjusting the work plan based on achievement of outcomes, evaluation results and changing budgets.
- Monitoring performance measures (both programmatic and financial) to assure satisfactory performance levels.

Monitoring and reporting activities that assist grants management staff (e.g., grants management officers and specialists, and project officers) in the identification, notification, and management of high-risk recipients.

Monitoring activities include routine and ongoing communication between CDC and recipients, site visits, and recipient reporting (including Work Plans, progress, program performance, and financial reporting). Consistent with applicable grants regulations and policies, CDC expects the following to be included in post-award monitoring for cooperative agreements:

- Tracking recipient progress in achieving the desired outcomes.
- Ensuring the adequacy of recipient systems that underlie and generate data reports.
- Creating an environment that fosters integrity in program performance and results.

Monitoring may also include the following activities deemed necessary to monitor the award:

- Ensuring that Work Plans are feasible based on the budget and consistent with the intent of the award.
- Ensuring that recipients are performing at a sufficient level to achieve outcomes within stated timeframes.
- Working with recipients on adjusting the Work Plan based on achievement of outcomes, evaluation results and changing resources.
- Monitoring performance measures (both programmatic and financial) to assure satisfactory performance levels.

ELC CAMP or other systems may be utilized for the programmatic documentation of performance.

B. Award Information

1. Funding Instrument Type:
CA (Cooperative Agreement)
CDC's substantial involvement in this program appears in the CDC Program Support to Recipients Section.

2. Award Mechanism:
U51

3. Fiscal Year:
2024

Estimated Total Funding:
$240,000,000

4. Approximate Total Fiscal Year Funding:
$240,000,000
This amount is subject to the availability of funds.

5. Approximate Period of Performance Funding:
$1,150,000,000

6. Total Period of Performance Length:
5 year(s)

7. Expected Number of Awards:
65

8. Approximate Average Award:

$3,538,462

Per Budget Period

Figure is estimate only.

This amount is subject to the availability of funds.

9. Award Ceiling:
$0
Per Budget Period

None.

10. Award Floor:
$0
Per Budget Period

None.

11. Estimated Award Date:
August 01, 2024

12. Budget Period Length:
12 month(s)

Throughout the period of performance, CDC will continue the award based on the availability of funds, the evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the federal government. The total number of years for which federal support has been approved (period of performance) will be shown in the "Notice of Award." This information does not constitute a commitment by the federal government to fund the entire period. The total period of performance comprises the initial competitive segment and any subsequent non-competitive continuation award(s).

13. Direct Assistance
Direct Assistance (DA) is available through this NOFO.

If you are successful and receive a Notice of Award, in accepting the award, you agree that the award and any activities thereunder are subject to all provisions of 45 CFR Part 75, currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

C. Eligibility Information

1. Eligible Applicants

Eligibility Category:
99 (Unrestricted (i.e., open to any type of entity above), subject to any clarification in text field entitled "Additional Information on Eligibility")

2. Additional Information on Eligibility

To maximize the impact of available funding, the ELC program has chosen to leverage the legislative authorities associated with this funding to limit recipients to those meeting the population thresholds described below. Working with recipients of sizeable populations allows ELC to take advantage of economy of scale in implementing programs and reducing the marginal cost of additional resources added per population served. This strategy allows ELC to reach the greatest number of people for its budget while also balancing the need for direct support to some of the United States' largest cities and counties.

Pursuant to 42 USC 300hh-31, eligible applicants include:

- The 51 State health departments or their bona fide agents, including the District of Columbia.
- Local health agencies or their bona fide agents, if they serve a city population of 1.5M or more (i.e., Chicago, Houston, New York City, Philadelphia). If the city does not have a public health department, then the county covering the jurisdiction may apply (i.e., Los Angeles, CA covered by Los Angeles County and Phoenix, AZ covered by Maricopa County).
- All U.S. territories and affiliates in the Caribbean and Pacific (American Samoa, Commonwealth of the Northern Mariana Islands, Federated States of Micronesia, Guam, Puerto Rico, Republic of Palau, Republic of the Marshall Islands, and U.S. Virgin Islands).

*Population for county and city jurisdictions. Source: U.S. Census Bureau, Population Division - Annual Estimates of the Resident Population for Counties in the United States: April 1, 2020, to July 1, 2021 - Release Date: March 2022.

3. Justification for Less than Maximum Competition

4. Cost Sharing or Matching

Cost Sharing / Matching Requirement:
No

5. Maintenance of Effort

D. Required Registrations

1. Required Registrations

An organization must be registered at the three following locations before it can submit an application for funding at www.grants.gov.

PLEASE NOTE: Effective April 4, 2022, applicants must have a Unique Entity Identifier (UEI) at the time of application submission (SF-424, field 8c). The UEI is generated as part of SAM.gov registration. Current SAM.gov registrants have already been assigned their UEI and can view it in SAM.gov and Grants.gov. Additional information is available on the GSA website, SAM.gov, and Grants.gov- Finding the UEI.

a. Unique Entity Identifier (UEI):

All applicant organizations must obtain a Unique Entity Identifier (UEI) number by registering in SAM.gov prior to submitting an application. A UEI number is a unique twelve-digit identification number assigned to the registering organization.

If funds are awarded to an applicant organization that includes sub-recipients, those sub-recipients must provide their UEI numbers before accepting any funds.

b. System for Award Management (SAM):

The SAM is the primary registrant database for the federal government and the repository into which an entity must submit information required to conduct business as a recipient. All applicant organizations must register with SAM, and will be assigned a SAM number and a Unique Entity Identifier (UEI). All information relevant to the SAM number must be current at all times during which the applicant has an application under consideration for funding by CDC. If an award is made, the SAM information must be maintained until a final financial report is submitted or the final payment is received, whichever is later. The SAM registration process can require 10 or more business days, and registration must be renewed annually. Additional information about registration procedures may be found at SAM.gov and the SAM.gov Knowledge Base.

c. Grants.gov: The first step in submitting an application online is registering your organization atwww.grants.gov, the official HHS E-grant Web site. Registration information is located at the "Applicant Registration" option atwww.grants.gov.

All applicant organizations must register at www.grants.gov. The one-time registration process usually takes not more

than five days to complete. Applicants should start the registration process as early as possible.

Step	System	Requirements	Duration	Follow Up
1	System for Award Management (SAM)	1. Go to SAM.gov and create an Electronic Business Point of Contact (EBiz POC) (You will need to have an active SAM account before you can register on grants.gov). The UEI is generated as part of your registration.	7-10 Business Days but may take longer and must be renewed once a year	For SAM Customer Service Contact https://fsd.gov/ fsd-gov/ home.do Calls: 866-606-8220
2	Grants.gov	1. Set up an account in Grants.gov, then add a profile by adding the organization's new UEI number. 2. The EBiz POC can designate user roles,	Allow at least one business day (after you enter the EBiz POC name and EBiz POC email in SAM) to receive a UEI (SAM)	Register early! Applicants can register within minutes.

		including Authorized Organization Representative (AOR). 3. AOR is authorized to submit applications on behalf of the organization in their workspace.	which will allow you to register with Grants.gov and apply for federal funding.	

2. Request Application Package

Applicants may access the application package at www.grants.gov. Additional information about applying for CDC grants and cooperative agreements can be found here: https://www.cdc.gov/grants/applying/pre-award.html

3. Application Package

Applicants must download the SF-424, Application for Federal Assistance, package associated with this funding opportunity at www.grants.gov.

4. Submission Dates and Times

If the application is not submitted by the deadline published in the NOFO, it will not be processed. Office of Grants Services (OGS) personnel will notify the applicant that their application did not meet the deadline. The applicant must receive pre-approval to submit a paper application (see Other Submission Requirements section for additional details). If the applicant is authorized to submit a paper application, it must be received by the deadline provided by OGS.

a. Letter of Intent Deadline (must be emailed)

The LOI date will generate once the Synopsis is published if Days or a Date are entered.
Not applicable

b. Application Deadline

April 30, 2024, no later than 11:59 pm U.S. Eastern Time, at www.grants.gov. If Grants.gov is inoperable and cannot receive applications, and circumstances preclude advance notification of an extension, then applications must be submitted by the first business day on which Grants.gov operations resume.

Due Date for Informational Conference Call

ELC will hold an information webinar.

Date: February 20, 2024
Time: 3:00 PM Eastern Time (US and Canada)
Topic: Informational Webinar for ELC Cooperative Agreement (CK24-0002)

Register in advance for this webinar:
https://cdc.zoomgov.com/webinar/register/WN_dzVsHPEJRBqOqZ7HxuttPA

Or an H.323/SIP room system: H.323: 161.199.138.10 (US West) or 161.199.136.10 (US East)
Meeting ID: 160 865 3428 Passcode: 74827076 SIP: 1608653428@sip.zoomgov.com Passcode: 74827076

After registering, you will receive a confirmation email containing information about joining the webinar.

5. Pre-Award Assessments

Risk Assessment Questionnaire Requirement

CDC is required to conduct pre-award risk assessments to determine the risk an applicant poses to meeting federal programmatic and administrative requirements by taking into account issues such as financial instability, insufficient management systems, non-compliance with award conditions, the charging of unallowable costs, and inexperience. The risk assessment will include an evaluation of the applicant's CDC Risk Questionnaire, located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, as well as a review of the applicant's history in all available systems; including OMB-designated repositories of government-wide eligibility and financial integrity systems (see 45 CFR 75.205(a)), and other sources of historical information. These systems include, but are not limited to: FAPIIS (https://www.fapiis.gov/), including past performance on federal contracts as per Duncan Hunter National Defense Authorization Act of 2009; Do Not Pay list; and System for Award Management (SAM) exclusions.

CDC requires all applicants to complete the Risk Questionnaire, OMB Control Number 0920-1132 annually. This questionnaire, which is located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, along with supporting documentation must be submitted with your application by the closing date of the Notice of Funding Opportunity Announcement. If your organization has completed CDC's Risk Questionnaire within the past 12 months of the closing date of this NOFO, then you must submit a copy of that questionnaire, or submit a letter signed by the authorized organization representative to include the original submission date, organization's EIN and UEI.

When uploading supporting documentation for the Risk Questionnaire into this application package, clearly label the documents for easy identification of the type of documentation. For example, a copy of Procurement policy submitted in response to the questionnaire may be labeled using the following format: Risk Questionnaire Supporting Documents _ Procurement Policy.

Duplication of Efforts

Applicants are responsible for reporting if this application will result in programmatic, budgetary, or commitment overlap with another application or award (i.e. grant, cooperative agreement, or contract) submitted to another funding source in the same fiscal year. Programmatic overlap occurs when (1) substantially the same project is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific objective and the project design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source. Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source. Commitment overlap occurs when an individual's time commitment exceeds 100 percent, whether or not salary support is requested in the application. Overlap, whether programmatic,

budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. Any overlap will be resolved by the CDC with the applicant and the PD/PI prior to award.

Report Submission: The applicant must upload the report in Grants.gov under "Other Attachment Forms." The document should be labeled: "Report on Programmatic, Budgetary, and Commitment Overlap."

6. Content and Form of Application Submission

Applicants are required to include all of the following documents with their application package at www.grants.gov.

7. Letter of Intent

Is a LOI:
Not Applicable

8. Table of Contents

(There is no page limit. The table of contents is not included in the project narrative page limit.): The applicant must provide, as a separate attachment, the "Table of Contents" for the entire submission package.

Provide a detailed table of contents for the entire submission package that includes all of the documents in the application and headings in the "Project Narrative" section. Name the file "Table of Contents" and upload it as a PDF, Word, or Excel file format under "Other Attachment Forms" at www.grants.gov.

9. Project Abstract Summary

A project abstract is included on the mandatory documents list and must be submitted at www.grants.gov. The project abstract must be a self-contained, brief summary of the proposed project including the purpose and outcomes. This summary must not include any proprietary or confidential information. Applicants must enter the summary in the "Project Abstract Summary" text box at www.grants.gov.

10. Project Narrative

Multi-component NOFOs may have a maximum of 15 pages for the "base" (subsections of the Project Description that the components share with each other, which may include target population, inclusion, collaboration, etc.); and up to 4 additional pages per component for

Project Narrative subsections that are specific to each component.

Text should be single spaced, 12 point font, 1-inch margins, and number all pages. Page limits include work plan; content beyond specified limits may not be reviewed.

Applicants should use the federal plain language guidelines and Clear Communication Index to respond to this Notice of Funding Opportunity Announcement. Note that recipients should also use these tools when creating public communication materials supported by this NOFO. Failure to follow the guidance and format may negatively impact scoring of the application.

The ELC application must be written according to the following outline. The entire application should contain a single, overarching 'Background & Overview' (see section A below, for more detail). Applications for each ELC program or project must contain a complete 'Project

Approach' narrative that includes a problem statement, justification, and applicant capacity (see section B below, for more detail). Each Program/Project Narrative must be succinct, easily understood, and in the order outlined in this section (which will be reflected in the application templates applicants will use which the ELC Program will distribute). The narratives must address outcomes and activities to be conducted over the next budget period, but should also address the entire project period as identified in the CDC Project Description sections.

A. Background & Overview (Only one per application)**:** Applicants must provide a description of relevant background information that includes the context of the problem. Specifically:

I. **Applicant Overview and Main Challenges**: Provide information on the population size of the jurisdiction under the applicant's authority, demographic characteristics, and morbidity and mortality related to infectious diseases (e.g., priority infectious diseases in the jurisdiction).

II. **Structure and Organization:** Provide an overview of the structure of applicant's health department (e.g., centralized, decentralized, hybrid) and where leadership involved in this ELC Cooperative Agreement reside within the health department's structure and describe the current process for supporting local public health concerns (including tribal governments within the jurisdiction, if applicable) and associated health departments. Next, describe challenges or limitations expected across organizational (especially as it relates to the integration of epidemiology, laboratory and health information systems), fiscal, administrative, and/or programmatic areas. Also include actions to overcome these challenges, to achieve full implementation of the activities proposed in this application. This could include references to resources being requested through ELC's 'Leadership, Management and Administration' Project. Describe plans to ensure adequate planning and implementation of activities (e.g., hiring, contracting, procurement, collaborations, etc.) are quickly executed with rigorous tracking and oversight to avoid delays and reduce the potential for unobligated funds remaining at the end of the budget and project period.

III. **ELC Program Leadership, Governance, Integration, and Tracking and Reporting:**

   a. **ELC Governance Team:** Each recipient shall maintain an active ELC Governance Team that consists of five (5) individuals who have leadership roles for the health department in epidemiology, laboratory, and health information systems (i.e., one person representing each area); plus the Project Director (PD) if the PD is someone other than one of the three above individuals (the Team thus will include 3 or 4 persons). The fifth position is the Financial Lead who oversees the use and accounting of funds awarded under the ELC Cooperative Agreement. Persons appointed to the Governance Team should have authority over their respective areas (e.g., the State Laboratory Director, State Epidemiologist, IT/Informatics Director or persons specifically designated and empowered by these authorities). The required role of this Team is to work together to assure sufficient and appropriate oversight and integration of epidemiology, laboratory, and health information systems in the recipient's ELC planning and implementation of the portfolio.

      i. List the ELC Governance Team members, including name, position/title, and contact information.

      ii. Provide as an attachment to this application, Statement of the ELC Governance Team, signed by all Governance Team members, explicitly

stating their agreement to serve on the team and confirming their understanding and support of the overall content of the application.

1. Epidemiology, laboratory, and health information systems integration. For the FY 2024-2029 Project Period, provide a plan to document efforts to maintain and/or strengthen epidemiology, laboratory and health information systems integration. Include a clear description of the process for engaging the recipient's ELC Governance Team during the course of the ELC project period for general oversight, planning, review and agreement on annual continuation applications, review and agreement on significant ELC process actions (e.g., redirection, and supplemental requests, etc.) This should include periodic regular meetings of the Governance Team to discuss ELC plans, activities, awards, progress report, evaluation and performance measures, etc. Strong applications will include the shared decision-making process of the ELC Governance Team. Plan to make the Governance Team available for quarterly conference calls with CDC ELC staff.

b. **Local engagement:** CDC's ELC Cooperative Agreement depends upon health departments working with local partners to meet local needs and for larger health departments to request resources for local entities (usually local health departments) within their jurisdictions. In this section, please provide a plan for 'meaningful engagement' of local health entities within your jurisdiction. This plan should include the following components:

NOTE: Please see Section H. Other Information for additional language and instructions related to item b. Local engagement.

III. **Programs/Projects:** List of the Program/Project component activities being addressed in the application.

IV. **Success Stories**: Please provide stories, using the ELC Success Story template available in ELC CAMP, to capture recent accomplishments that highlight the impact of the ELC Cooperative Agreement in the jurisdiction. They will be used to educate stakeholders, decision makers, and policymakers about the impact of ELC.

B. Project Approach (for each ELC Program or Project):

I. **Problem Statement:** Applicants must describe core information around the needs within the recipient's jurisdiction or populations being served relative to the specific ELC Program or Project. The core information must help reviewers understand how the applicant's response to the NOFO will address the public health problem and support public health priorities. (See CDC Project Descriptions.)

II. **Justification:** Explain the importance of the proposed activities, including why its implementation would address specific gaps mentioned in the ‘Problem Statement’, and advance and/or improve public health in the recipient's jurisdiction. For each ELC Program or Project applied for, applicants must provide a clear and concise description of the strategic approach they will use to achieve the project period outcomes.

III. **Applicant Capacity:** Describe the current resources, processes, and steps planned to implement this activity and achieve expected milestones.

a. **Current Capacity:** For each program or project component applied, address the jurisdiction's current capacity to successfully implement the proposed strategies and activities (including describing staff and other infrastructure already in place that will be built upon).

b. **Progress Report:** If the jurisdiction was funded for a project component in the previous funding period, a progress report must be provided on those activities. The progress reporting time period should range from the beginning of the last funding period to the time of application. Funding period start dates are 8/1/2024 for CK24-0002 activities. The progress report section should:

- Describe major activities conducted, the progress of those activities, and significant milestones accomplished as a result of those activities.
- If applicable, include the reasons that goals (e.g., targets for performance measures) were not met or activities (e.g., milestones) were incomplete, and a discussion of assistance needed to resolve the situation.
- If applicable, describe any barriers encountered, and how the barriers were addressed during implementation of these activities.
- **Evaluation Plan for 2024:** If needed, ELC will work with awardees during the first six months of the project period to finalize an evaluation and performance measurement plan to monitor the progress of the activities implemented and outcomes achieved. Applicants must provide an overall jurisdiction evaluation and performance measurement plan for each program/project. This plan must address the following points:

  - Identify key program staff who will participate in collecting and reporting performance measurement data.
  - Describe your plans and ability to collect data and report on the performance measures listed in the 2024 Notice of Funding Opportunity.
  - Discuss how you and your program staff will use (e.g., to inform program improvement, identify gaps, program management, etc.) and share performance measurement data collected.
  - If applicable: Discuss any barriers or challenges expected for collecting data (i.e., responding to performance measures), and reporting on results. Describe how these potential barriers would be overcome. In addition, applicants may also describe other measures to be developed or additional data sources and data collection methods that applicants will use to evaluate their activities and outcomes.

a. Background

Applicants must provide a description of relevant background information that includes the context of the problem (See CDC Background).

b. Approach

i. Purpose

Applicants must describe in 2-3 sentences specifically how their application will address the problem as described in the CDC Background section.

ii. Outcomes

Applicants must clearly identify the outcomes they expect to achieve by the end of the period of performance. Outcomes are the results that the program intends to achieve. All outcomes must indicate the intended direction of change (e.g., increase, decrease, maintain). (See the logic model in the Approach section of the CDC Project Description.)

iii. Strategies and Activities

Applicants must provide a clear and concise description of the strategies and activities they will use to achieve the period of performance outcomes. Applicants must select existing evidence-based strategies that meet their needs, or describe in the Applicant Evaluation and Performance Measurement Plan how these strategies will be evaluated over the course of the period of performance. (See CDC Project Description: Strategies and Activities section.)

1. Collaborations

Applicants must describe how they will collaborate with programs and organizations either internal or external to CDC. Applicants must address the Collaboration requirements as described in the CDC Project Description.

2. Population(s) of Focus and Health Disparities

Applicants must describe the specific population(s) of focus in their jurisdiction and explain how to achieve the goals of the award and/or alleviate health disparities. The applicants must also address how they will include specific populations that can benefit from the program that is described in the Approach section. Applicants must address the Population(s) of Focus and Health Disparities requirements as described in the CDC Project Description, including (as applicable to this award) how to address health disparities in the design and implementation of the proposed program activities.

c. Applicant Evaluation and Performance Measurement Plan

Applicants must provide an evaluation and performance measurement plan that demonstrates how the recipient will fulfill the requirements described in the CDC Evaluation and Performance Measurement and Project Description sections of this NOFO. At a minimum, the plan must describe:

- How applicant will collect the performance measures, respond to the evaluation questions, and use evaluation findings for continuous program quality improvement. The Paperwork Reduction Act of 1995 (PRA): Applicants are advised that any activities involving information collections (e.g., surveys, questionnaires, applications, audits, data requests, reporting, recordkeeping and disclosure requirements) from 10 or more individuals or non-Federal entities,

including State and local governmental agencies, and funded or sponsored by the Federal Government are subject to review and approval by the Office of Management and Budget. For further information about CDC's requirements under PRA see https://www.cdc.gov/os/integrity/reducepublicburden/index.htm.

- How key program partners will participate in the evaluation and performance measurement planning processes.
- Available data sources, feasibility of collecting appropriate evaluation and performance data, data management plan (DMP), and other relevant data information (e.g., performance measures proposed by the applicant).

Where the applicant chooses to, or is expected to, take on specific evaluation studies, they should be directed to:

- Describe the type of evaluations (i.e., process, outcome, or both).
- Describe key evaluation questions to be addressed by these evaluations.
- Describe other information (e.g., measures, data sources).

Recipients will be required to submit a more detailed Evaluation and Performance Measurement plan (including the DMP elements) within the first 6 months of award, as described in the Reporting Section of this NOFO.

d. Organizational Capacity of Applicants to Implement the Approach

Applicants must address the organizational capacity requirements as described in the CDC Project Description.

11. Work Plan

(Included in the Project Narrative's page limit)

Applicants must prepare a work plan consistent with the CDC Project Description Work Plan section. The work plan integrates and delineates more specifically how the recipient plans to carry out achieving the period of performance outcomes, strategies and activities, evaluation and performance measurement.

The Work Plan integrates and delineates more specifically how the recipient plans to carry out achieving the period of performance outcomes, strategies and activities, evaluation and performance measurement.

Applicants should include the following detail on implementation plans for each ELC Program or Project activity:

1. Purpose: Describe in 2-3 sentences specifically how the Work Plan will address the problem as described in the component Program's or Project's 'Problem Statement'. Outcomes: Clearly identify the expected outcomes to be achieved by the end of the project period. Refer to outcomes listed in the component Program's or Project's 'Outcomes' section.
2. Outcomes are the results that the program intends to achieve. All outcomes must indicate the intended direction of change (i.e., increase, decrease, maintain, complete). (See the program Logic Model in the overall Approach section of the CDC Project Description.)

In addition to the project period outcomes required by CDC, applicants should include any additional outcomes they anticipate.

3. Milestones: For each ELC Program or Project applied for, applicants must provide a clear and concise description of the project period milestones. Briefly introduce the activity(ies) being proposed and describe what the expected outputs (e.g., milestones) and outcomes will be over the first 12-month budget period. Also provide a brief discussion of what will be achieved (i.e., expected outputs and outcomes) over the entire five-year project period. (See CDC Project Description: Strategies and Activities section.) Finally, include a Work Plan (described in detail below Section D. Application and Submission Information; Section 11: Work Plan)
4. If applicable, describe collaborations with programs and organizations either internal or external to CDC and describe the extent to which the strategies and activities will target specific population(s) in their recipient's jurisdiction.

12. Budget Narrative

Applicants must submit an itemized budget narrative. When developing the budget narrative, applicants must consider whether the proposed budget is reasonable and consistent with the purpose, outcomes, and program strategy outlined in the project narrative. The budget must include:

- Salaries and wages
- Fringe benefits
- Consultant costs
- Equipment
- Supplies
- Travel
- Other categories
- Contractual costs
- Total Direct costs
- Total Indirect costs

Indirect costs could include the cost of collecting, managing, sharing and preserving data.

Indirect costs on grants awarded to foreign organizations and foreign public entities and performed fully outside of the territorial limits of the U.S. may be paid to support the costs of compliance with federal requirements at a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000. Negotiated indirect costs may be paid to the American University, Beirut, and the World Health Organization.

If applicable and consistent with the cited statutory authority for this announcement, applicant entities may use funds for activities as they relate to the intent of this NOFO to meet national standards or seek health department accreditation or reaccreditation through the Public Health Accreditation Board (see: http://www.phaboard.org). Applicant entities to whom this provision applies include state, local, territorial governments (including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna

Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau), or their bona fide agents, political subdivisions of states (in consultation with states), federally recognized or state-recognized American Indian or Alaska Native tribal governments, and American Indian or Alaska Native tribally designated organizations. Activities include those that enable a public health organization to deliver public health services such as activities that ensure a capable and qualified workforce, up-to-date information systems, and the capability to assess and respond to public health needs. Use of these funds must focus on achieving a minimum of one national standard that supports the intent of the NOFO. Proposed activities must be included in the budget narrative and must indicate which standards will be addressed.

Vital records data, including births and deaths, are used to inform public health program and policy decisions. If applicable and consistent with the cited statutory authority for this NOFO, applicant entities are encouraged to collaborate with and support their jurisdiction's vital records office (VRO) to improve vital records data timeliness, quality and access, and to advance public health goals. Recipients may, for example, use funds to support efforts to build VRO capacity through partnerships; provide technical and/or financial assistance to improve vital records timeliness, quality or access; or support vital records improvement efforts, as approved by CDC.

Applicants must name this file "Budget Narrative" and can upload it as a PDF, Word or Excel file format at www.grants.gov. If requesting indirect costs in the budget, a copy of the indirect cost-rate agreement is required. If the indirect costs are requested, include a copy of the current negotiated federal indirect cost rate agreement or a cost allocation plan approval letter for those Recipients under such a plan. Applicants must name this file "Indirect Cost Rate" and upload it at www.grants.gov.

Applicants must submit a discrete and separate itemized budget and budget narrative for each ELC Program or Project they are applying for. When developing the budget narrative, applicants must consider whether the proposed budget is reasonable and consistent with the purpose, outcomes, and program strategy outlined in the project narrative.

Be sure to consider and include requests for travel that are required for proposed activities. Please include travel for ELC Governance Team members and a financial representative to the ELC Annual Meeting. Travel that is approved and funded by CDC will be considered a required activity. The budget must include:

- Salaries and wages
- Fringe benefits
- Equipment
- Supplies
- Travel
- Other categories
- Contractual costs
- Total Direct costs
- Total Indirect costs

For guidance on completing a detailed budget, see Budget Preparation Guidelines at: http://www.cdc.gov/od/pgo/funding/grants/foamain.shtm.

Applicants must submit a Budget Summary. Please name this file 'Budget Narrative Summary' and upload it as a PDF file at www.grants.gov. A detailed Budget request and accompanying justification should be submitted using the ELC template. If requesting indirect costs in the budget, a copy of the indirect cost-rate agreement is required. If the indirect cost rate is a provisional rate, the agreement must have been made less than 12 months earlier. Applicants must name this file 'Indirect Cost Rate' and upload it at www.grants.gov.

13. Employee Whistleblower Rights and Protections

Employee Whistleblower Rights and Protections: All recipients of an award under this NOFO will be subject to a term and condition that applies the requirements set out in 41 U.S.C. § 4712, "Enhancement of contractor protection from reprisal for disclosure of certain information" and 48 Code of Federal Regulations (CFR) section 3.9 to the award, which includes a requirement that recipients and subrecipients inform employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. § 4712. For more information see: https://oig.hhs.gov/fraud/whistleblower/.

13a. Funds Tracking

Proper fiscal oversight is critical to maintaining public trust in the stewardship of federal funds. Effective October 1, 2013, a new HHS policy on subaccounts requires the CDC to set up payment subaccounts within the Payment Management System (PMS) for all new grant awards. Funds awarded in support of approved activities and drawdown instructions will be identified on the Notice of Award in a newly established PMS subaccount (P subaccount). Recipients will be required to draw down funds from award-specific accounts in the PMS. Ultimately, the subaccounts will provide recipients and CDC a more detailed and precise understanding of financial transactions. The successful applicant will be required to track funds by P-accounts/sub accounts for each project/cooperative agreement awarded.

Applicants are encouraged to demonstrate a record of fiscal responsibility and the ability to provide sufficient and effective oversight. Financial management systems must meet the requirements as described 45 CFR 75 which include, but are not limited to, the following:

- Records that identify adequately the source and application of funds for federally-funded activities.
- Effective control over, and accountability for, all funds, property, and other assets.
- Comparison of expenditures with budget amounts for each Federal award.
- Written procedures to implement payment requirements.
- Written procedures for determining cost allowability.
- Written procedures for financial reporting and monitoring.

13b. Copyright Interests Provisions

This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. Pursuant to applicable grant regulations and CDC's Public Access Policy, Recipient agrees to submit into the National Institutes of Health (NIH) Manuscript Submission (NIHMS) system an electronic version of the final, peer-reviewed manuscript of any such work developed under this award upon acceptance for publication, to be

made publicly available no later than 12 months after the official date of publication. Also at the time of submission, Recipient and/or the Recipient's submitting author must specify the date the final manuscript will be publicly accessible through PubMed Central (PMC). Recipient and/or Recipient's submitting author must also post the manuscript through PMC within twelve (12) months of the publisher's official date of final publication; however the author is strongly encouraged to make the subject manuscript available as soon as possible. The recipient must obtain prior approval from the CDC for any exception to this provision.

The author's final, peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Recipient and its submitting authors working under this award are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this provision and the license reserved by CDC. The manuscript will be hosted in both PMC and the CDC Stacks institutional repository system. In progress reports for this award, recipient must identify publications subject to the CDC Public Access Policy by using the applicable NIHMS identification number for up to three (3) months after the publication date and the PubMed Central identification number (PMCID) thereafter.

13c. Data Management Plan

As identified in the Evaluation and Performance Measurement section, applications involving data collection or generation must include a Data Management Plan (DMP) as part of their evaluation and performance measurement plan unless CDC has stated that CDC will take on the responsibility of creating the DMP. The DMP describes plans for assurance of the quality of the public health data through the data's lifecycle and plans to deposit the data in a repository to preserve and to make the data accessible in a timely manner. See web link for additional information: https://www.cdc.gov/grants/additional-requirements/ar-25.html.

14. Funding Restrictions

Restrictions that must be considered while planning the programs and writing the budget are:

- Recipients may not use funds for research.
- Recipients may not use funds for clinical care except as allowed by law.
- Recipients may use funds only for reasonable program purposes, including personnel, travel, supplies, and services.
- Generally, recipients may not use funds to purchase furniture or equipment. Any such proposed spending must be clearly identified in the budget.
- Reimbursement of pre-award costs generally is not allowed, unless the CDC provides written approval to the recipient.
- Other than for normal and recognized executive-legislative relationships, no funds may be used for:
    - publicity or propaganda purposes, for the preparation, distribution, or use of any material designed to support or defeat the enactment of legislation before any legislative body
    - the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the

enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before any legislative body

- See Additional Requirement (AR) 12 for detailed guidance on this prohibition and additional guidance on anti-lobbying restrictions for CDC recipients.
- The direct and primary recipient in a cooperative agreement program must perform a substantial role in carrying out project outcomes and not merely serve as a conduit for an award to another party or provider who is ineligible.

15. Other Submission Requirements

a. Electronic Submission: Applications must be submitted electronically by using the forms and instructions posted for this notice of funding opportunity atwww.grants.gov. Applicants can complete the application package using Workspace, which allows forms to be filled out online or offline. Application attachments can be submitted using PDF, Word, or Excel file formats. Instructions and training for using Workspace can be found at www.grants.gov under the "Workspace Overview" option.

b. Tracking Number: Applications submitted through www.grants.gov are time/date stamped electronically and assigned a tracking number. The applicant's Authorized Organization Representative (AOR) will be sent an e-mail notice of receipt whenwww.grants.gov receives the application. The tracking number documents that the application has been submitted and initiates the required electronic validation process before the application is made available to CDC.

c. Validation Process: Application submission is not concluded until the validation process is completed successfully. After the application package is submitted, the applicant will receive a "submission receipt" e-mail generated by www.grants.gov. A second e-mail message to applicants will then be generated bywww.grants.gov that will either validate or reject the submitted application package. This validation process may take as long as two business days. Applicants are strongly encouraged to check the status of their application to ensure that submission of their package has been completed and no submission errors have occurred. Applicants also are strongly encouraged to allocate ample time for filing to guarantee that their application can be submitted and validated by the deadline published in the NOFO. Non-validated applications will not be accepted after the published application deadline date.

If you do not receive a "validation" e-mail within two business days of application submission, please contact www.grants.gov. For instructions on how to track your application, refer to the e-mail message generated at the time of application submission or review the Applicants section on www.grants.gov.

d. Technical Difficulties: If technical difficulties are encountered at www.grants.gov, applicants should contact Customer Service atwww.grants.gov. The www.grants.gov Contact Center is available 24 hours a day, 7 days a week, except federal holidays. The Contact Center is available by phone at 1-800-518-4726 or by e-mail at support@grants.gov. Application submissions sent by e-mail or fax, or on CDs or thumb drives will not be accepted. Please note thatwww.grants.gov is managed by HHS.

e. Paper Submission: If technical difficulties are encountered at www.grants.gov, applicants should call thewww.grants.gov Contact Center at 1-800-518-4726 or e-mail them

at support@grants.gov for assistance. After consulting with the Contact Center, if the technical difficulties remain unresolved and electronic submission is not possible, applicants may e-mail CDC GMO/GMS, before the deadline, and request permission to submit a paper application.

Such requests are handled on a case-by-case basis.

An applicant's request for permission to submit a paper application must:

1. Include the www.grants.gov case number assigned to the inquiry
2. Describe the difficulties that prevent electronic submission and the efforts taken with the www.grants.gov Contact Center to submit electronically; and
3. Be received via e-mail to the GMS/GMO listed below at least three calendar days before the application deadline. Paper applications submitted without prior approval will not be considered. If a paper application is authorized, OGS will advise the applicant of specific instructions for submitting the application via email.

E. Review and Selection Process

1. Review and Selection Process: Applications will be reviewed in three phases

a. Phase 1 Review

All applications will be initially reviewed for eligibility and completeness by the Office of Grants Services. Complete applications will be reviewed for responsiveness by Grants Management Officials and Program Officials. Non-responsive applications will not advance to Phase II review. Applicants will be notified that their applications did not meet eligibility and/or published submission requirements.

b. Phase II Review

A review panel will evaluate complete, eligible applications in accordance with the criteria below.

i. Approach

ii. Evaluation and Performance Measurement

iii. Applicant's Organizational Capacity to Implement the Approach

Not more than thirty days after the Phase II review is completed, applicants will be notified electronically if their application does not meet eligibility or published submission requirements.

i. Approach	**Maximum Points:** 0
ii. Evaluation and Performance Measurement	**Maximum Points:** 0
iii. Applicant's Organizational Capacity to Implement the Approach	**Maximum Points:** 0
Budget	**Maximum Points:** 0
Background and Overview	**Maximum Points:** 20

Each applicant will be required to provide a single Background and Overview narrative for their overall application, refer to Section D10. Project Narrative section for specific requirements.

Problem Statement and Justification **Maximum Points:** 40

Applicants will be required to provide a Problem Statement and Justification narrative for **each Program or Project** applied for, Refer to Section D10. Project Narrative section for specific requirements.

Applicant Capacity **Maximum Points:** 40

Applicants will be required to provide Applicant Capacity narrative for **each Program/Project** applied for. Refer to Section D10. Project Narrative section for specific requirements**.**

An objective merit review utilizing subject matter experts will be conducted to evaluate complete and responsive applications according to the criteria listed in the three broad sections below. The review will be conducted by subject matter experts from programs across the agency.

All recipients will receive some level of funding. Additional information regarding the level of support provided can be found in each Program or Project Attachment under "Funding Strategy".

Budgets will be reviewed but not scored.

c. Phase III Review

Based on each Program or Project's funding availability, disease burden, geographic priorities, and jurisdictional risk, applicants may be funded out of rank order.

All recipients will be funded at some level. Additional information regarding the level of support provided can be found in each Program or Project Attachment under "Funding Strategy".

Not more than thirty days after the Phase II review is completed, applicants will be notified electronically of CDC's intent to fund.

Budgets will be reviewed but not scored.

Review of risk posed by applicants.

Prior to making a Federal award, CDC is required by 31 U.S.C. 3321 and 41 U.S.C. 2313 to review information available through any OMB-designated repositories of government-wide eligibility qualification or financial integrity information as appropriate. See also suspension and debarment requirements at 2 CFR parts 180 and 376.

In accordance 41 U.S.C. 2313, CDC is required to review the non-public segment of the OMB-designated integrity and performance system accessible through SAM (currently the Federal Recipient Performance and Integrity Information System (FAPIIS)) prior to making a Federal award where the Federal share is expected to exceed the simplified acquisition threshold, defined in 41 U.S.C. 134, over the period of performance. At a minimum, the information in the system for a prior Federal award recipient must demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics. CDC may make a Federal award to a recipient who does not fully meet these standards, if it is determined that the information is not relevant to the current Federal award under consideration or there are specific conditions that can appropriately mitigate the effects of the non-Federal entity's risk in accordance with 45 CFR §75.207.

CDC's framework for evaluating the risks posed by an applicant may incorporate results of the evaluation of the applicant's eligibility or the quality of its application. If it is determined that a Federal award will be made, special conditions that correspond to the degree of risk assessed may be applied to the Federal award. The evaluation criteria is described in this Notice of Funding Opportunity.

In evaluating risks posed by applicants, CDC will use a risk-based approach and may consider any items such as the following:

(1) Financial stability;

(2) Quality of management systems and ability to meet the management standards prescribed in this part;

(3) History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;

(4) Reports and findings from audits performed under subpart F 45 CFR 75 or the reports and findings of any other available audits; and

(5) The applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

CDC must comply with the guidelines on government-wide suspension and debarment in 2 CFR part 180, and require non-Federal entities to comply with these provisions. These provisions restrict Federal awards, subawards and contracts with certain parties that are debarred, suspended or otherwise excluded from or ineligible for participation in Federal programs or activities.

2. Announcement and Anticipated Award Dates

Awards will be communicated by the CDC Office of Grants Services via official Notice of Award to be released August 1, 2024.

F. Award Administration Information

1. Award Notices

Recipients will receive an electronic copy of the Notice of Award (NOA) from CDC OGS. The NOA shall be the only binding, authorizing document between the recipient and CDC. The NOA will be signed by an authorized GMO and emailed to the Recipient Business Officer listed in application and the Program Director.

Any applicant awarded funds in response to this Notice of Funding Opportunity will be subject to annual SAM Registration and Federal Funding Accountability And Transparency Act Of 2006 (FFATA) requirements.

Unsuccessful applicants will receive notification of these results by e-mail with delivery receipt.

When authorized by the Office of Grants Services, recipients may incur costs prior to receipt of official NOA.

2. Administrative and National Policy Requirements

Recipients must comply with the administrative and public policy requirements outlined in 45 CFR Part 75 and the HHS Grants Policy Statement, as appropriate.

Brief descriptions of relevant provisions are available at https://www.cdc.gov/grants/additional-requirements/index.html.

The HHS Grants Policy Statement is available at http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf.

If you receive an award, you must follow all applicable nondiscrimination laws. You agree to this when you register in SAM.gov. You must also submit an Assurance of Compliance (HHS-690). To learn more, see the HHS Office for Civil Rights website.

3. Reporting

Reporting provides continuous program monitoring and identifies successes and challenges that recipients encounter throughout the period of performance. Also, reporting is a requirement for recipients who want to apply for yearly continuation of funding. Reporting helps CDC and recipients because it:

- Helps target support to recipients;
- Provides CDC with periodic data to monitor recipient progress toward meeting the Notice of Funding Opportunity outcomes and overall performance;
- Allows CDC to track performance measures and evaluation findings for continuous quality and program improvement throughout the period of performance and to determine applicability of evidence-based approaches to different populations, settings, and contexts; and
- Enables CDC to assess the overall effectiveness and influence of the NOFO.

The table below summarizes required and optional reports. All required reports must be sent electronically to GMS listed in the "Agency Contacts" section of the NOFO copying the CDC Project Officer.

Report	When?	Required?
Recipient Evaluation and Performance Measurement Plan, including Data Management Plan (DMP)	Please refer to Section A.2.b. Evaluation and Performance Measurement of this NOFO for guidance on performance measurement.	Yes

Annual Performance Report (APR)	APR is submitted as a part of the continuation application.	Yes
Data on Performance Measures	Please see each Program/Project specific performance measure section for additional guidance (see Attachments).	Yes
Federal Financial Reporting Forms	Interim FFR (or equivalent) reporting of projected unobligated at the end of the budget period is due at the time of the continuation application. Annual FFR due 90 days after the end of the budget period	Yes
Final Performance and Financial Report	90 days after end of period of performance	Yes
Payment Management System (PMS) Reporting	Quarterly reports due January 30; April 30; July 30; and October 30	Yes

a. Recipient Evaluation and Performance Measurement Plan (required)

With support from CDC, recipients must elaborate on their initial applicant evaluation and performance measurement plan. This plan must be no more than 20 pages; recipients must submit the plan 6 months into the award. HHS/CDC will review and approve the recipient's monitoring and evaluation plan to ensure that it is appropriate for the activities to be undertaken as part of the agreement, for compliance with the monitoring and evaluation guidance established by HHS/CDC, or other guidance otherwise applicable to this Agreement.

Recipient Evaluation and Performance Measurement Plan (required): This plan should provide additional detail on the following:

Performance Measurement

• Performance measures and targets

• The frequency that performance data are to be collected.

• How performance data will be reported.

• How quality of performance data will be assured.

• How performance measurement will yield findings to demonstrate progress towards achieving NOFO goals (e.g., reaching specific populations or achieving expected outcomes).

• Dissemination channels and audiences.

• Other information requested as determined by the CDC program.

Evaluation

• The types of evaluations to be conducted (e.g. process or outcome evaluations).

• The frequency that evaluations will be conducted.

• How evaluation reports will be published on a publicly available website.

• How evaluation findings will be used to ensure continuous quality and program improvement.

• How evaluation will yield findings to demonstrate the value of the NOFO (e.g., effect on improving public health outcomes, effectiveness of NOFO, cost-effectiveness or cost-benefit).

• Dissemination channels and audiences.

HHS/CDC or its designee will also undertake monitoring and evaluation of the defined activities within the agreement. The recipient must ensure reasonable access by HHS/CDC or its designee to all necessary sites, documentation, individuals and information to monitor, evaluate and verify the appropriate implementation the activities and use of HHS/CDC funding under this Agreement.

b. Annual Performance Report (APR) (required)
The recipient must submit the APR via www.Grantsolutions.gov no later than120 days prior to the end of the budget period. This report must not exceed 45 pages excluding administrative reporting. Attachments are not allowed, but web links are allowed.

This report must include the following:

- **Performance Measures:** Recipients must report on performance measures for each budget period and update measures, if needed.
- **Evaluation Results:** Recipients must report evaluation results for the work completed to date (including findings from process or outcome evaluations).
- **Work Plan:** Recipients must update work plan each budget period to reflect any changes in period of performance outcomes, activities, timeline, etc.
- **Successes**
    - Recipients must report progress on completing activities and progress towards achieving the period of performance outcomes described in the logic model and work plan.
    - Recipients must describe any additional successes (e.g. identified through evaluation results or lessons learned) achieved in the past year.
    - Recipients must describe success stories.
- **Challenges**
    - Recipients must describe any challenges that hindered or might hinder their ability to complete the work plan activities and achieve the period of performance outcomes.

- Recipients must describe any additional challenges (e.g., identified through evaluation results or lessons learned) encountered in the past year.

- **CDC Program Support to Recipients**
  - Recipients must describe how CDC could help them overcome challenges to complete activities in the work plan and achieving period of performance outcomes.

- **Administrative Reporting** (No page limit)
  - SF-424A Budget Information-Non-Construction Programs.
  - Budget Narrative – Must use the format outlined in "Content and Form of Application Submission, Budget Narrative" section.
  - Indirect Cost Rate Agreement.

The recipient must submit the Annual Performance Report via https://www.grantsolutions.gov 120 days prior to the end of the budget period.

c. Performance Measure Reporting (optional)
CDC programs may require more frequent reporting of performance measures than annually in the APR. If this is the case, CDC programs must specify reporting frequency, data fields, and format for recipients at the beginning of the award period.

Performance Measure Reporting is **required**.

d. Federal Financial Reporting (FFR) (required)
The annual FFR form (SF-425) is required and must be submitted 90 days after the end of the budget period through the Payment Management System (PMS). The report must include only those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of unobligated funds, and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) cash transaction data. Failure to submit the required information by the due date may adversely affect the future funding of the project. If the information cannot be provided by the due date, recipients are required to submit a letter of explanation to OGS and include the date by which the Grants Officer will receive information.

Beginning in budget period 2, an interim FFR (or approved equivalent) that illustrates the projected amount of unobligated funds at the end of the budget period is required to be submitted with the continuation application.

e. Final Performance and Financial Report (required)
The Final Performance Report is due 90 days after the end of the period of performance. The Final FFR is due 90 days after the end of the period of performance and must be submitted through the Payment Management System (PMS). CDC programs must indicate that this report should not exceed 40 pages. This report covers the entire period of performance and can include information previously reported in APRs. At a minimum, this report must include the following:

- Performance Measures – Recipients must report final performance data for all process and outcome performance measures.
- Evaluation Results – Recipients must report final evaluation results for the period of performance for any evaluations conducted.
- Impact/Results/Success Stories – Recipients must use their performance measure results and their evaluation findings to describe the effects or results of the work completed over the period of performance, and can include some success stories.
- A final Data Management Plan that includes the location of the data collected during the funded period, for example, repository name and link data set(s)
- Additional forms as described in the Notice of Award (e.g., Equipment Inventory Report, Final Invention Statement).

Details of Final Performance and Financial Report will cover the above items, and will be required to be submitted on ELC Templates.

4. Federal Funding Accountability and Transparency Act of 2006 (FFATA)

Federal Funding Accountability and Transparency Act of 2006 (FFATA), P.L. 109–282, as amended by section 6202 of P.L. 110–252 requires full disclosure of all entities and organizations receiving Federal funds including awards, contracts, loans, other assistance, and payments through a single publicly accessible Web site, http://www.USASpending.gov.

Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by applicants: 1) information on executive compensation when not already reported through the SAM, and 2) similar information on all sub-awards/subcontracts/consortiums over $30,000.

For the full text of the requirements under the FFATA and HHS guidelines, go to:

- https://www.gpo.gov/fdsys/pkg/PLAW-109publ282/pdf/PLAW-109publ282.pdf,
- https://www. fsrs.gov/documents /ffata_legislation_ 110_252.pdf
- http://www.hhs.gov/grants/grants/grants-policies-regulations/index.html#FFATA.

5. Reporting of Foreign Taxes (International/Foreign projects only)

A. Valued Added Tax (VAT) and Customs Duties – Customs and import duties, consular fees, customs surtax, valued added taxes, and other related charges are hereby authorized as an allowable cost for costs incurred for non-host governmental entities operating where no applicable tax exemption exists. This waiver does not apply to countries where a bilateral agreement (or similar legal document) is already in place providing applicable tax exemptions and it is not applicable to Ministries of Health. Successful applicants will receive information on VAT requirements via their Notice of Award.

B. The U.S. Department of State requires that agencies collect and report information on the amount of taxes assessed, reimbursed and not reimbursed by a foreign government against commodities financed with funds appropriated by the U.S. Department of State, Foreign Operations and Related Programs Appropriations Act (SFOAA) (“United States foreign assistance funds”). Outlined below are the specifics of this requirement:

1) Annual Report: The recipient must submit a report on or before November 16 for each foreign country on the amount of foreign taxes charged, as of September 30 of the same year, by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant during the prior United States fiscal year (October 1 – September 30), and the amount reimbursed and unreimbursed by the foreign government. [Reports are required even if the recipient did not pay any taxes during the reporting period.]

2) Quarterly Report: The recipient must quarterly submit a report on the amount of foreign taxes charged by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant. This report shall be submitted no later than two weeks following the end of each quarter: April 15, July 15, October 15 and January 15.

3) Terms: For purposes of this clause:
"Commodity" means any material, article, supplies, goods, or equipment;
"Foreign government" includes any foreign government entity;
"Foreign taxes" means value-added taxes and custom duties assessed by a foreign government on a commodity. It does not include foreign sales taxes.

4) Where: Submit the reports to the Director and Deputy Director of the CDC office in the country(ies) in which you are carrying out the activities associated with this cooperative agreement. In countries where there is no CDC office, send reports to VATreporting@cdc.gov.

5) Contents of Reports: The reports must contain:

a. recipient name;
b. contact name with phone, fax, and e-mail;
c. agreement number(s) if reporting by agreement(s);
d. reporting period;
e. amount of foreign taxes assessed by each foreign government;
f. amount of any foreign taxes reimbursed by each foreign government;
g. amount of foreign taxes unreimbursed by each foreign government.

6) Subagreements. The recipient must include this reporting requirement in all applicable subgrants and other subagreements.

6. Termination

CDC may impose other enforcement actions in accordance with 45 CFR 75.371- Remedies for Noncompliance, as appropriate.

The Federal award may be terminated in whole or in part as follows:

(1) By the HHS awarding agency or pass-through entity, if the non-Federal entity fails to comply with the terms and conditions of the award;

(2) By the HHS awarding agency or pass-through entity for cause;

(3) By the HHS awarding agency or pass-through entity with the consent of the non-Federal entity, in which case the two parties must agree upon the termination conditions, including the effective date and, in the case of partial termination, the portion to be terminated; or

(4) By the non-Federal entity upon sending to the HHS awarding agency or pass-through entity written notification setting forth the reasons for such termination, the effective date, and, in the case of partial termination, the portion to be terminated. However, if the HHS awarding agency or pass-through entity determines in the case of partial termination that the reduced or modified portion of the Federal award or subaward will not accomplish the purposes for which the Federal award was made, the HHS awarding agency or pass-through entity may terminate the Federal award in its entirety.

G. Agency Contacts

CDC encourages inquiries concerning this NOFO.

Program Office Contact

For programmatic technical assistance, contact:

First Name:
Jason

Last Name:
Snow
Project Officer
Department of Health and Human Services
Centers for Disease Control and Prevention

Address:
1600 Clifton RD NE

Atlanta, GA 30333

Telephone:
404-639-4577

Email:
JNSnow@cdc.gov

Grants Management Office Information

For **financial, awards management, or budget assistance,** contact:

First Name:
Karen

Last Name:
Zion
Grants Management Specialist

Department of Health and Human Services
Office of Grants Services

Address:

Telephone:

Email:
KZion@cdc.gov
For assistance with **submission difficulties related to** www.grants.gov, contact the Contact Center by phone at 1-800-518-4726.

Hours of Operation: 24 hours a day, 7 days a week, except on federal holidays.

CDC Telecommunications for persons with hearing loss is available at: TTY 1-888-232-6348

H. Other Information

Following is a list of acceptable attachments **applicants** that can be uploaded as a PDF, Word, or Excel file format as part of their application at www.grants.gov. Applicants may not attach documents other than those listed; if other documents are attached, applications will not be reviewed.

- Project Abstract
- Project Narrative
- Budget Narrative
- Report on Programmatic, Budgetary and Commitment Overlap
- Table of Contents for Entire Submission

For international NOFOs:

- SF424
- SF424A
- Funding Preference Deliverables

Optional attachments, as determined by CDC programs:
Resumes / CVs

Position descriptions

Letters of Support

Organization Charts

Indirect Cost Rate, if applicable

Bona Fide Agent status documentation, if applicable

Continued text from D. Project Narrative, item A. III. b. Local engagement. This plan should include the following components:

i. **Current support for Local Public Health**: Provide a brief description of how your state or territorial health department supports public health at the local level. In particular, the ELC is interested in active efforts to strengthen local capacity. For example, does your jurisdiction assist locals in providing community outreach and education and/or help with investigating and tracing cases, clusters and outbreaks? How does your state or territorial health department manage infectious disease reporting systems that locals utilize?

ii. **Assessment of local capacity and gaps:** Explain how you learn, or will learn, about local needs. How will your health department prioritize those needs for attention, including with resources available through this cooperative agreement? Please include unmet needs that are highest priority and could be met with additional resources, and is there additional support you could provide without additional resources? How do you plan to stay up-to-date on local needs, and how will this be a partnership between local entities and your jurisdiction's overall public health infrastructure? How will these needs and gaps be analyzed and communicated, including back to ELC?

iii. **Communications strategies:** Please provide a plan that will sustain, and enhance, communications between your health department and local public health. For example, "Roadshows" where state staff travel to local entities to build relationships and share information could be a useful tool in some environments. What types of meetings (whether "in-person" or virtual) will you maintain or establish with your local entities, and how will you ensure they are well-attended and meaningful/effective?

iv. **Data sharing strategies:** Beyond sharing routine communications in meetings, what types of data pipelines can be established or enhanced so that local entities may be empowered with meaningful public health data that is actionable on the local level? These data could come from surveillance systems, analyses, laboratory data, etc. How will you handle issues around data integrity, timeliness, confidentiality, etc.?

v. **Providing available resources:** If additional financial resources (cross-cutting or otherwise) became available, and at a sufficient level, describe a plan to resource locals (either directly through financial assistance or indirectly through, for example, regional epidemiologists or lab support) based upon the "assessment of local capacity and gaps" previously described. If financial resources are to be transferred, please explain the mechanism(s) that would be used (i.e., contracts, reimbursement system, etc.).

vi. **Assessing Progress and Impact:** Since each jurisdiction is unique, it is difficult to rely on a single measure to demonstrate the impact of ELC activities. Therefore, ELC is asking each recipient to develop a single indicator to report to ELC, on an annual basis, assessing the recipients' meaningful engagement. Ninety (90) days post-award, ELC Project Officers will work with each recipient to review their "local engagement plan".

Note on Budget: Ensure that your budget justification contains requests for resources needed to successfully implement this local engagement plan. Although section iv. *Providing Available Resources* may require a large resource allocation to fully resolve the needs and gaps identified, your plan should request needs to fully conduct local needs assessments and communication of those needs. Likewise, ensure you include costs related to proposals for activities such as "roadshows" and in-person meetings. Although a large resource increase is not anticipated in FY

2024 to meet all local needs, planning for increases that may become available is critical; as is communicating those needs to CDC.

I. Glossary

Activities: The actual events or actions that take place as a part of the program.

Administrative and National Policy Requirements, Additional Requirements (ARs): Administrative requirements found in 45 CFR Part 75 and other requirements mandated by statute or CDC policy. All ARs are listed in the Template for CDC programs. CDC programs must indicate which ARs are relevant to the NOFO; recipients must comply with the ARs listed in the NOFO. To view brief descriptions of relevant provisions, see https://www.cdc.gov/grants/additional-requirements/index.html. Note that 2 CFR 200 supersedes the administrative requirements (A-110 & A-102), cost principles (A-21, A-87 & A-122) and audit requirements (A-50, A-89 & A-133).

Approved but Unfunded: Approved but unfunded refers to applications recommended for approval during the objective review process; however, they were not recommended for funding by the program office and/or the grants management office.

Assistance Listings: A government-wide collection of federal programs, projects, services, and activities that provide assistance or benefits to the American public.

Assistance Listings Number: A unique number assigned to each program and NOFO throughout its lifecycle that enables data and funding tracking and transparency

Award: Financial assistance that provides support or stimulation to accomplish a public purpose. Awards include grants and other agreements (e.g., cooperative agreements) in the form of money, or property in lieu of money, by the federal government to an eligible applicant.

Budget Period or Budget Year: The duration of each individual funding period within the period of performance. Traditionally, budget periods are 12 months or 1 year.

Carryover: Unobligated federal funds remaining at the end of any budget period that, with the approval of the GMO or under an automatic authority, may be carried over to another budget period to cover allowable costs of that budget period either as an offset or additional authorization. Obligated but liquidated funds are not considered carryover.

Community engagement: The process of working collaboratively with and through groups of people to improve the health of the community and its members. Community engagement often involves partnerships and coalitions that help mobilize resources and influence systems, improve relationships among partners, and serve as catalysts for changing policies, programs, and practices.

Competing Continuation Award: A financial assistance mechanism that adds funds to a grant and adds one or more budget periods to the previously established period of performance (i.e., extends the “life” of the award).

Continuous Quality Improvement: A system that seeks to improve the provision of services with an emphasis on future results.

Contracts: An award instrument used to acquire (by purchase, lease, or barter) property or services for the direct benefit or use of the Federal Government.

Cooperative Agreement: A financial assistance award with the same kind of interagency relationship as a grant except that it provides for substantial involvement by the federal agency funding the award. Substantial involvement means that the recipient can expect federal programmatic collaboration or participation in carrying out the effort under the award.

Cost Sharing or Matching: Refers to program costs not borne by the Federal Government but by the recipients. It may include the value of allowable third-party, in-kind contributions, as well as expenditures by the recipient.

Direct Assistance: A financial assistance mechanism, which must be specifically authorized by statute, whereby goods or services are provided to recipients in lieu of cash. DA generally involves the assignment of federal personnel or the provision of equipment or supplies, such as vaccines. DA is primarily used to support payroll and travel expenses of CDC employees assigned to state, tribal, local, and territorial (STLT) health agencies that are recipients of grants and cooperative agreements. Most legislative authorities that provide financial assistance to STLT health agencies allow for the use of DA. https://www.cdc.gov/grants/additional-requirements/index.html.

Equity: The consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment (from Executive Order 13985).

Evaluation (program evaluation): The systematic collection of information about the activities, characteristics, and outcomes of programs (which may include interventions, policies, and specific projects) to make judgments about that program, improve program effectiveness, and/or inform decisions about future program development.

Evaluation Plan: A written document describing the overall approach that will be used to guide an evaluation, including why the evaluation is being conducted, how the findings will likely be used, and the design and data collection sources and methods. The plan specifies what will be done, how it will be done, who will do it, and when it will be done. The NOFO evaluation plan is used to describe how the recipient and/or CDC will determine whether activities are implemented appropriately and outcomes are achieved.

Federal Funding Accountability and Transparency Act of 2006 (FFATA): Requires that information about federal awards, including awards, contracts, loans, and other assistance and payments, be available to the public on a single website at www.USAspending.gov.

Fiscal Year: The year for which budget dollars are allocated annually. The federal fiscal year starts October 1 and ends September 30.

Grant: A legal instrument used by the federal government to transfer anything of value to a recipient for public support or stimulation authorized by statute. Financial assistance may be money or property. The definition does not include a federal procurement subject to the Federal Acquisition Regulation; technical assistance (which provides services instead of money); or assistance in the form of revenue sharing, loans, loan guarantees, interest subsidies, insurance, or direct payments of any kind to a person or persons. The main difference between a grant and a cooperative agreement is that in a grant there is no anticipated substantial programmatic involvement by the federal government under the award.

Grants.gov: A "storefront" web portal for electronic data collection (forms and reports) for federal grant-making agencies at www.grants.gov.

Grants Management Officer (GMO): The individual designated to serve as the HHS official responsible for the business management aspects of a particular grant(s) or cooperative agreement(s). The GMO serves as the counterpart to the business officer of the recipient organization. In this capacity, the GMO is responsible for all business management matters associated with the review, negotiation, award, and administration of grants and interprets grants administration policies and provisions. The GMO works closely with the program or project officer who is responsible for the scientific, technical, and programmatic aspects of the grant.

Grants Management Specialist (GMS): A federal staff member who oversees the business and other non-programmatic aspects of one or more grants and/or cooperative agreements. These activities include, but are not limited to, evaluating grant applications for administrative content and compliance with regulations and guidelines, negotiating grants, providing consultation and technical assistance to recipients, post-award administration and closing out grants.

Health Disparities: Preventable differences in the burden of disease, injury, violence, or opportunities to achieve optimal health that are experienced by populations that have been socially, economically, geographically, and environmentally disadvantaged.

Health Equity: The state in which everyone has a fair and just opportunity to attain their highest level of health. Achieving this requires focused and ongoing societal efforts to address historical and contemporary injustices; overcome economic, social, and other obstacles to health and healthcare; and eliminate preventable health disparities.

Health Inequities: Particular types of health disparities that stem from unfair and unjust systems, policies, and practices and limit access to the opportunities and resources needed to live the healthiest life possible.

Healthy People 2030: National health objectives aimed at improving the health of all Americans by encouraging collaboration across sectors, guiding people toward making informed health decisions, and measuring the effects of prevention activities.

Inclusion: The act of creating environments in which any individual or group can be and feel welcomed, respected, supported, and valued to fully participate. An inclusive and welcoming climate embraces differences and offers respect in words and actions for all people.

Indirect Costs: Costs that are incurred for common or joint objectives and not readily and specifically identifiable with a particular sponsored project, program, or activity; nevertheless, these costs are necessary to the operations of the organization. For example, the costs of operating and maintaining facilities, depreciation, and administrative salaries generally are considered indirect costs.

Letter of Intent (LOI): A preliminary, non-binding indication of an organization's intent to submit an application.

Lobbying: Direct lobbying includes any attempt to influence legislation, appropriations, regulations, administrative actions, executive orders (legislation or other orders), or other similar deliberations at any level of government through communication that directly expresses a view on proposed or pending legislation or other orders, and which is directed to staff members or

other employees of a legislative body, government officials, or employees who participate in formulating legislation or other orders. Grass roots lobbying includes efforts directed at inducing or encouraging members of the public to contact their elected representatives at the federal, state, or local levels to urge support of, or opposition to, proposed or pending legislative proposals.

Logic Model: A visual representation showing the sequence of related events connecting the activities of a program with the programs' desired outcomes and results.

Maintenance of Effort: A requirement contained in authorizing legislation, or applicable regulations that a recipient must agree to contribute and maintain a specified level of financial effort from its own resources or other non-government sources to be eligible to receive federal grant funds. This requirement is typically given in terms of meeting a previous base-year dollar amount.

Memorandum of Understanding (MOU) or Memorandum of Agreement (MOA): Document that describes a bilateral or multilateral agreement between parties expressing a convergence of will between the parties, indicating an intended common line of action. It is often used in cases where the parties either do not imply a legal commitment or cannot create a legally enforceable agreement.

Nonprofit Organization: Any corporation, trust, association, cooperative, or other organization that is operated primarily for scientific, educational, service, charitable, or similar purposes in the public interest; is not organized for profit; and uses net proceeds to maintain, improve, or expand the operations of the organization. Nonprofit organizations include institutions of higher educations, hospitals, and tribal organizations (that is, Indian entities other than federally recognized Indian tribal governments).

Notice of Award (NoA): The official document, signed (or the electronic equivalent of signature) by a Grants Management Officer that: (1) notifies the recipient of the award of a grant; (2) contains or references all the terms and conditions of the grant and Federal funding limits and obligations; and (3) provides the documentary basis for recording the obligation of Federal funds in the HHS accounting system.

Objective Review: A process that involves the thorough and consistent examination of applications based on an unbiased evaluation of scientific or technical merit or other relevant aspects of the proposal. The review is intended to provide advice to the persons responsible for making award decisions.

Outcome: The results of program operations or activities; the effects triggered by the program. For example, increased knowledge, changed attitudes or beliefs, reduced tobacco use, reduced morbidity and mortality.

Performance Measurement: The ongoing monitoring and reporting of program accomplishments, particularly progress toward pre-established goals, typically conducted by program or agency management. Performance measurement may address the type or level of program activities conducted (process), the direct products and services delivered by a program (outputs), or the results of those products and services (outcomes). A "program" may be any activity, project, function, or policy that has an identifiable purpose or set of objectives.

Period of performance –formerly known as the project period - : The time during which the recipient may incur obligations to carry out the work authorized under the Federal award. The start and end dates of the period of performance must be included in the Federal award.

Period of Performance Outcome: An outcome that will occur by the end of the NOFO's funding period

Plain Writing Act of 2010: The Plain Writing Act of 2010 requires that federal agencies use clear communication that the public can understand and use. NOFOs must be written in clear, consistent language so that any reader can understand expectations and intended outcomes of the funded program. CDC programs should use NOFO plain writing tips when writing NOFOs.

Program Official: Person responsible for developing the NOFO; can be either a project officer, program manager, branch chief, division leader, policy official, center leader, or similar staff member.

Program Strategies: Strategies are groupings of related activities, usually expressed as general headers (e.g., Partnerships, Assessment, Policy) or as brief statements (e.g., Form partnerships, Conduct assessments, Formulate policies).

Public Health Accreditation Board (PHAB): A nonprofit organization that works to promote and protect the health of the public by advancing the quality and performance of public health departments in the U.S. through national public health department accreditation http://www.phaboard.org.

Social Determinants of Health: The non-medical factors that influence health outcomes. The conditions in which people are born, grow, work, live, and age, and the wider set of forces and systems shaping the conditions of daily life. These forces (e.g., racism, climate) and systems include economic policies and systems, development agendas, social norms, social policies, and political systems. https://www.cdc.gov/about/sdoh/index.html

Statute: An act of the legislature; a particular law enacted and established by the will of the legislative department of government, expressed with the requisite formalities. In foreign or civil law any particular municipal law or usage, though resting for its authority on judicial decisions, or the practice of nations.

Statutory Authority: Authority provided by legal statute that establishes a federal financial assistance program or award.

System for Award Management (SAM): The primary vendor database for the U.S. federal government. SAM validates applicant information and electronically shares secure and encrypted data with federal agencies' finance offices to facilitate paperless payments through Electronic Funds Transfer (EFT). SAM stores organizational information, allowing www.grants.gov to verify identity and pre-fill organizational information on grant applications.

Technical Assistance: Advice, assistance, or training pertaining to program development, implementation, maintenance, or evaluation that is provided by the funding agency.

UEI: The Unique Entity Identifier (UEI) number is a twelve-digit number assigned by SAM.gov. When applying for Federal awards or cooperative agreements, all applicant organizations must obtain a UEI number as the Universal Identifier. UEI number assignment is

free. If an organization does not know its UEI number or needs to register for one, visit www.sam.gov.

Work Plan: The summary of period of performance outcomes, strategies and activities, personnel and/or partners who will complete the activities, and the timeline for completion. The work plan will outline the details of all necessary activities that will be supported through the approved budget.

Section I: Cross-cutting Emerging Infectious Disease Capacity, Systems, and Leadership

Program A: Cross-cutting Epidemiology and Laboratory Capacity

Program Activity Contact Information:

Jason Snow, JNSnow@cdc.gov

Funding Opportunity Description:

a. Overview

The Epidemiology and Laboratory Capacity for Prevention and Control of Infectious Diseases (ELC) Cooperative Agreement's *Program A: Cross-cutting Epidemiology and Laboratory Capacity* is intended to improve fundamental capabilities of recipient health departments. This flexible funding helps meet health departments' essential public health needs and supports the redirection of resources to confront rapidly emergent situations. ELC enhances epidemiology and laboratory capacity by addressing programmatic gaps; response to emerging/re-emerging infectious diseases; and aligning and utilizing innovative technologies. Flexible funding has proven to be an effective model for strengthening epidemiology and laboratory capacity among health departments.[1]

b. Health Equity

Health equity is a priority with significant impact on infectious disease public health. The COVID-19 pandemic has further underscored existing health inequities related to infectious diseases in the United States. Groups that have historically been marginalized have higher burden of many infectious diseases—this includes people with lower incomes, racial and ethnic minority groups, and people who are uninsured, among others. Identifying and addressing health inequities and their drivers is essential to preventing and controlling infectious disease health threats, promoting health and well-being, and saving lives.

In the coming years, the ELC Program will be addressing aspects of equity in its cooperative agreement. The ELC Program strongly encourages recipients to incorporate actions across their ELC workplan to reduce health inequities and advance health equity in their jurisdiction. This may include improving demographic data quality, using equity-centered approaches to analyze, interpret, and disseminate data, improving use of inequities data to inform public health decisions, or other efforts to incorporate a health equity focus for program activities.

ELC has identified three (3) cross-program health equity focus areas:

1) Enhance collection and completeness of sociodemographic data (e.g., race and ethnicity, location/residence, industry and occupation) and dissemination and use of data to understand and monitor inequities.
2) Expand and sustain equitable prevention and intervention strategies in communities and settings placed at increased risk.
3) Develop and sustain multi-level, multi-sector partnerships and community engagement to identify, understand, prevent, and reduce inequities.

[1] Chung, Christina; Fischer, Leah; O'Connor, Angelica; Shultz, Alvin; 2017 "CDC's "Flexible" Epidemiologist: A Strategy for Enhancing Health Department Infectious Disease Epidemiology Capacity." Journal of Public Health Management and Practice. May/Jun;23(3):295-30.1

c. Healthy People

PHI-D04 – Increase proportion of state public health labs that provide services that support emerging issues. https://health.gov/healthypeople/objectives-and-data/browse-objectives/public-health-infrastructure/increase-proportion-state-public-health-labs-provide-services-support-emerging-issues-phi-d04

d. Local Health Department and Tribal Engagement

While cross-cutting funding is relatively limited versus some other ELC programs, the ELC requires that recipients reflect local needs in their strategies for local support, collected as a part of the applications. In CK24-002, there is a requirement for providing local public health "meaningful engagement" plans; resources to support work described in these plans may be sought in this section. While ELC will likely be limited in being able to fund many new positions, other activities such as "roadshows" or outreach events, state/local health meetings, trainings, etc. may be supported through this section.

Where appropriate, ELC recipients are encouraged to coordinate with tribal nations while acknowledging and respecting tribal sovereignty. ELC recipients should describe how they support tribes in areas such as testing, data sharing, and providing technical assistance with surveillance or outbreaks. Coordination and collaboration with tribal nations and the federal government should also aim to understand and address public health issues on tribal lands within the recipient geographic area.

e. Other National Public Health Priorities and Strategies

N/A

CDC Project Description:

a. Problem Statement

A challenge that is often compounded with Federal funding is that the funds are often allocated to HHS and CDC by disease categories or disease 'funding lines' (e.g., Food Safety, Lyme Disease, etc.); however, health departments need to operate with flexibility. Since predicting future outbreaks remains outside our current public health capabilities, having flexible funding that can be used, as needs arise, to address emerging/re-emerging infections is critical in building and maintaining health department capacity. This cross-cutting program is designed to help meet those ever-changing needs.

b. Purpose

The purpose of *Program A: Cross-cutting Epidemiology and Laboratory Capacity* is to provide support to maintain and strengthen infectious disease epidemiology and laboratory capacity so that state, local, and territorial and affiliate public health agencies can effectively respond, prevent, and control known and emerging (or re-emerging) infectious diseases. This program is intended to address activities for needs that do not clearly fall under specific disease components and/or are cross-cutting, including the basic 'core' elements of an epidemiology and laboratory program and to address emerging and re-emerging infectious diseases.

c. Outcomes

1. Timelier outbreak investigations
2. More accurate, complete and timely surveillance data that is disseminated to stakeholders
3. Modernized laboratory testing techniques
4. More efficient Public Health Laboratories (PHLs)
5. Improved coordination between PHLs and their partners.
6. Increased interoperability and data exchange between public health and key partners.
7. Better integrated surveillance information systems to meet public health needs.
8. Strong public health interventions, tools, and policies using a health equity lens
9. Strong multi-level and community partnerships.
10. Enhanced capacity for timely and accessible communications and outreach tailored for diverse populations.
11. Better skilled and experienced epidemiology and laboratory workforce

Funding Strategy:

Funds should be used for personnel (e.g., multi-disease purpose 'ELC Flexible Epidemiologist', and/or 'Laboratorian'), supplies, travel, systems (e.g., courier/lab networks), statistical software, and other requisite support to build, enhance, and/or maintain epidemiological and laboratory capacity within the recipient's jurisdiction. Funds may also be requested here to support epidemiology and laboratory components of local public health engagement (e.g., outreach activities, trainings, etc.).

Funds may be used for addressing key priorities in the recipient's jurisdiction related to health disparities and health equity.

Hurricane Funding Availability for Florida, North Carolina, Puerto Rico, and South Carolina

Additional funding (made available through the *Consolidated Appropriations Act of 2023, p. 1855; Division N – Disaster Relief Supplemental Appropriations Act, 2023*) is available to recipients who submitted disaster declarations in response to hurricanes Fiona and Ian (**i.e., Florida, North Carolina, Puerto Rico, and South Carolina**). Applicants must clearly indicate in both their applications and budgets which proposed activities will be supported with this funding versus ELC *Program A: Cross-Cutting Epidemiology and Laboratory Capacity.*

Total availability of funds for *Program A: Cross-cutting Epidemiology & Laboratory Capacity*: $24,000,000

- Approximate number of awards: 65
- Approximate average per award: $369,000

***Please note:**

1. For State Health Departments (SHDs), when entering budget requests, recipients must use the 'Public Health Allocation' to indicate the portion of financial support going toward Local/regional Health Department (LHD) support versus staying at the SHD level. This allocation data helps ELC answer inquiries regarding the financial support to LHDs which is crucial given the important role LHDs have in addressing infectious diseases.

2. Travel Support
    a. ELC Annual Meeting: All requests for financial assistance to support travel should be made in *Project B: Leadership, Management & Administration*.

    b. Travel for ELC-funded personnel should be made in the 'Travel' cost category. Travel support for non-ELC funded personnel should be made in the 'Other' cost category.

3. Requests for cross-cutting leadership, program management, finance, and epi/lab integration staff should be submitted under *Project B: Leadership, Management & Administration*.

4. Funding for activities that would help evaluate the impact of epidemiology and laboratory capacity building activities could be requested in this section.

Required Tasks:

Acceptance of funding conveys acknowledgement and indication that the following requirements will be met.

1. Governance Team members:
    a) All Governance Team members must participate on regularly scheduled monitoring calls with their designated ELC Project Officer. These meetings are held approximately every quarter but may be convened at varying intervals depending upon recipient and/or program needs.
    All ELC recipients are required to maintain an active ELC Governance Team comprised of a Project Director (PD) and representatives from epidemiology, laboratory, health information systems, and fiscal (the PD may serve as a representative for one of these areas).
2. If funded for Peer-to-Peer activities, completion of a post-visit report is required within 45 days of the visit (see ELC for template).

3. Recipients are expected to meet all deadlines for:
    a. Quarterly milestone progress status
    b. Quarterly financial reporting of core funding (expenditures & ULOs)
    c. Performance measure reporting
    d. Submission and/or update of success stories

Strategies and Activities:

0) Strategy to Address Required Tasks

a) Address Required Tasks in Program A guidance. Recipients have the option to use this activity to briefly describe how they are addressing required tasks and assign budget line items to that do not directly align to another activity in this guidance.

☐ Required ☒ Optional

Area A: Surveillance, Detection, and Response

1) Enhance Workforce Capacity

a) Conduct ELC Workforce Capacity Assessment to identify gaps and/or training needs in epidemiology and laboratory activities no later than end of Quarter 2, i.e., January 31, 2025. Other assessments may be used as needed.

☒ Required ☐ Optional

b) Update and implement a training plan based on results from the ELC Workforce Capacity Assessment or other assessment tools, if appropriate.

☒ Required ☐ Optional

c) Enhance skills and maintain pace with novel laboratory and epidemiology techniques by participating in trainings or creating training opportunities for professional development (e.g., forums, seminars, workshops) for staff.

i) The level of training may be dependent on funds available. If professional development opportunities are funded via ELC, they must be completed and improvement (and/or maintenance of skills) reflected in progress reports.

☒ Required ☐ Optional

d) Self-Selected Peer-to-Peer: In-person visits to facilitate knowledge sharing and/or training on a topic relevant to the participating recipients' needs. Specific details should be negotiated between the participating ELC recipients and may involve reciprocal arrangements where host recipient may later be hosted; however, such an arrangement is not a requirement.

i) Host a one-on-one peer-to-peer visit(s) and/or training for a specified group (e.g., laboratory regional network members)

ii) Attend one-on-one peer-to-peer visit(s) and/or training for a specified group (e.g., laboratory regional network members)

☐ Required ☒ Optional

2) Enhance investigation and outbreak response

a) Plan and implement approaches to support outbreak response across the spectrum of infectious diseases. For example, this activity may include the daily outbreak response support a 'flexible-epidemiologist' may provide your health department.

☐ Required ☒ Optional

b) Enhance capacity to respond to outbreaks in a timely manner (e.g., establishing investigation teams and/or student workforce or cross training staff).

☐ Required ☒ Optional

c) Align and utilize innovative technologies (e.g., integrated disease surveillance systems, outbreak management systems, data visualization platforms enterprise infrastructure, shared services and building blocks) for more thorough and accurate detection of infectious diseases.

☐ Required ☒ Optional

3) Improve Surveillance and Reporting

a) Support infectious disease surveillance. For example, this activity may describe how recipient utilizes cross-cutting epidemiology support to meet core surveillance needs not addressed by your 'categorical' programs. This may also include supporting epi/lab coordination for more efficient data use and public health action or coordination with public health (or other) laboratories.

Health information systems support should be included in Project C: Health Information Systems Capacity.

☐ Required ☒ Optional

b) Improve use and/or review surveillance data to assess public health status of the community, identify opportunities for prevention/intervention, and define public health priorities. Case report data should include, at a minimum, fields for the collection of race and ethnicity data.

☐ Required ☒ Optional

c) Improve coordination and exchange of surveillance data with local health departments, other recipients, and partners by using data visualization tools (e.g., Tableau, Power BI, etc.).

☐ Required ☒ Optional

d) [For State ELC Recipients only.] The State Health Department will focus on an infectious disease area where surveillance could be enhanced by partnering with one or more Local Health Departments within their jurisdiction. The goal of this Activity is to demonstrate how State/Local partnerships can improve surveillance efforts.

☐ Required ☒ Optional

4) Strengthen laboratory testing for surveillance, detection, preparedness, and response

This strategy is focused on expanding and improving recipient PHL core and outbreak testing capacity.

a) Conduct appropriate testing to support detection, surveillance, and outbreak response.

☒ Required ☐ Optional

b) For ELC recipient PHLs, complete laboratory capacity assessment in ELC CAMP no later than the end of Quarter 2, i.e., January 31, 2025.

☒ Required ☐ Optional

5) Improve efficiency of laboratory operations

This strategy is focused on improving the efficiency of recipient PHL operations to provide reliable and timely core and outbreak testing services. The activities in this strategy will cover the entire 5-year period of performance, with continuing cycles of gap identification, mitigation, and reassessment.

a) Conduct a gap analysis for at least one cross-cutting laboratory process or subject area (e.g., accessioning, equipment maintenance, inventory management) to identify inefficiencies. Recipients may choose their own gap analysis tool. Report findings in ELC CAMP no later than the end of Quarter 2, i.e., January 31, 2025.

☒ Required ☐ Optional

b) Develop and implement plan to mitigate findings identified in the laboratory gap analysis. Complete report in ELC CAMP by the end of the budget period.

☐ Required ☒ Optional

6) Hurricane Fiona and Ian recovery (FL, NC, PR, SC)

a) Health and environmental assessments

☐ Required ☒ Optional

b) Enhanced surveillance to monitor adverse health impacts

☐ Required ☒ Optional

c) Laboratory surge capacity, including activities to identify environmental health impacts and vector-borne, foodborne, waterborne, and other infectious diseases that arise as a result of the hurricanes (e.g., leptospirosis, and infection with high mortality and morbidity which is associated with contaminated water).

☐ Required ☒ Optional

Area B: Prevention and Intervention

7) Implement public health interventions and tools

a) Improve use of surveillance data for prevention and response (e.g., identifying risk populations to drive interventions, data quality checks, more robust analysis).

☐ Required ☒ Optional

b) Implement evidence-based prevention tools and/or interventions (e.g., policy, engineering, service delivery, education, and/or communication campaigns) to achieve improved prevention practices and reduction of disease.

☐ Required ☒ Optional

c) Conduct process and/or outcome evaluations of activities undertaken with cross-cutting ELC resources (i.e., this Program A). Ideas could include: cost-effectiveness analysis and/or public health impact of cross-cutting epidemiologists on outbreak response, an evaluation of tools and/or interventions to determine if intended outcomes and/or effects were achieved and identify opportunities for improvement, supporting an evaluation specialist to monitor and assess performance measures across the entire ELC Cooperative Agreement. (Note: this activity replaces Project D: Impact and Evaluation from the previous NOFO).

☐ Required ☒ Optional

d) [For State ELC Recipients only] The State Health Department will focus on an infectious disease area where prevention efforts could be enhanced by partnering with one or more Local Health Departments within their jurisdiction. The goal of this Activity is to demonstrate how State/Local partnerships can improve prevention efforts.

☐ Required ☒ Optional

8) Hurricane Fiona and Ian recovery (FL, NC, PR, SC)

a) Dissemination of public health information on environmental risks, infectious diseases risks, mold cleanup, and food and water safety.

☐ Required ☒ Optional

Area C: Communication, Coordination, and Partnerships

9) Coordinate and engage with partners

a) Foster sustainable collaborations among city, county, health districts, regional, federal, tribal, and community partners to improve outbreak response and the prevention of infectious diseases.

Note: Implementation plan must align with information that is provided in overall NOFO response regarding collaborations with local health departments and tribes.

☒ Required ☐ Optional

b) Disseminate public health information external to the health department regarding emerging and re-emerging infectious disease health threats.

☐ Required ☒ Optional

10) Improve coordination and outreach among laboratory partners

This strategy is focused on improving communication and coordination between the recipient PHL and their jurisdictional laboratory testing partners.

a) Conduct a laboratory landscape analysis to identify laboratory testing partners within the recipient jurisdiction. Complete report in ELC CAMP no later than the end of Quarter 3, i.e., April 30, 2025.

☒ Required ☐ Optional

b) Conduct outreach to laboratory partners to assess testing capabilities and surge capacity. Complete report in ELC CAMP by the end of the budget period.

☐ Required ☒ Optional

c) Develop a plan to leverage laboratory testing partners within your jurisdiction for surge testing. Recipients should consider reaching out to their preparedness colleagues as there may be related efforts funded through other CDC cooperative agreements/programs.

☐ Required ☒ Optional

Collaborations:

a. With CDC-Funded Programs

Collaborations with other CDC-funded programs are strongly encouraged, especially when activities in this program supports emerging disease-specific needs found in other programs and projects elsewhere in the guidance. Examples include Public Health Emergency Preparedness, Immunization and Vaccines for Children, and Public Health Infrastructure Grant.

b. With Organizations External to CDC

Where appropriate, partnerships with public health organizations [e.g., Association of Public Health Laboratories (APHL), Association of State and Territorial Health Officials (ASTHO), Big Cities Health Coalition

(BCHC), Council of State and Territorial Epidemiologists (CSTE), National Association of County and City Health Officials (NACCHO)] are encouraged.

Population(s) of Focus

N/A

Evaluation and Performance Measurement:

To reduce reporting burden and streamline reporting, ELC has only one performance measure for this program area, and it is a streamlined version of a legacy measure designed to assess the impact of ELC-funded personal on recipient outbreak response. However, ELC will be quantifying laboratory improvements and competencies aligned with activities funded in this program; and ELC is introducing new "passive indicators" relating to completeness of race and ethnicity data designed to support health equity outcomes, as well as an indicator related to changes in competency changes over time as training priorities are addressed.

Performance measures included here are representative and may not be final at the time of NOFO publication. Please see the CK-24-0002 Performance Measure Guidance document for all final measures and descriptions.

a. ACTIVE Performance Measures

1. Number of outbreaks investigated by ELC-funded personnel.

b. PASSIVE Indicators

1. Completeness of race and ethnicity data for select notifiable diseases (e.g., excludes HIV/STDs/TB/Hepatitis C).
2. Workforce Competency Improvements (Program A – Cross-Cutting Lab and Epi, HIS and Leadership).

Project B: ELC Leadership, Management, and Administration

Program Activity Contact Information:

Jason Snow, JNSnow@cdc.gov

Funding Opportunity Description:

a. Overview

The Epidemiology and Laboratory Capacity for the Prevention and Control of Infectious Diseases (ELC) Cooperative Agreement has expanded enormously since it began over 2 ½ decades ago. Growing from awarding approximately $2 million in 1995, the ELC now averages between $200 and $300 million in annually appropriated funds (i.e., non-supplemental) awards and supports multiple categorical and cross-cutting programs, projects, and activities for its recipients.

Greater resources and opportunities for support have also brought unique challenges in the areas of leadership, management and administration of the cooperative agreement and the growing menu of activities offered under the ELC umbrella. The *Project B: ELC Leadership, Management, and Administration* section aims to provide dedicated support for recipients to strategically manage and optimize their ELC portfolio.

b. Health Equity

Health equity is a core priority with significant impact on infectious disease public health. The COVID-19 pandemic has further underscored existing health inequities related to infectious diseases in the United States. Groups that have historically been marginalized have higher burden of many infectious diseases—this includes people with lower incomes, racial and ethnic minority groups, and people who are uninsured, among others. Identifying and addressing health inequities and their drivers is essential to preventing and controlling infectious disease health threats, promoting health and well-being, and saving lives.

Recipients are encouraged to coordinate activities related to health equity across their ELC portfolio.

c. Healthy People

PHI-D04 – Increase proportion of state public health labs that provide services that support emerging issues. https://health.gov/healthypeople/objectives-and-data/browse-objectives/public-health-infrastructure/increase-proportion-state-public-health-labs-provide-services-support-emerging-issues-phi-d04

d. Local Health Department and Tribal Engagement

While cross-cutting funding is relatively limited versus some other ELC programs, the ELC requires that recipients reflect local needs in their strategies for local support, collected as a part of the applications. In CK24-002, there is a requirement for providing local public health "meaningful engagement" plans; resources to support work described in these plans may be sought in this section. While ELC will likely be limited in being able to fund many new positions, other activities such as "roadshows" or outreach events, state/local health meetings, trainings, etc. may ~~also~~ be supported ~~through~~ this section.

Where appropriate, ELC recipients are encouraged to coordinate with tribal nations while acknowledging and respecting tribal sovereignty.

e. Other National Public Health Priorities and Strategies

N/A

CDC Project Description:

a. Problem Statement

As the ELC Cooperative Agreement has grown in scope and funding, it has resulted in significant increases in the resources required for proper administration by the recipient. Now more than ever, the management of the ELC Cooperative Agreement requires careful attention to detail and coordination across numerous organizations and sub-organizations within each health department. Effective management of the recipient's ELC portfolio of program/project activities require programmatic knowledge and technical expertise, along with fluency in financial and administrative elements of the cooperative agreement.

b. Purpose

The purpose of the *Project B: Leadership, Management, and Administration* section is to provide health departments with dedicated resources to assist in the leadership, management, coordination, and administration of their ELC Cooperative Agreement programs and projects. While this support is provided in the Cross-cutting section, these resources broadly benefit the management of the entire ELC portfolio.

c. Outcomes

1. Improved programmatic and fiscal management of ELC portfolio (e.g., accurate reporting of financials, workplan progress, performance measures, etc.).
2. Enhanced coordination, including improved epidemiology, laboratory, and health information systems integration.
3. Improved strategic management of ELC programming (e.g., gaps addressed, implementation of public health best practices, understanding of programmatic performance and impact of ELC funded programs/projects and optimization of resources).
4. Better coordination and engagement with local public health

Funding Strategy:

Total availability of funds for *Program B: Leadership, Management, & Administration*: $5,800,000

- Approximate number of awards: 43
- Approximate average per award: $125,953

<u>ELC Annual Meeting Travel Support</u>

All recipients should include a budget request to support a 3-day trip to Atlanta, Georgia for the *ELC Annual Meeting*. Projections should include travel for all ELC Governance Team members as well as a fiscal representative.

- Estimated funding:
- Travel to the ELC Annual Meeting
  - Estimated number of awards: 65
  - Estimated average per award: $6,000

<u>*Please note:</u>

1. For State Health Departments (SHDs), when entering budget requests, recipients must use the 'Public Health Allocation' to indicate the portion of financial support going toward 'Local/Regional Health Department (LHD)' support versus staying at the SHD level. This allocation data helps ELC answer inquiries regarding the financial support to LHDs which is crucial given the important role LHDs have in addressing infectious diseases.
2. For Local Health Departments (LHDs), when entering budget requests, please ensure the 'Public Health Allocation' is set to 100% 'Local/Regional Health Department (LHD)' support.
3. For Territorial Health Departments, if you have local/regional jurisdictions, please follow the instructions for State Health Departments in #1.
4. If **only** requesting travel support to the *ELC Annual Meeting*, applicants do not need to complete a full Work Plan. Applicants should use the Required Task and associate the Budget Line Items (BLIs) for travel support necessary for attendance. If financial support for anything other than the *ELC Annual Meeting* is requested, then the applicant must fill out the entire *Project B: Leadership* Work Plan.

Required Tasks:

Acceptance of funding conveys acknowledgement the following requirements will be met:

1. Recipients must actively engage with local health departments and jurisdictions within the recipient's jurisdiction on infectious disease preparedness, prevention, and control. Recipients must collaborate with local health departments to ensure appropriate use of resources and partnerships to achieve the outcomes of this project.
2. ELC Governance Team members and a designated fiscal representative must attend the *ELC Annual Meeting* in Atlanta, GA. This meeting provides critical information to recipients and should not be considered optional travel. Letters of support to attend may be obtained from the ELC.
3. Governance Team members must regularly meet with one another and other relevant staff to discuss their portfolio of ELC program/project activities. It is recommended that internal Governance Team meetings occur on a quarterly basis and outputs are documented in ELC CAMP. Governance Team includes a Project Director (PD), Epidemiology Lead, Laboratory Lead, Health Information Systems Lead, and Financial Lead. Recipients should document a summary of Governance Team meetings by uploading a report in the 'Files' section of ELC CAMP.
4. The Project Director and Financial Lead, at a minimum, must meet quarterly to review financials and ensure that:

    a. Data entered into the Payment Management System (PMS) is accurate in terms of charges and disbursements.

    b. Expenditures and unliquidated obligations (ULOs) reported in ELC CAMP during quarterly workplan

    progress monitoring is accurate.
5. Governance Team member names and contact information shall be entered and maintained in ELC CAMP throughout the budget period. In addition to maintaining Governance Team member information in ELC CAMP, key personnel (i.e., Project Director and Authorizing Official/Financial) must be officially updated in GrantSolutions any time a change is made. This is done through submission of a 'Change of Key Personnel' amendment.
    a. Governance Team members:

i. ELC Governance Team members and a designated fiscal representative, once a year, must attend the *ELC Annual Meeting* in Atlanta, GA. This meeting provides critical information to recipients and should not be considered optional travel. Letters of support may be obtained from the ELC.
ii. Governance Team members must participate on regularly scheduled monitoring calls with designated ELC Project Officer. These meetings are held approximately every quarter but may be convened at varying intervals depending on the information for discussion.
iii. Governance Team members must regularly meet with one another and other relevant staff to discuss their portfolio of ELC activities. It is recommended that internal Governance Team meetings occur on a quarterly basis and outputs are documented.

6. Recipients are expected to meet all deadlines for:
   a. Quarterly milestone progress status.
   b. Quarterly reporting of financials, including expenditures and unliquidated obligations (ULOs), for core-funded programs/projects.
   c. Performance measure reporting.
   d. Submission and/or update of success stories.

Strategies and Activities:

0) Strategy to Address Required Tasks

Address Required Tasks in program/project guidance.

☐ Required ☒ Optional

Area C: Communication, Coordination, and Partnerships

1) Improve Health Department's ELC Leadership, Management and Administration

a) Manage and promote ELC activities across all ELC programs and projects.

i) Further enhance work with health department staff to develop activities within the ELC scope with special focus on ELC programs such as Cross-cutting, Foodborne & Waterborne, HAI/AR, and Vector-borne. Also, monitor implementation and effectiveness of ELC activities and work with CDC to overcome barriers and challenges occurring during implementation of activities.

ii) Develop and maintain succession and sustainability planning (especially with respect to staff) for the continuation and improvement of ELC activities.

iii) Promote activities that advance the three health equity focus areas.

☒ Required ☐ Optional

b) Actively plan, coordinate, and implement ELC activities across epidemiology, laboratory, and health informatics interests at health department and within the recipient's jurisdiction.

i) Actively seek (through perhaps an epidemiology-laboratory liaison position) to coordinate ELC activities and data/information pertinent to health department's mission with respect to infectious diseases.

ii) Identify barriers impacting epidemiology-laboratory integration and develop a plan and timeline for mitigating barriers.

iii) Enhanced coordination of ELC-related activities with local health departments within recipient's jurisdiction (including tribal governments), including identifying and requesting resources for local needs.

☒ Required ☐ Optional

c) Manage financial aspects of ELC Cooperative Agreement, including resource tracking and quarterly reporting of expenditures and unliquidated obligations (ULOs) for all funded programs/projects.

☒ Required ☐ Optional

d) Develop and implement a plan to address one of the three (3) 'Outcomes' for Project B: Leadership, Management, & Administration.

i) Select one of the three (3) 'Outcomes' listed in Project B: Leadership, Management, & Administration and develop an 'Implementation Plan'.

ii) Identify the current gap or need that will be addressed [e.g., in BP4, workplan progress reporting showed milestone achieve by dates not being met 50% of the time; in BP4 financial reporting was late 33% of the time and did not include unliquidated obligations (ULOs)].

iii) Propose a plan to improve performance using the personnel resources being requested in this project.

iv) Each quarter's progress reporting should be used to demonstrate the support provided in this project is meeting a need in leadership and/or program or fiscal management of ELC funding.

☒ Required ☐ Optional

Collaborations:

a. With CDC-Funded Programs

Collaborations with other CDC funded programs is strongly encouraged, especially where this cross-cutting project supports other ELC portfolio activities and initiatives.

b. With Organizations External to CDC

Where appropriate, other partnerships with national public health organizations (e.g., APHL, CSTE, NACCHO, ASTHO) are encouraged.

Populations of Focus:

N/A

Evaluation and Performance Measurement:

The performance measures listed here are measures that recipients are expected to report on during spring of 2024 for calendar year 2023.

Performance measures included here are representative and may not be final at the time of NOFO publication. Please see the CK-24-0002 Performance Measure Guidance document for all final measures and descriptions.

a. ACTIVE Performance Measures

1. Percentage of funded positions filled
2. Percentage of contracts executed

b. PASSIVE Indicators

1. Percentage of milestones on-track

Project C: Health Information System (HIS) Capacity

Program Activity Contact Information:

Michele Hoover, Lead Public Health Advisor, (404) 498-2705, mlh5@cdc.gov; Megan Light Mueller, ELC Informatics SME, (404) 718-1119, wpa8@cdc.gov; Teresa Jue, ELC Informatics SME, (404) 639-2061, qhx2@cdc.gov

Funding Opportunity Description:

a. Overview

Core ELC Health Information Systems (HIS) and Data Modernization funding is expected to coordinate with and leverage, but not duplicate, progress made via other ELC awards (Accelerating Data Modernization in Jurisdictions, Data Modernization 2), Public Health Infrastructure Grant (PHIG) A3 Component, Public Health Emergency Preparedness (PHEP), and other funding opportunities and investments. ELC HIS lead(s) should partner with the Data Modernization Director and supporting team and advisory committee required as part of the PHIG A3 Component to integrate data modernization efforts across jurisdictions and to leverage funding streams, so that all budgets are taken under consideration when developing HIS and DMI-related workplans and budgets.

Health information systems and data modernization activities embedded in other ELC Program/Project guidance should complement activities in Project C: Health Information Systems.

b. Health Equity

Health information systems should have the capacity to collect, store, and send detailed demographic and occupational data, when available, in order to support public health surveillance activities and contribute to policy and mitigation actions. For example, data elements like detailed race, ethnicity, age, and location, may be analyzed to determine vulnerable populations and geographic areas impacted by diseases of public health significance.

Recipients should work to ensure functionality to collect such data and collaborate with data submitters to ensure appropriate data elements are as complete and accurate as possible.

c. Healthy People

Healthy People 2030 Health Information Technology objectives https://health.gov/healthypeople/objectives-and-data/browse-objectives/health-it

d. Local Health Department and Tribal Engagement

Recipients are expected to engage with local health department and tribal partners to ensure systems and services for public health surveillance needs are met at all levels of the community. As part of the Public Health Infrastructure Grant A3 Component: Data Modernization supplemental guidance, recipients are expected to maintain advisory committee(s) to integrate data modernization efforts across the jurisdiction and to leverage multiple funding streams. Advisory committee members could include representation from local health department governing board representative(s), local jurisdiction and associations, regional working groups, and tribal representatives.

Please review guidance for specific activities that require collaboration with local health departments and tribal partners.

e. Other National Public Health Priorities and Strategies

These activities are aligned with CDC's Public Health Data Strategy (PHDS), including public health laboratories, and IT transformation efforts. These efforts include components focused on expanding core data, informatics, and IT capacity; advancing interoperable systems and tools; and strengthening and expanding collaboration with and support for partners.

CDC's Laboratory Data Exchange (LDX) Strategy intends to establish a seamless, bidirectional, automated laboratory data exchange ecosystem that will move data faster, ensure higher data quality, and reduce reporting burden for partners. It aligns with CDC's Data Modernization Initiative Strategic Implementation Plan. Activities included in this guidance support the LDX efforts. Activities indicated by an asterisk (*) are included in the CDC LDX Strategy. Activities indicated with a cross (†) are included in a CDC strategy related to modern and foundational data infrastructure. These activities should be prioritized by recipients for implementation.

CDC's PHDS outlines the data, technology, policy, and administrative actions needed for the efficient and secure exchange and analysis of critical core data across healthcare and the public health ecosystem to overcome existing public health data challenges. PHDS aligns modernization efforts at all levels of public health and across partners, building on ongoing and past initiatives such as the Data Modernization Initiative (DMI).

These activities also complement the Centers for Medicare & Medicaid Services Promoting Interoperability (PI) Programs focused on increased accessibility and improved facilitation of data exchange between providers, patients, and public health (https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html?redirect=/EHrIncentivePrograms/).

CDC Project Description:

a. Problem Statement

State, local, and territorial public health agencies require standardized processes and interoperable systems to access the timely, high-quality data that are critical to carrying out key public health functions. Many are faced with challenges in building the health information systems capacity needed to produce, transmit, manage, and analyze these data in an efficient way. For instance, clinical and laboratory partners often exchange data that are not standardized or rely on labor-intensive, paper-based methods. In addition, in many recipient's jurisdictions, the systems for analyzing and sharing these data are stand-alone, outdated, or lack critical functionally.

b. Purpose

The purpose of this NOFO is to provide public health agencies the support to maintain, improve, and modernize health information systems and data science infrastructure. Improvements should be forward-thinking and strategic. Recipients should plan to advance standards-based electronic data exchange, increase interoperability, and sustain and/or enhance information systems used to protect public health and safety of the American people. Enhancements should increase capacity of public health agencies to effectively detect, respond, prevent, and control known and emerging (or re-emerging) infectious diseases.

c. Outcomes

Mid-Term Outcomes

- Improved surveillance
    - Improved completeness of data
    - Improved timeliness of reporting
    - Increased use of data and distribution to public health partners
- Acquisition, management, and use of data are automated and efficient
- Electronic mechanisms for data exchange are in place

Long-Term Outcomes

- More efficient and accurate public health reporting
- More rapid detection of cases and outbreaks
- Improved use of data to
    - Inform public health response and control
    - Improve public health practice
    - Inform program and policy development
    - Develop and implement public health best practices and/or guidelines

Funding Strategy:

Funds should be utilized for personnel, travel, supplies, equipment, or contractual support for proposed activities.

- Estimated total availability of funds: $28,000,000
- Estimated number of awards given: 65
- Estimated average per award: $430,000

Distribution of funding for each activity will be dependent on recipient needs, the quality and composition of the application, and prior performance, as well as the availability of funds and agency priorities. Funding allocations and activities will be discussed on a webinar (date TBD). Note that funding for systems development or acquisition costs may not be available.

Funding for memberships to professional organizations, furniture, and construction are considered out of scope for this project.

<u>*Please note:</u>

1. For State Health Departments (SHDs), when entering budget requests, recipients must use the 'Public Health Allocation' to indicate the portion of financial support going toward 'Local/Regional Health Department (LHD)' support versus staying at the SHD level. This allocation data helps ELC answer

inquiries regarding the financial support to LHDs which is crucial given the important role LHDs have in addressing infectious diseases.

2. For LHDs, when entering budget requests, please ensure the 'Public Health Allocation' is set to 100% LHD support.
3. For Territorial Health Departments, if you have local/regional jurisdictions, please follow the instructions for State Health Departments in #1.

Required Tasks:

Acceptance of funding conveys acknowledgement and indication that the following requirements will be met.

1. Participate in ELC HIS implementation, support, training, and monitoring efforts.
   a. Designate primary and secondary persons with overall responsibility for HIS activities. HIS lead(s) should participate as members of the ELC governance team.
   b. Designate dedicated primary and secondary Electronic Case Reporting (eCR) leads (should not be shared between activities) and any additional eCR staff to address required activities.
   c. Designate one or more persons to participate in CDC collaborative national process to establish standardized data for case-based surveillance.
   d. Workplan progress must be completed at least 24 hours in advance of scheduled calls (Quarter 2 and Quarter 4). If workplan progress is not submitted, calls will be rescheduled.
   e. Performance measures must be completed within 30 days after the end of the quarter.
2. Request and participate in CDC ELC HIS Technical Assistance (TA) (e.g., ELR, eCR, DMI). Recipients may request TA via the TA Request Form. (https://app.smartsheet.com/b/form/4fe7d6f0c607491abe1ea88209d5aaff) or by email to EDX@cdc.gov throughout the project period.
3. If implementing major system enhancements (e.g., integrated disease surveillance system, Laboratory Information Management System (LIMS), Electronic Test Orders and Results (ETOR) web portal, Vital Records Registration Systems), including new or replacement systems, develop and submit a detailed implementation plan that includes but is not limited to the following:
   a. Rationale for enhancing or acquiring a new/replacement systems and information used to make the decision (e.g., gap analysis, options explored prior to making the decision)
   b. As appropriate, provide standard(s) being used and its relation to any existing Office of the National Coordinator for Health Information Technology (ONC) adopted standards, including data elements related to health equity. If standards are not being used, describe how standards will be adopted during the award
   c. Tasks and efforts required with appropriate and realistic milestones
   d. Timeline for completion and transition plans that include overlap between old and new systems for validation and continuity of reporting activities
   e. Person(s) responsible for these activities
   f. Implementation plans must be submitted to EDX@cdc.gov. Plans will be reviewed and approved by CDC **PRIOR** to the start of procurement and implementation
4. Participate in workgroups and Communities of Practice
   a. National Syndromic Surveillance Program (NSSP) Community of Practice, if funded
   b. Vital Statistics Modernization Community of Practice, if funded for vital statistics activities

c. Electronic Case Reporting (eCR) learning community activities, including the Council for State and Territorial Epidemiologists (CSTE) eCR Workgroup, the APHL/CSTE Public Health eCR Data Quality Subgroup, the CSTE Reportable Conditions Knowledge Management System (RCKMS) community of practice, and the HL7 Public Health Working Group.
d. Surveillance and Informatics workgroups (e.g., data standardization, eSHARE, evaluation, community of practice)

5. Work with CDC to measure key aspects of implementation (e.g., reporting the percent of lab report volume received through Electronic Laboratory Reporting (ELR) at least once during the project period, updating the Master Facility Table in BioSense)
6. Participate in requirements gathering and/or beta testing of system related enhancements or solutions that will be shared across multiple jurisdictions
7. Maintain existing Electronic Laboratory Reporting (ELR) transmissions
8. Maintain current transmissions of case data to CDC until replaced by new, approved transmissions.
9. Maintain advisory committee(s) per Public Health Infrastructure Grant A3 Component: Data Modernization supplemental guidance to integrate data modernization efforts across your jurisdiction and to leverage multiple funding streams. Advisory committee members may include, but are not limited to:
   a. Jurisdictional PHEP director or principal investigator
   b. Jurisdictional ELC director or principal investigator
   c. Jurisdictional Vital Stats Registrar(s)
   d. Jurisdictional DMI Director and/or lead(s)
   e. Jurisdictional immunization representative
   f. Jurisdictional lead for establishing data standardization
   g. Local health department governing board representative, local jurisdictions and associations, or regional working groups
   h. Tribal representatives

Strategies and Activities:

The following sections are separated by responsible party and activities are designated as Level 1, 2, or 3.

Responsible parties:

- Public Health Department (PHD)
- Public Health Laboratory (PHL)
- Enterprise Infrastructure* (EI)

**Enterprise infrastructure applies to both Public Health Department and Public Health Laboratory.*

Activity Levels:

- Level 1: Foundational activities
- Level 2: Advancing Data Modernization Initiatives (DMI)
- Level 3: Optimization

Systems may not necessarily fall into a single level and recipients will not be classified into a specific level or maturity. Level 1 consists of foundational activities that all recipients should engage with first. Level 2 activities build on Level 1 to continue advancing your data modernization journey.

It is understood that recipients may currently be engaged in activities across Levels. However, going forward, proposed workplans and activities should address activities in lower Levels first, if not already completed. Not all sections have associated levels.

0) Strategy to Address Required Tasks

Address Required Tasks in program/project guidance.

☒ Required ☐ Optional

Area A: Surveillance, Detection, and Response

1) Sustain and Enhance PHD Integrated Disease Surveillance System(s)

a) Level 1: Enhance existing information system(s) by adding or improving functionality

This may range from minimal to large scale updates to systems. Recipients should include the personnel, operating environment, and supporting software necessary for them to function. Prioritized activities are listed below, but other activities may be requested with justification.

- Ensure the ability to add new conditions and data elements to the surveillance system(s) and transmit data to CDC, including additional demographic and social variables (e.g., detailed race, detailed ethnicity, tribal affiliation, language, nativity, sexual orientation, gender identity, occupation, disability status, education, income)
- Enhance systems and processes to enable the automated processing and use of electronic data sources, e.g., ELR (ORU^R01 or LRI), eCR (eICR and RR), data from tribal, city, or county health departments (if in a separate system).
- Develop easy-to-use self-service administration and functionality (e.g., customizable reports and filters, ability to update investigation forms, workflows, queues)
- Integrate and consolidate free-standing surveillance databases (e.g., paper-based, Access, Excel), where appropriate.
- Collaborate with end-users across the jurisdiction (e.g., local health departments, tribal organizations, healthcare users) to solicit feedback and recommendations to ensure the integrated system meets surveillance needs at all levels.

☒ Required ☐ Optional

b) Level 2: Enhance existing information system(s) by adding or improving functionality

This may range from minimal to large scale updates to systems. Recipients should include the personnel, operating environment, and supporting software necessary for them to function. Prioritized activities are listed below, but other activities may be requested with justification.

- Enhance systems and processes to enable the automated processing and use of ELR susceptibility findings.
- Enhance systems to streamline case classification based on available case or lab data
- Implement strategies to link cases in integrated surveillance information system to outbreaks by using local, state, and national outbreak identifiers.

- Integrate and consolidate free-standing electronic surveillance systems (e.g., STD, HIV, TB, Blood Lead, Birth Defects).
- Enhance systems needed to support the sending and receiving of data via Representational State Transfer (REST) or Fast Healthcare Interoperability Resources (FHIR) Application programming interfaces (API)s

☐ Required ☒ Optional

c) *Implement (if appropriate) new/replacement information system(s)*

New/replacement information systems must include considerations for modernized public health infrastructure as described in Strategy 2d. Replacement systems should be designed to address all activities listed in the section above and work with modernized data infrastructure as described in the Enterprise Infrastructure section.

Note: If implementing new or replacement systems, including integrated web portals, develop an implementation plan, including appropriate milestones and timeline to completion. Implementation plans will be reviewed and approved for consistency with the activities set forth in the ELC awards by CDC **prior** to the start of procurement & implementation. (See Required Tasks for more details)

☐ Required ☒ Optional

2) Sustain and Enhance PHD Electronic Data Exchange: Electronic Laboratory Reporting (ELR)

a) *Level 1: Maintain & enhance ELR*

Maintain and enhance ELR to enable public health agencies (PHAs) to receive reports from laboratories in a more efficient electronic format

- Recipients with less than 75% of all laboratory results received via ELR must propose and execute a plan to increase the volume and percentage of laboratory reports to public health epidemiology programs received through ELR to at least 75%.
- Continue prioritization and onboarding of ELR senders, including previously COVID-19-only labs and CDC laboratories
- Expand acceptable and allowable formats, when appropriate, to receive laboratory data (e.g., csv from non-traditional testing sites)

☒ Required ☐ Optional

b) *Level 2: Maintain & enhance ELR*

- Develop tools for data senders for vocabulary mapping and validation to streamline onboarding processes and timelines.
- Develop or enhance ELR data quality assurance processes to improve timeliness of reporting, adherence to the implementation guide, mapping to standard codes (LOINC/SNOMED), etc. and provide feedback and work with reporting facilities to improve reporting (e.g., data visualization, feedback reports, validation tools).
- Onboard additional tests/results as they become available.

☐ Required ☒ Optional

3) Sustain and Enhance PHD Electronic Data Exchange: Electronic Case Reporting (eCR)

a) *Ensure Electronic Initial Case Reports (eICRs) and Reportability Responses (RRs) are received by public health agency*

Ensure eICRs and RRs are received by the PHA. All levels for this activity must be addressed in implementation plan

Level 1:

- Establish and/or maintain connection to Association of Public Health Laboratories (APHL) Informatics Messaging Services (AIMS) for eCR
- Monitor connection and eCR data flow and report any anomalies to APHL eCR team for investigation.

Level 2:

- Consider transitioning to a Simple Storage Service (S3) connection for eCR if utilizing Secure File Transfer Protocol (SFTP)
- Prepare for eCR documents beyond CDA R1.1 eICRs and RRs (e.g., Be ready to receive additional data elements in CDA R3.1 eICR or FHIR R2.0 eICR)

☒ Required ☐ Optional

b) Expand and refine condition authoring in RCKMS

All levels for this activity must be addressed in implementation plan

Level 1:

- Develop and implement a plan for authoring reportable conditions for jurisdiction that at a minimum addresses the following: 1) All reportable conditions for jurisdiction authored to at least "published to test" with 30 days, 2) Moving the authored conditions to "published to production", targeting 10% of the reportable conditions transitioned each year, 3) Maintaining and updating versions of conditions "published to production", 4) Tracking and updating how many conditions available in RCKMS are reportable in jurisdiction, 5) Working with programmatic epidemiologists to develop and refine authored rules. (Describe the authoring plan in the narrative Implementation Plan section of the application.)

Level 2:

- Engage with healthcare organizations (HCOs) to determine and author useful information in RRs (e.g., condition-specific testing or treatment information, local outbreak information for certain conditions). Update authoring plan to define process and timeline to regularly update this information.

☒ Required ☐ Optional

c) Use eICR/RR data that are received by PHAs

All levels for this activity must be addressed in implementation plan

Level 1:

- Make eCR data available to epidemiologists and case investigators, at least through a human-readable format of the eICR, while working on integration of eCR data into the PHA's surveillance system(s). Communicate with and train epidemiologists and case investigators at the state and/or local level and within tribes, as appropriate, on anticipated change of workflow and business processes and how to access and use the eCR data.
- Assess and enhance technical infrastructure and capacity for eCR and request eCR technical assistance and/or direct support as needed.
- Integrate eICRs and RRs into the primary integrated surveillance system. Ingest and make eCR data available to epidemiologists and case investigators through the surveillance system's production environment.
- Evaluate integration of eICR and RR into secondary surveillance systems, if applicable.
- For the 35 states with federally recognized tribes, begin discussion with the tribes (or their designated public health authority) to determine an approach for tribes to access complete eCR data.

Level 2:

- Enhance systems and processes to expand eICR/RR data elements populating discrete surveillance system fields, expand the number of conditions with production eCR data available, and enable automated processing and use of eICR (i.e., without the need for manual intervention [human review] when appropriate).
- For the 35 states with federally recognized tribes, work together with the tribes (or their designated public health authority) to determine an approach for tribes to access complete eCR data.
- Integrate eICR and RR into secondary surveillance systems, if applicable. Make eCR data available to epidemiologists and case investigators through secondary surveillance systems' production environments.

☒ Required ☐ Optional

d) Improve and maintain eCR data quality

All levels for this activity must be addressed in implementation plan

Level 1:

- Develop and enhance eCR data quality assurance processes to assess and improve HCO adherence to the eCR implementation guides, ensure timely updates from the Electronic Reporting and Surveillance Distribution (eRSD), etc. and provide feedback to and work with HCOs to improve eCR data received by PHAs (e.g., data visualization, feedback reports, validation tools).

Level 2:

- Collaborate with HCOs and healthcare providers to improve completeness and quality of eICR data through improved Electronic Health Record (EHR) field completion rate for critical data elements.

☒ Required ☐ Optional

e) Collaborate with HCOs to accelerate HCO onboarding and reduce manual reporting

All levels for this activity must be addressed in implementation plan

Level 1:

- Engage and communicate with HCOs regarding eCR and onboarding, and continue to work with CDC, APHL, and CSTE to onboard HCOs. Develop and implement an engagement plan for in-jurisdiction HCOs, including how onboarding status and progress will be tracked, whether or how incentives will be used, and processes to promote onboarding for in-jurisdiction HCOs. (Describe the HCO engagement plan in the narrative Implementation Plan section of the application.)
- Update PHA websites with information on promoting interoperability, including declaring readiness for eCR, and eCR as a method to fulfill case reporting requirements
- Develop and implement eCR data quality criteria and processes for evaluating HCOs and turning off manual reporting. Target: 10% of in-jurisdiction healthcare facilities in production approved to discontinue manual reporting and 50% are actively engaged with PHAs for data validation for 5 conditions (or 2 condition groups) each year. Track which HCOs have been approved to turn off manual reporting, for which conditions or condition groups, and the date(s) they were approved.
- Work with CDC to track and transition all HCOs to implementing the full Electronic Reporting and Surveillance Distribution (eRSD) (e.g., including all conditions triggering), if they have not already.
- In coordination with CDC eCR team, facilitate routine receipt of facility list updates from HCOs.

Level 2:

- Further prioritize using eCR data instead of using manual/legacy provider reporting. Target: 20% of in-jurisdiction healthcare facilities in production approved to discontinue manual reporting and 75% are actively engaged with PHAs for data validation for 10 conditions (or 4 condition groups) each year.
- Perform an evaluation of eCR data completeness, timeliness, and/or impact, possibly in collaboration with HCO(s).
- Encourage HCOs to work with their EHR/Health Information Technology (HIT) product vendors to implement the CDA R3.1 eICR and/or FHIR eICR.

Level 3:

- Collaborate with HCOs to utilize RRs with healthcare providers

☒ Required ☐ Optional

4) Sustain and Enhance PHD Electronic Data Exchange: National Syndromic Surveillance

a) Maintain or enhance Syndromic Surveillance Information System. This activity is required if funded.

i) Explore, evaluate, and incorporate new data sources (e.g., poison control, emergency medical services) at recipient's jurisdiction that can enhance syndromic surveillance

ii) Other enhancements

☒ Required (if funded) ☐ Optional

b) Collect and use syndromic surveillance data

Collect and use syndromic surveillance data to analyze and monitor harmful effects of exposures to diseases and hazardous conditions. This activity is required if funded.

i) Maintain and improve existing transmissions to the NSSP BioSense Platform

ii) Increase coverage (Target for emergency departments (ED): 100%) and number of facilities submitting syndromic surveillance data to the BioSense Platform for ED and urgent care facilities with messages that include the NSSP priority 1 and 2 data elements.

iii) Increase quality and timeliness of syndromic surveillance data

(a) Enhance completeness and validity of data, focusing on NSSP Priority 1 and 2 data elements

(b) Enhance timeliness of messages sent to recipient systems and to NSSP BioSense Platform

(c) Develop or enhance data quality control and assurance processes

iv) Increase use of syndromic surveillance data

c) Develop or enhance syndrome monitoring and response protocols

d) Participate in at least one collaborative project with CDC subject matter experts. At a minimum, collaborative projects shall include state-level data or more granular syndromic data with CDC staff. Examples including opting-in to displaying state-level data on public-facing dashboards and permitting disease-specific programs to use data for routine surveillance.

e) Participate in at least one collaborative project with state or local health department subject matter experts to expand the usage of syndromic surveillance data. Examples including working with jurisdictional suicide or overdose programs or environmental health to develop surveillance strategies.

☒ Required (if funded) ☐ Optional

5) Sustain and Enhance PHD Electronic Data Exchange: Collect and Transmit Standardized Surveillance Data

a) *Level 1: Collect and Transmit Standardized Surveillance Data*

Support CDC's ability to collect, monitor, control, and prevent diseases and other health threats by standardizing the reporting of surveillance data. All funded city, county, and state health departments are required to collaborate to ensure all nationally notifiable conditions are transmitted to CDC from the 60 identified state and territorial reporters.

- Demonstrate collaboration across city, county, and state health departments to ensure all nationally notifiable conditions are transmitted to CDC from the 60 designated submitters
- Collect standardized, core data elements, currently defined by Generic v2 based Message Mapping Guide (MMG)
- Develop, implement, and maintain ability to transmit core data elements to CDC for nationally notifiable conditions, including data transmissions for new conditions during a public health emergency response
- Develop plan and approach to implement new standardized data elements

☒ Required ☐ Optional

b) Level 2: Collect and Transmit Standardized Surveillance Data

Support CDC's ability to collect, monitor, control, and prevent diseases and other health threats by standardizing the reporting of surveillance data. All funded city, county, and state health departments are required to collaborate to ensure all nationally notifiable conditions are transmitted to CDC from the 60 identified state and territorial reporters.

- Implement plan to incorporate new standardized data elements
- Participate in pilot projects and other efforts to support case surveillance modernization
- Improve quality and completeness of data, including data elements to support health equity
- Explore and adopt new formats and transmission methods for reporting to CDC (e.g., FHIR, CSV, APIs, CDC DEX) as they become available

☐ Required ☒ Optional

6) Sustain and Enhance PHD Electronic Data Exchange: Interjurisdictional data exchange

a) Create the capacity to transfer ELR, eICR, and case data between recipients

Create the capacity to transfer ELC, eICR, and case investigations between recipients. These transfers refer to the electronic sending of ELR, eCR, and case data between two recipients for a lab report or a case that was reported to one recipient but belongs to another recipient

☐ Required ☒ Optional

7) Sustain and Enhance PHD Electronic Data Exchange: Vital Statistics

The majority of the 57 vital records jurisdiction recipients have made significant progress toward implementation of the Fast Healthcare Interoperability Resources (FHIR)-based interoperability with CDC's National Center for Health Statistics (NCHS) for mortality data. Many are expected to complete the certification process and begin production use of FHIR-based interoperability for mortality data over the next 18 months. Building on the experience and significant progress made with interoperability between

jurisdictions and NCHS for mortality, the focus is being broadened to include birth and fetal death data. This includes implementation of FHIR-based interoperability for birth and fetal death data with NCHS and development of enhanced capacity for timely linkage of birth, death, and fetal death data. Regardless of technical maturity, each of the 57 vital record jurisdiction recipients will receive the same base funding amount to work towards the required activities. Recipients that do not need the full funding amount to complete the required activities are asked to propose other 'optional' activities related to NVSS modernization consistent with the recipient's needs.

a) *Level 1: Develop & maintain technical capacity & systems for FHIR-based data exchange*

Develop and maintain technical capacity and systems for FHIR-based interoperability with NCHS for birth, fetal death, and death data. Development and implementation will be conducted in a phased approach that aligns with the timeline each recipient has developed in conjunction with NCHS. This activity is required if funded.

Development will include but not limited to:

- Making necessary upgrades to existing jurisdictional systems needed to support FHIR standards and record-level messaging of birth, fetal death, and death data
- Implementing application programming interfaces (APIs) to support sending and receipt of FHIR messages
- Maintain existing information systems (e.g., electronic birth and death registration systems), including the personnel and operating environment and supporting software necessary for them to function

☒ Required (if funded) ☐ Optional

b) *Level 2: Develop & maintain technical capacity & systems for FHIR-based data exchange*

Development will include but not limited to:

- Engaging in testing and piloting between recipient's Electronic Birth, Fetal death, and Death Registration Systems and NCHS
- For recipients determined to be ready for production interoperability with NCHS, successfully completing a series of tests to demonstrate readiness (i.e., certification) before approved to send NCHS data using FHIR in production for each record type (birth, fetal death, and death)
- Once the recipient has been approved for production, sending data for that record type using FHIR and ceasing to use the legacy feed
- Develop jurisdictional capacity to routinely link maternal death records and associated birth/fetal death record, and provide NCHS timely linkage information (i.e., certificate numbers) to assess and improve the quality of maternal death data. For records that do not clearly indicate that the mother was pregnant at the time of death, the inability to locate a matching birth or fetal death record may indicate that the death record was erroneously identified as a maternal death; these records should be reviewed, and if necessary, corrected by the medical certifier

☐ Required ☒ Optional

c) Level 1: Propose and implement additional vital statistics related modernization

- FHIR-based interoperability between medical examiner/coroner case management systems and electronic death registration systems

☐ Required ☒ Optional

d) Level 2: Propose and implement additional vital statistics related modernization

- Interoperability between recipient's electronic birth and/or death registration system and one or more surveillance system or registry
- Pilot interoperability between hospital EHR and recipient's electronic birth and/or death registration systems
- Other innovative projects that will improve the timeliness and/or quality of vital records data

☐ Required ☒ Optional

For Freely Associated States ONLY (Federated States of Micronesia, Republic of Palau, Republic of the Marshall Islands)

e) *Develop & maintain technical capacity & systems*

The objective of this activity is to support the freely associated states to collect and report vital records data that align with U.S. Standards Certificates and Reports. Representatives from the Freely Associated States are welcome to participate in NVSS Community of Practice, however participation is not required.

This activity is required, if funded

i) Assess and develop implementation plan for the procurement and implementation of new or upgraded vital records registration systems

i. Maintain existing information systems (e.g., electronic birth and death registration systems), including the personnel and operating environment and supporting software necessary for them to function

ii. Enhance existing information systems to align with U.S. Standards Certificates and Reports and other program prescribed standards. Functionality should include the collection of data elements comparable for the National Vital Statistics System.

☒ Required (if funded) ☐ Optional

Area B: Prevention and Intervention

8) Sustain and Enhance PHL Laboratory Information Management Systems (LIMS)

a) Level 1: Enhance existing information system(s) by adding or improving functionality

This may range from minimal to large scale updates to systems. Recipients should include the personnel, operating environment, and supporting software necessary for them to function.

Prioritized activities are listed below, but other activities may be requested with justification.

- Map local test, result, and specimen source codes to LOINC and SNOMED standards. CDC, in collaboration with partners, develops and publishes LOINC codes for specific tests (e.g., COVID, HIV, MPox) and can be found in the LOINC In Vitro Diagnostic (LIVD) tool (https://www.cdc.gov/csels/dls/livd-codes.html)
- Configure all tests and associated workflows that are in LIMS, including new tests and EUAs in a timely manner
- Prioritize & interface laboratory instruments with the LIMS to reduce/eliminate data entry of test results, as appropriate
- Configure, collect, package, & send laboratory data via preferred method as specified for **at least two** CDC-sponsored lab networks (e.g., PHLIP, LRN (HL7 v2.5.1), DAART (HL7 v2.5.1), Rabies)
- Create and send ELR based on Promoting Interoperability (formerly Meaningful Use (MU)) standards for all reportable conditions to or within the public health department

☒ Required ☐ Optional

b) Level 2: Enhance existing information system(s) by adding or improving functionality

Prioritized activities are listed below, but other activities may be requested with justification.

- Configure, collect, package, & send laboratory data via preferred method as specified for **all** CDC-sponsored lab networks (e.g., PHLIP, LRN (HL7 v2.5.1), DAART (HL7 v2.5.1), Rabies)
- Enhance systems to enable the automated processing and use of HL7 (v2.5.1 or FHIR) electronic test orders that are received and to create HL7 test results
- Accept and ingest electronic results from CDC laboratories into the public health LIMS
- Develop easy to use self-service administration and functionality (e.g., customizable reports and filters, implementation of barcodes for streamlined accessioning, workflows, queues, results approval/release)
- Integrate advanced molecular detection (AMD) sequencing data and workflows (e.g., accessioning, result approvals) into a centralized LIMS

☐ Required ☒ Optional

c) Level 3: Enhance existing information system(s) by adding or improving functionality

Prioritized activities are listed below, but other activities may be requested with justification.

- Improve capacity to analyze lab data to understand and make informed decisions about issues such as gaps in testing and community mitigation efforts
    - Include data elements such as tests ordered and completed (by device/platform), rates of positivity, source of samples, specimen collection

sites, and test type to be used to create data visualizations that will be shared with the public, local health departments, or federal partners

☐ Required ☒ Optional

d) *Implement (if appropriate) new/replacement information system(s).*

New/Replacement systems should be designed to address all activities listed in the section above and work with modernized data infrastructure as described in the Enterprise Infrastructure section.

Note: If implementing new or replacement systems, including integrated web portals, develop an implementation plan, including appropriate milestones and timeline to completion. Implementation plans will be reviewed and approved for consistency with the activities set forth in the ELC awards by CDC **prior** to the start of procurement & implementation. (See Required Tasks for more details

☐ Required ☒ Optional

9) Sustain and Enhance PHL Electronic Data Exchange: Electronic Test Orders and Results (ETOR)

a) Level 1: Implement or enhance a web portal for ETOR

This may range from an initial implementation to expanding the web portal to include more laboratory program areas. Recipients should include the personnel, operating environment, and supporting software necessary for them to function.

Web portals are an easier way to implement ETOR compared to integrating systems. They can be utilized while integrated solutions are being established and may often be the best solution for ETOR with low-volume submitters or those with less technical expertise.

Level 1:

- Implement an integrated ETOR web portal for all orderable tests within **at least two** laboratory program areas
- Develop and maintain user documentation to support ETOR web portal end user training
- Ensure access for at least two public health laboratory staff and epidemiology staff to CDC's Specimen Test Order and Reporting (CSTOR) portal

☒ Required ☐ Optional

b) Level 2: Implement or enhance a web portal for ETOR

- Implement an integrated ETOR web poral for all orderable tests
- Ensure ability to enhance and maintain a web portal for multiple years
- Establish PHL to PHL ETOR (either state to state or local to state)

☐ Required ☒ Optional

c) Level 1: Implement an integrated ETOR solution

This should include prioritization of laboratory program, partner engagement, system assessment, and potential engagement with an intermediary. Recipients should include the personnel, technical assistance, software and hardware needs necessary.

Integrated ETOR solutions reduce the reliance on staff allowing for automation of test ordering and resulting, enhancing data quality and completeness, and improving timeliness. These are good solutions for high-volume submitters and high-volume laboratory programs (e.g., newborn screening). Direct integration requires that systems must directly communicate in the same way and must be established for each partner. Utilizing an intermediary (i.e., indirect integration) allows each system to maintain its native format and uses tools and services (e.g., message translation and transformation) to enable data exchange between partners. The PHL connects once to an intermediary reducing point-to-point connections.

- Plan for ETOR implementation. Prioritize laboratory program area. Engage with intermediary team (ReportStream, AIMS)
- Identify, prioritize and perform outreach with HCO or other submitters for integrated ETOR onboarding
- Develop a plan to provide incentives to HCOs to support costs related to establishing ETOR interfaces

☒ Required ☐ Optional

d) Level 2: Implement an integrated ETOR solution

- Establish ETOR with **at least one HCO** via direct or indirect integration
    - Best practice would include both receiving orders and sending results through an intermediary to reduce point-to-point connections (indirect integration)
- Implement and provide incentives to HCOs to support costs related to establishing ETOR interfaces
- Send electronic orders to CDC laboratories from the public health LIMS
- Establish PHL to PHL ETOR (either state to state or local to state)

☐ Required ☒ Optional

Area C: Communications, Coordination, and Partnership

10) Implement and maintain sustainable enterprise infrastructure

Activities in this section apply to both the public health department and public health laboratory.

These activities will support the development of modern infrastructure, processing, and data lake environments that will be used as data sources for systems & registries, and as the foundation for analytics, dashboarding, and data sharing. Data streams include but are not limited to: eCR, ELR, ADT, VXU, Vital Records.

Prioritized activities are listed below but other activities may be requested with justification

a) Participate in CDC-sponsored activities supporting modernized infrastructure

Recipients will participate in CDC requirements gathering, pilots, or beta testing of modernized infrastructure that will be shared across multiple jurisdictions

☒ Required ☐ Optional

b) Level 1: Explore and migrate systems to cloud-based/hosted environment

Level 1:

- Explore efficiencies and develop implementation plans to move existing or new information systems, data sources, data pipelines, and other tools to a cloud-based/hosted environment. Plans should align with CDC's North Star Architecture approach

☒ Required ☐ Optional

c) Level 2: Explore and migrate systems to cloud-based/hosted environment

- Transition and migrate existing or new information systems, data sources, data pipelines, and other tools to a cloud-based/hosted environment that leverage consolidated data hosting approaches (e.g., data lakes), flexible data structures, and non-proprietary standards and approaches to getting data in and out of systems
    - Sample data sources include but are not limited to: infectious disease data, vital records, chronic disease registry, birth defects, immunization registry, maternal and child health systems, early hearing/early detection data, department of motor vehicles information.

☐ Required ☒ Optional

d) Level 3: Explore and migrate systems to cloud-based/hosted environment

- For cloud-based/hosted systems, develop plans for optimization and expand use of cloud-native tooling. Identify opportunities to reduce the complexity of data ingestion and processing and explore solutions that perform unified processing across data streams

☐ Required ☒ Optional

e) Level 1: Identify and implement scalable data management platforms or software

- Develop use cases for cloud-based data lakes/warehouses for improved data quality and efficiencies for data analyses, visualizations, and processing
- Develop and implement policies and procedures to enable single source of truth across data sources (matching/duplication rules, updating rights, merging) e.g., through master person/patient index
- Identify opportunities to link or add reporting entities to improve completeness and/or representativeness of data

☒ Required ☐ Optional

f) Level 2: Identify and implement scalable data management platforms or software

- Develop performance monitoring for data ingestion pipelines to better identify problems, troubleshoot them in real time, and improve data quality
- Implement or expand the use of analytics and visualization platforms (e.g., integration of Advanced Molecular Detection (AMD) data and surveillance data)
- Increase the usage of modern data processing and analytics tools that use open technologies (e.g., open source, standards, and architecture)
- Enable lab-epi collaboration by identifying and implementing a universal case identifier, or similar linking variable(s), to include with laboratory and case data transmission (e.g., patient identifier that links data from public health information systems; identifier to link PulseNet data to case reports).
- Develop record linkage capabilities (e.g., MPI) at the broadest organizational level to increase secure data linkages between diverse data sets across person, place, and time, and to increase data completeness
- Develop systems, tools, or dashboards for public release of public health data, such as case surveillance, syndromic surveillance, laboratory tests, hospitalizations, and healthcare capacity, in a visual and/or tabular format at the county level or other geographical unit

☐ Required ☒ Optional

g) Level 3: Identify and implement scalable data management platforms or software

- Implement Privacy Preserving Record Linkage with CDC
- Implement indexing based on United States Core Data for Interoperability (USCDI) standards, where applicable
    - Develop gap analysis and transition plan to support USCDI and USCDI+ for public health
- Enhance interoperability and accessibility of data between systems (e.g., integrated disease surveillance system, LIMS, immunization registry, vital records) and complementary data sources (e.g., health equity, social determinants, patient history) via enterprise infrastructure (e.g., data lake, data warehouse) or direct connections
- Propose other innovative projects for modernizing data quality, exchange, management, sharing, and use

☐ Required ☒ Optional

h) Level 1: Implement shared services to facilitate data exchange & system functions

- Identify activities that use shared services or infrastructure to enhance existing or facilitate new data exchange or information system functionality. Projects may include services and infrastructure located outside of the recipient's jurisdiction; existing

services and infrastructure in the jurisdiction for use by others; or building new services and infrastructure. Given limited resources available, proposals should include incremental or scalable activities.
- Reduce point-to-point connections and new sender connections, as appropriate, by leveraging trusted intermediaries (e.g., AIMS, ReportStream, HIEs, QHINs), especially for laboratory test orders and results.

☒ Required ☐ Optional

i) Level 2: Implement shared services to facilitate data exchange & system functions

- Implement identified shared services or infrastructure to enhance existing or facilitate new data exchange or information system functionality. Projects may include services and infrastructure located outside of the recipient's jurisdiction; existing services and infrastructure in the jurisdiction for use by others; or building new services and infrastructure. Given limited resources available, proposals should include incremental or scalable activities.
- Enable an Application Programming Interface (API) architecture to serve as a data source for existing or new information systems.
- Send 1-2 data streams of core data sources to CDC's Enterprise Data Exchange (DEX) Platform using APIs, when available.
- Propose other innovative projects for modernizing data quality, exchange, management, sharing, and use.

☐ Required ☒ Optional

Collaborations:

a. With CDC-Funded Programs

Recipients are expected to closely coordinate across their agency and local health departments in the planning, execution, and management of activities under this ELC program with related efforts funded through the Public Health Emergency Preparedness (PHEP), Accelerating Data Modernization in jurisdictions, Data Modernization 2, Strengthening U.S. Public Health Infrastructure, Workforce, and Data Systems Grant, and categorical cooperative agreements (e.g., STD, HIV/AIDS, TB.)

b. With Organizations External to CDC

Recipients are encouraged to participate with CDC and its partners in assessment, planning, development, and implementation efforts related to electronic data exchange, public health information systems, and hosted environments containing shared informatics services, tools, and infrastructure for public health use. These partners include, among others, the Association of State and Territorial Health Officials (ASTHO), Council of State and Territorial Epidemiologists (CSTE), Association of Public Health Laboratories (APHL), the National Association of County and City Health Officials (NACCHO), and the Public Health Informatics Institute (PHII).

Populations of Focus:

N/A

Evaluation and Performance Measurement:

Performance measures included here are representative and may not be final at the time of NOFO publication. Please see the CK-24-0002 Performance Measure Guidance document for all final measures and descriptions.

a. ACTIVE Performance Measures

C.1 Percent of lab report volume received through ELR (self-report)

C.2 Percentage of all ELR records automatically processed into downstream system(s) without manual intervention

C.3 Percentage of emergency departments (EDs) sending HL7 Promoting Interoperability compliant syndromic surveillance messages to the Health Department and BioSense platform

C.4 Number of Submitters with established electronic test ordering and results (ETOR) using system integration (direct or indirect) or a web portal

C.5 (A.1) Dedicated agency staff to lead and coordinate data modernization efforts*

C.6 (A.2) Established workforce, data, and health information system capabilities, needs and opportunities*

C.7 (A.3) Enhanced workforce capacities and capabilities to accelerate data and health information system modernization*

C.8 (A.4) Demonstrated use of shared services to enhance existing system or data exchange*

C.9 Number of healthcare organizations engaged to implement electronic case reporting (eCR)

C.10 Number of conditions published to production and test in Reportable Conditions Knowledge Management System (RCKMS)

C.11 Proportion of reportable cases with at least one associated electronic initial case report (eICR)

C.12 Demonstration of automatic processing of electronic initial case reports (eICRs) in the jurisdiction integrated surveillance system(s)

C.13 Proportion of test orders and results processed through Electronic Test Orders and Result Reporting (ETOR) at the Public Health Lab

C.14 Systems or programs at the Public Health Lab with Electronic Test Orders and Results (ETOR) interfaces

*Performance measures indicated with an asterisk(*) are collected in collaboration with the Public Health Infrastructure Grant and data will be shared across CDC programs to reduce burden and streamline data collection processes.

b. PASSIVE Indicators

Monitoring Activity: Integrated Surveillance Information Systems

Monitoring Activity: Implementation of new/replacement information systems

C.15 Percent of conditions that are state and nationally notifiable submitted to CDC in a modernized approved format

C.16 Percent of records reported to the National Center for Health Statistics within ten days

C.17 Participation in Connectathon(s) or other interoperability testing event

C.18 Demonstration of capacity to receive data using APIs and FHIR messages

C.19 Demonstration of capacity to send data using APIs and FHIR messages

Project D: Advanced Molecular Detection (AMD)

Program Activity Contact Information:

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Funding Opportunity Description:

a. Overview

The Office of Advanced Molecular Detection (OAMD) supports expanding laboratory capacity as well as training and workforce development (WFD) in state, local, and territorial public health laboratories (PHL) and health departments (HD) for advanced molecular detection (AMD) technologies including next generation sequencing (NGS), genomic epidemiology, and bioinformatics. This will be accomplished through a Strategy of Enhancing Workforce Capacity that includes AMD-related training at the state, local, and territorial level and Bioinformatics technical assistance and support.

b. Health Equity

The Office of Advanced Molecular Detection (OAMD) integrates genomic sequencing technologies with bioinformatics and epidemiology expertise across the nation to quickly detect, track, and stop disease-causing pathogens. The AMD Program prioritizes protecting America's health by modernizing and building capacity in national public health laboratories. Recent public health emergencies have highlighted health disparities in the response to emerging infectious diseases. In an effort to achieve health equity while expanding pathogen genomics, OAMD encourages recipients to develop and implement processes to decrease known health disparities within their jurisdictions. This may include, but is not limited to, modernizing data workflows and improving demographic data quality. Increasing health equity practices in public health laboratories will help to improve disease detection in vulnerable populations and increase positive health outcomes.

c. Healthy People

PHI-D04 – Increase proportion of state public health labs that provide services that support emerging issues.

PHI-D05 – Increase the proportion of state public health labs that use emerging technology to provide enhanced services.

Public Health Infrastructure - Healthy People 2030 | health.gov

d. Local Health Department and Tribal Engagement

Recipients should consider engaging with local health departments and tribes to collaborate on AMD training opportunities and pathogen genomics workforce development.

e. Other National Public Health Priorities and Strategies

N/A

CDC Project Description:

a. Problem Statement

Advanced Molecular Detection (AMD) technologies, particularly next-generation sequencing (NGS), bioinformatics, and genomic epidemiology, are revolutionizing innovative detection and enabling faster,

more accurate and more cost-effective ways of preventing, detecting, and responding to known, emerging, and resistant pathogens. As the first generation of these innovative technologies have been installed in public health laboratories, workforce needs and workflows are being restructured to implement them effectively. This is particularly important as new processes are being applied to an expanding list of pathogens using multiple methods for innovative workflows, data collection, data analysis, and data integration. In the face of these changes, there is a need to ensure basic, intermediate, and advanced levels of AMD laboratory, bioinformatics, genomic epidemiology, and workforce development capacity in state, local, and territorial health departments and public health laboratories. There is also a need to define the opportunities that these technologies present at the state, local, and territorial level.

b. Purpose

The Office Advanced Molecular Detection supports training in pathogen genomics, bioinformatics, and data integration. These training opportunities strengthen state, local, and territorial public health laboratory capacity to process, analyze, compare, and report genomic data independently or in collaboration with fellow public health colleagues. http://www.cdc.gov/amdModernizing infectious disease laboratories, training staff, and expanding the application of new technologies will ensure that Americans have the strongest protection against infectious disease threats.

HantaNet System (AMD Tier 2)

The Enteric Diseases PulseNet system has highlighted the benefits of a national surveillance and data sharing system to rapidly respond to food-borne enteric disease outbreaks. Here, we propose to develop a similar model for Hantavirus national surveillance and data sharing ("HantaNet") to rapidly respond to rodent-borne disease outbreaks. For Budget Period 1 (BP1), additional opportunities are being made available for financial support to strengthen surveillance, detection, and preparedness for Hantavirus diseases at state public health labs and at CDC.

The HantaNet system is providing financial assistance, using AMD funding, to those recipients who have need and ability to conduct activities to achieve the following goals and objectives in BP1:

1. Develop and standardize hantavirus diagnostic and sequencing protocols and bioinformatic support.
2. Design HantaNet cloud-based lab and epidemiological database (including defining data reporting quality standards) and associated visualization of data.

c. Outcomes

1. Public health workforce that is effective in detecting, responding, and preventing infectious disease threats.
2. Enhanced collaborations between epi/lab and regional/local public health departments to expand the knowledge base for AMD technologies and pathogen genomics.
3. Establishing and/or enhancing workforce competencies and capabilities in genomic and metagenomic sequencing, bioinformatics, and molecular epidemiology.
4. Increased bioinformatics and genomic epidemiology analytic capacity in state, local health, and territorial departments.
5. Increased use of AMD technologies to measurably support and enhance public health action.

Funding Strategy:

Total availability of funds for Project AMD: **$4,000,000**.

- Approximate number of awards: 64
- The approximate average award per recipient varies by activity. See below for award estimates.

The total of **$4,000,000** is to support:

1. AMD-related training at the state, local, and territorial level
2. Bioinformatics technical assistance and support
3. AMD Regional Workforce Development
   Applicants should apply either to be an AMD 'Training Lead' or 'Participant':

   a. Training Lead
      Funds should be requested to cover the costs of the training plus any in-state or out-of-state travel expenses for trainers and participants, specifically:

      - Costs associated with developing, implementing, and facilitating in-person or virtual regional AMD training sessions.
      - In-state or out-of-state travel expenses for training instructors and participants to participate in peer-to-peer AMD trainings.
      - Travel costs to attend approved national or regional conferences and/or travel related to AMD Training Lead coordination meetings and conferences, as appropriate.
      - Travel costs associated with the Training Lead providing consultation throughout the defined region, including on-site or peer-to-peer training sessions.
      - Costs associated with providing web-based consultations including platforms like Zoom.
        - Approximate number of awards: 10
        - Approximate average per award: $150,000 to $300,000, however, the amount awarded will be dependent on demonstrated need

   b. Training Participant:
      Funds should be requested for:

      - Travel-related costs to attend regional AMD trainings and/or AMD related workshops.
      - Costs associated with software and minor incurred costs associated with AMD workforce development training. Appropriate justification is required to accompany requests.
        - Approximate number of awards: 64
        - Approximate average per award: $3,000 - $10,000, however, the amount awarded will be dependent on demonstrated need

      Funding should **not** be requested for personnel, equipment, service contracts and maintenance agreements, sequencing supplies, kits, reagents, consumables, cloud computing, or computational resources. These line items can be considered for funding via the AMD *Sequencing & Analytics* 1 and AMD *Sequencing & Analytics 2* awards.

4. AMD Bioinformatics Regional Resource (BRR) Lead
   Funds should be requested for:

   - Support for full-time bioinformatics staff member(s), who serves as the bioinformatics subject matter expert for the entire defined region*. Funding may be requested for salary, fringe, and other minor costs associated with supporting the assigned region.
   - Travel costs associated with the BRR providing consultation and technical assistance throughout the defined region. Requests may include travel for on-site visits with regional public health laboratories and health departments.
   - Travel costs for BRR to attend approved national or regional conferences.
   - Costs associated with providing web-based consultations including platforms like Zoom.
   - Cloud computing or computational resources to support regional bioinformatics needs, including, as necessary, third-party consultation and contract support. This may include computers needed to support regional bioinformatics support*.
   - Costs associated with providing cloud-based training environments for bioinformatics consultations and/or training^.

   *AMD Regions Advanced Molecular Detection Investment (cdc.gov)

   ^If these costs have already been covered via the *AMD Sequencing & Analytics 1* or *AMD Sequencing & Analytics 2* award, please do not request them to be covered under this award.

   - Approximate number of awards: 10
   - Approximate average per award: $200,000 to $350,000, however, the amount awarded will be dependent on demonstrated need

HantaNet System

CDC anticipates making a total of $160,000 available for Budget Period 1 to qualifying ELC recipients. This funding is for three awards for one-year funding for the proposed pilot activity. Additional funding is not guaranteed for Budget Period 2, but we anticipate a possible expansion, given pilot project success, in year three out of a five-year funding period.

The focus for BP1 is the procurement of equipment, reagents, supplies, bioinformatic programs and database programs. Staff support is allowable, but this funding is not guaranteed in BP2. Staff training, conference travel, and publications costs are also covered under proposed activities.

***Please note:**

1. For State Health Departments (SHDs), when entering budget requests, recipients must use the 'Public Health Allocation' to indicate the portion of financial support going toward 'Local/Regional Health Department (LHD)' support versus staying at the SHD level. This allocation data helps ELC answer inquiries regarding the financial support to LHDs which is crucial given the important role LHDs have in addressing infectious diseases.
2. For Local Health Departments (LHDs), when entering budget requests, please ensure the 'Public Health Allocation' is set to 100% 'Local/Regional Health Department (LHD)' support.

3. For Territorial Health Departments, if you have local/regional jurisdictions, please follow the instructions for State Health Departments in #1.

Required Tasks:

Acceptance of funding conveys acknowledgement and indication that the following requirements will be met.

1. Recipients are expected to meet all deadlines for:
   a. Report Expenditures and ULOs quarterly in CAMP
   b. Submit and/or update success stories
   c. AMD Training Leads and BRRs will participate in meetings to collaborate with CDC and other partners, as requested
   d. AMD Training Lead and Bioinformatics Regional Resource will submit end-of-year reports detailing project activities.

Strategies and Activities:

0) Strategy to Address Required Tasks

a) Address Required Tasks in project guidance.

☐ Required ☒ Optional

Area A: Surveillance, Detection, and Response

1) Enhance Workforce Capacity

a) Develop Training Plans and Lead AMD Regional Workforce Development Trainings

Recipients are encouraged to work with training participants within their defined AMD region*, other regional training leads, and Bioinformatics Regional Resource Leads (BRRs) to develop discrete regional or broader training plans. Collaboration with universities or other public or private institutions with NGS and bioinformatics capacity to develop trainings is encouraged. There may be multiple Training Leads within a defined region.

i) Conduct training needs assessment before scheduling training.
ii) Collaborate with Bioinformatics Regional Resource leads, co-region AMD Training Leads (if applicable), and other partners to develop and implement training plans including developing core competencies for AMD training and curriculum development. Audiences should include AMD lab scientists, bioinformaticians, and genomic epidemiologists.
iii) Coordinate training activities with training participants.
iv) Host new and/or existing trainings in collaboration with local, regional, or national partners where possible.
v) Host distance or virtual trainings in collaboration with local, regional, or national partners where possible.
vi) Conduct training evaluations to measure impact of course(s) and performing continuous improvement of the training program.

*AMD Regions Advanced Molecular Detection Investment (cdc.gov)

☐ Required ☒ Optional

b) *Participate in AMD Regional Workforce Development Training*:

Recipients are encouraged to apply under this activity to send staff to participate in regional or national AMD trainings. Recipients applying in this section should request funds to engage in regional AMD training activities (or similar activities) as listed:

i) Send staff to be trained at in-person courses and workshops on pathogen genomics, wet-lab sequencing, bioinformatics, and/or other AMD-related activities. Typically, AMD Training Leads host one to two regional trainings per budget period and may provide peer-to-peer AMD training; please contact your AMD Training Lead for details.
ii) Enable staff participation in virtual or distanced-based AMD training, webinars, and other structured online workforce development activities.
iii) Participate in AMD workforce needs assessments as requested by AMD Training Leads and/or Bioinformatics Regional Resource Leads.
iv) Provide evaluation and feedback on training materials and content delivery.

☐ Required ☒ Optional

c) *Develop and Implement AMD Bioinformatics Resources, Provide Technical Assistance, and Collaborate with AMD Training Leads as Consultants*:

Recipients are encouraged to work with AMD Training Leads to foster the development of bioinformatics and AMD capacity nationally. There may be multiple Bioinformatics Regional Resource Leads within a defined region.

AMD Training Leads and Bioinformatics Regional Resources may be from the same regional public health laboratory or may be from different jurisdictions within one region. Recipients may choose to use this component to support a new or existing bioinformatician to perform this activity.

Bioinformatics Resource leads should solicit funds to engage in activities including:

i) Assist the regional Training Lead(s) in developing and implementing trainings. Consultations may be in-person, by phone, or through other virtual meetings. This may involve, for example, assisting in the development of web-based modules that could be used within the region or nationally.
ii) Collaborate with AMD Training Leads and other partners to develop and implement new training plans including developing core competencies for training and curriculum development.
iii) Provide bioinformatics technical assistance and/or consultation to other states and localities in the region. This may involve, for example, performing ad hoc bioinformatics analysis for those states or localities or assisting a staff member in one of their laboratories in doing their own analysis.
iv) Coordinate and communicate with AMD Training Leads and participants for bioinformatics technical assistance.
v) Consult with local or state IT departments regarding IT policies necessary to support AMD implementation.

vi) Work with states or localities to resolve IT problems that are limiting the use of AMD technologies.

vii) Work with state labs and CDC to find sustainable, affordable solutions to state and local health department AMD-related informatics needs such as storage and cloud computing.

viii) Where needed and appropriate, work with state and local health departments to promote data sharing.

☒ Required ☐ Optional

2) Strengthen surveillance, detection, and preparedness for Hantavirus diseases at state public health labs and at CDC (Tier 2 – AMD HantaNet Pilot Project)

a) Develop and standardize Orthohantavirus diagnostic and sequencing protocols, including bioinformatic training and support.

i. Generate Orthohantavirus diagnostic/sequence data related to human-infections and vector-related surveillance.)

☒ Required ☐ Optional

b) Collaborate with epidemiologists in CDC's Viral Special Pathogens Branch (VSPB) to design HantaNet cloud-based lab and epidemiological database (including defining data reporting quality standards for human and vector surveillance).

☒ Required ☐ Optional

c) Create and pilot dashboard for lab, epidemiological and sequence data visualization.

☒ Required ☐ Optional

Collaborations:

a. With CDC-Funded Programs

Collaborations with other CDC-funded programs is strongly encouraged, especially when activities in this program support emerging disease-specific needs found in other programs and projects elsewhere in the guidance.

Collaboration and exchange of data, materials, and resources with other state health departments implementing AMD activities is encouraged.

For the HantaNet System

The Viral Special Pathogens Branch (VSPB) at CDC will collaborate with recipients and oversee the proposed work.

b. With Organizations External to CDC

Self-directed Regional Laboratory Networks supported should coordinate with the Association of Public Health Laboratories (APHL) to ensure there is no duplication of effort. Where appropriate, other partnerships with national public health organizations (e.g., CSTE, NACCHO, ASTHO) are encouraged.

There should be collaboration and exchange of data, materials, and resources amongst state health departments implementing AMD activities.

For the HantaNet System
Previous and current-funded recipients (state jurisdictions) are expected to collaborate together on this project. As well, previous and current-funded recipients are expected to collaborate with external groups that support the dashboard visualization component (i.e. – Applied Physics Lab (APL) at Johns Hopkins University).

Populations of Focus:

N/A

Evaluation and Performance Measurement:

Performance measures included here are representative and may not be final at the time of NOFO publication. Please see the CK-24-0002 Performance Measure Guidance document for all final measures and descriptions.

a. ACTIVE Performance Measures

Workforce Development PMs:

PM1. Training Leads will report the number of trainings by course type:

- Basic NGS and bioinformatics course
- Intermediate NGS and bioinformatics course
- Advanced NGS and bioinformatics course
- Genomic epidemiology course
- Other courses (please specify)

PM2. Training Participants will report the number and percent of AMD staff who completed at least one AMD-related training.

PM3. Bioinformatics Regional Resources (BRRs) will report the number of in-person consultations.

PM4. BRRs will report the number of virtual consultations.

b. PASSIVE Indicators

The AMD Program does not have any Passive Indicators to assess recipient progress toward outcomes.

Project E: National Wastewater Surveillance System

Program Activity Contact Information:

John Person: jperson@cdc.gov; Trevor McCoy: qid0@cdc.gov; Cristina Martinez: uff3@cdc.gov; Heidi Cox: qof4@cdc.gov; Martha Johnson: ueu9@cdc.gov

Funding Opportunity Description:

a. Overview

This program of CDC's Division of Infectious Disease Readiness and Innovation aims to protect public health through the prevention and control of diseases detectable in wastewater. This section describes the activities necessary for a comprehensive wastewater surveillance program in a recipient's jurisdiction.

This template section is divided into two tiers. Tier 1 and Tier 2 refer to levels of performance by recipients and do not correspond to a predetermined funding award for those levels of performance.

Tier 1 strategies and activities cover general wastewater surveillance, detection, and response; prevention and intervention; and communications and partnerships. Tier 1 strategies and activities include providing dedicated support staff for coordinating wastewater surveillance activities, data reporting, sample collection, laboratory testing, equipment, and supplies. These activities are essential to monitor and respond to changes in testing practices; identify sources of sporadic enteric disease; implement methods for improving outbreak detection and response; and improve overall capacity for outbreak detection and response. Activities may contain both epidemiologic and laboratory components.

Tier 2 includes activities for the National Wastewater Surveillance System Centers of Excellence.

All Tier 1 activities must be addressed before applying for activities under Tier 2. The project areas under each tier are briefly described below. While any Tier 2 section is optional for applicants, if a recipient is applying for a Tier 2 project, then all the activities within that Tier 2 project must be addressed.

Tier 1 includes:

The National Wastewater Surveillance System utilizes wastewater testing to understand disease prevalence trends in the community. NWSS partner sites coordinate with local partners, such as laboratories and wastewater utilities, to select sampling sites, facilitate laboratory testing, and submit data to the NWSS DCIPHER portal. Analyzed results are returned to partner sites to support public health action. In addition to community surveillance at wastewater treatment plants, NWSS partner sites may also propose to conduct sub-sewershed or targeted surveillance by sampling wastewater from facilities, institutions, or workplaces (e.g., nursing homes, universities, or correctional facilities). NWSS partner sites also engage with each of the other 64 jurisdictions and the 4 Centers of Excellence to support knowledge-sharing and accelerate the implementation and use of wastewater surveillance for public health action. NWSS partners may also propose to conduct testing for additional pathogens, targets, and sequencing variants. Additional information about NWSS can be found at www.cdc.gov/NWSS.

Tier 2 includes:

National Wastewater Surveillance System Centers of Excellence (NWSS CoEs): Four NWSS CoEs will be funded to support the implementation and continued development of wastewater surveillance for public

health action. NWSS CoEs will provide technical support to NWSS implementers in other jurisdictions, develop improved data metrics, develop and share communications materials, and improve data sharing and management systems. CoE applicants may propose additional activities that support the advancement of wastewater surveillance, however, this ELC funding cannot be used to support research-associated activities. If research activities are described for the purpose of providing program context, please clearly indicate that no ELC funds are requested to support such activities. NWSS CoEs will be headquartered in state health departments, each CoE must partner with at least one academic institution, and CoEs must partner with at least one wastewater utility. For additional information about the NWSS CoEs Contact NWSS@cdc.gov for more information.

b. Health Equity

CDC encourages NWSS recipients to apply health equity principles when developing sampling strategies, creating information resources and presentations, engaging with partners, and/or when developing and reviewing external or internal communication materials. Additionally, recipients should collect relevant health equity data elements that are aligned with national standards, develop community-based partnerships to advance health equity, and use health equity principles and established guidelines when implementing prevention and control measures.

c. Healthy People

N/A

d. Local Health Department and Tribal Engagement

Recipients should engage local, territorial, tribal (or tribal serving) health departments/jurisdictions, as appropriate, to accomplish NWSS program required tasks and activities. This can include providing supplemental funding (but any funding should not be duplicative of other federally funded cooperative agreements).

If tribes and regional tribally-designated organizations are involved in a Work Plan, please address how they are included in planning and implementation of the Work Plan. Tribal leadership should be made aware of any planning as soon as possible, deferring to tribal needs and protocols. Include documentation of agreement from appropriate tribes or regional tribally designated organizations relating to partnership and appropriately recognize tribal involvement in all work products. Additionally, recipients must be prepared to provide data use agreements, non-disclosure agreements, and other privacy protection documents for each individual tribe or regional tribally-designated organization. Data of the tribe/regional tribally-designated organization must be shared directly with their designated point of contact, and the data should not be shared publicly without tribal consent.

e. Other National Public Health Priorities and Strategies

- Public Health Emergency Preparedness and Response Capabilities: National Standards for State Local, Tribal, and Territorial Public Health (https://www.cdc.gov/cpr/readiness/capabilities.htm)
- CDC's Crisis and Emergency Risk Communication (CERC) (https://emergency.cdc.gov/cerc/)
- CDC's Public Health Data Strategy (https://www.cdc.gov/ophdst/public-health-data-strategy/index.html)

CDC Project Description:

a. Problem Statement

Wastewater surveillance can act as an essential tool for infectious disease preparation, prevention, and response. With access to modern technologies, more public health data is available than ever before, and wastewater is a grand repository of data that should not be overlooked. Wastewater surveillance has proven to be incredibly versatile in that it can be used for many things including monitoring seasonal diseases, deciding where to implement public health interventions, evaluating the effectiveness of those interventions, as a supplement to clinical surveillance in areas with low resources, and even as an early warning tool during emergency responses, which was demonstrated during the CDC's SARS-CoV-2 response. Strong national surveillance is key to detecting cases of illness as well as outbreaks, and implementing wastewater surveillance on a national level requires close collaboration between state, local, and federal agencies. Prompt, coordinated, and effective outbreak investigations and reporting are necessary to inform health risk communications, focus prevention strategies, and overall improve public health outcomes.

b. Purpose

The purpose of this project is to support and enhance capacity for wastewater surveillance as a tool for investigation and control of pathogens and other targets that are detectable in wastewater, and to implement evidence-based prevention practices through communication, partnerships, policy initiatives, and targeted interventions.

c. Outcomes

1. Collection wastewater samples from communities (utilities, wastewater treatment plants, municipalities, etc.) and target sewersheds (facilities, universities, schools, correctional facilities, upstream sampling locations, etc.)
2. Analysis, compilation, and dissemination wastewater data to the CDC, the public, and to participating utilities.
3. Utilization of modern laboratory techniques for surveillance and detections of pathogens or other targets in wastewater.
4. Use wastewater surveillance data to:
    a. Respond to outbreaks.
    b. Investigate outbreaks.
    c. Implement control and mitigation measures.
    d. Inform public health decision making.
5. Data quality, timeliness and security. This includes:
    a. Ensuring data submitted to CDC passes quality control standards.
    b. Submitting data weekly.
    c. Ensuring sewershed polygons are accurate and available.
    d. Ensuring information is secure and protective of the populations served.
6. Improvement of existing uses of wastewater surveillance in public health.

Funding Strategy:

Total availability of funds: $6,000,000

Approximate number of awards: 20

Approximate average per award: $300,000

Funds should be used for:

- Wastewater testing supplies and equipment
- Dedicated staff for wastewater surveillance
- Supporting wastewater utilities in sample collection
- Data management and support

Tier 1 NWSS Funding Note: A portion of the funds can be allocated to implementation partners, such as utilities and contract laboratories. Detailed justifications must be included in the budget that clearly describe how funds will be spent including a breakdown by salary, travel, supplies, etc.

Tier 2 CoE Funding Note: A substantive portion of the CoE budget should be allocated to the academic and utility partners for NWSS CoEs. Detailed justifications must be included in the budget that clearly describe how funds will be spent including a breakdown by salary, travel, supplies, etc. Budgets should be clear that no ELC funds are requested to support research activities; recipients are responsible for ensuring that their partners do not use ELC funds for research purposes.

***Please note:**

1. For State Health Departments (SHDs), when entering budget requests, recipients must use the 'Public Health Allocation' to indicate the portion of financial support going toward 'Local/Regional Health Department (LHD)' support versus staying at the SHD level. This allocation data helps ELC answer inquiries regarding the financial support to LHDs which is crucial given the important role LHDs have in addressing infectious diseases.
2. For Local Health Departments (LHDs), when entering budget requests, please ensure the 'Public Health Allocation' is set to 100% 'Local/Regional Health Department (LHD)' support.
3. For Territorial Health Departments, if you have local/regional jurisdictions, please follow the instructions for State Health Departments in #1.

Required Tasks:

Acceptance of funding conveys acknowledgment and indication that the following requirements will be met.

Administrative

1. Identify at least one designated point of contact(s) for Tier 1 and Tier 2
2. Participate in all Tier 1 regularly scheduled program calls, conference calls, webinars, office hours, working group calls, community of practice calls, site visits, and vision meetings
    a. Tier 2 recipients are required to participate in regularly scheduled calls, working group calls, community of practice calls, and vision meetings designated for Centers of Excellence
3. Participate in CDC site visits when applicable.
4. Participate in monthly NWSS CoE calls, workgroup calls, annual vision meeting, program site visits, and other meetings, as requested (Tier 2: NWSS CoE)

Workforce capacity

5. Ensure wastewater surveillance staff capacity through relevant key positions, trainings, and certifications.
6. Maintain supplies, equipment, infrastructure, data entry personnel necessary for surveillance, data sample delivery, and laboratory diagnostics and subtyping.
7. Identify one or more points of contact as NWSS coordinators.
8. Identify one or more laboratory points of contact for wastewater testing.

Surveillance

9. Conduct epidemiologic surveillance for pathogens
    a. Optionally, conduct epidemiologic surveillance for other targets beyond SARS-CoV-2.
10. Collaborate with CDC on data cleaning and closeout activities
11. Submit wastewater concentration data weekly to DCIPHER.
12. Read, sign, and return the Rules of Behavior (RoB) and Non-Disclosure Agreement (NDA) documents for NWSS DCIPHER.

Outbreak Detection, Response, and Control

13. When applicable, conduct or participate in analytic epidemiologic investigations in response to detections of select pathogens in wastewater.

Prevention and Partnerships

14. Develop and/or disseminate evidence-based health education and promotion materials/messages based on identified health threats and engage in proactive outreach and education to groups disproportionately impacted by infectious diseases.
15. Develop and maintain strategic partnerships with diverse partners (including public health, industry, community, institutional, and other prevention partners) to support surveillance, investigations, and collaboratively identify and implement evidence-based interventions to reduce illnesses in high-risk settings (e.g., correctional institutions, long-term care facilities, and daycares) or populations.

Strategies and Activities:

0) Strategy to Address Required Tasks

a. Address Required Tasks in project guidance.

☐ Required ☒ Optional

Area A: Surveillance, Detection and Response

Tier 1: Wastewater Surveillance Systems. While any Tier 1 section is optional for applicants, if a recipient is applying for a Tier 1 project, then all the activities within that project are required.

1) Surveillance data management (Tier 1)

a) Data Coordination

Coordinate data management, record keeping and reporting for wastewater testing to produce reliable, actionable, and high-quality data for public health action. Implement wastewater sampling strategies and protocols for submission of data to the health department and CDC.

☒ Required ☐ Optional

b) Submit wastewater data

Submit wastewater data from one or more wastewater systems to the NWSS DCIPHER portal at least weekly. Provide required set of wastewater data elements to the NWSS DCIPHER portal, including sewershed boundary shapefiles. Provide sewershed-level case data as requested.

☒ Required ☐ Optional

c) *Data timeliness and quality*

Optimize protocols for data timeliness and quality, including minimizing the time from sample collection to data submission to CDC and maximizing quality of submitted data.

☒ Required ☐ Optional

2) Surveillance data analysis (Tier 1)

a) Interpretation and use of wastewater data

Review and interpret wastewater surveillance data to inform epidemiologic and programmatic decisions related to SARS-CoV-2 infection, other pathogens or targets.

☒ Required ☐ Optional

b) Disseminate data

Disseminate data to key implementing partners such as wastewater utilities, local health departments, communities, and schools.

☒ Required ☐ Optional

3) Enhance laboratory capacity for wastewater testing (Tier 1)

a) Plan and implement laboratory workflows

Plan and implement laboratory workflows to safely receive, process, and test wastewater samples within the public health laboratory.

☒ Required ☐ Optional

b) Automated data transfer

Evaluate and, if feasible, implement automated, machine-to-machine data transfer to the

NWSS DCIPHER portal to facilitate streamlined reporting.

☒ Required ☐ Optional

4) Wastewater Sequencing (Tier 1)

a) Prospective Sequencing

Develop and implement a plan for prioritizing wastewater samples for prospective sequencing targeting SARS-CoV-2 and other pathogen targets

☐ Required ☒ Optional

b) Link Sequencing data

Develop or maintain the ability to link wastewater laboratory sequencing data with sewershed-level clinical sequence surveillance data, and other sources as needed.

☐ Required ☒ Optional

5) Other optional wastewater surveillance strategy (Tier 1)

a) Other optional wastewater surveillance strategy

☐ Required ☒ Optional

6) Enhance workforce capacity (Tier 2)

a) Develop trainings

Develop and conduct trainings to strengthen the knowledge base of, improve data collection, analysis, and interpretation of wastewater surveillance, and improve information systems in other health departments/jurisdictions.

☒ Required ☐ Optional

b) Create learning courses

Develop, deliver, or consult with other health departments/jurisdictions for in-person and online courses (including live learning courses).

☒ Required ☐ Optional

c) Site visits

Conduct in-person/remote site visits and reverse site visits with other health departments/jurisdictions.

☒ Required ☐ Optional

7) Surveillance metric development (Tier 2)

a) Surveillance metrics for public health action

Develop wastewater surveillance metrics that help prioritize sites for public health actions.

☒ Required ☐ Optional

b) Link data sources

Identify and link additional public health data sources to enhance the utility of wastewater surveillance data.

☒ Required ☐ Optional

8) Knowledge transfer (Tier 2)

a) Wastewater surveillance consultation:

Participate in consultations with other health departments/jurisdictions (e.g., in response to requests for technical assistance, peer-to-peer exchanges of ideas, etc.).

☒ Required ☐ Optional

b) Disseminate resources: Health Departments

Disseminate resources to improve wastewater-based disease surveillance knowledge, decision making, and information systems in other health departments/jurisdictions, e.g., by posting to CDC NWSS DCIPHER.

☒ Required ☐ Optional

c) Disseminate resources: Public

Make wastewater surveillance resources available to the public, e.g., by posting to public-facing websites.

☒ Required ☐ Optional

d) Disseminate resources: Academic Partners

Create reports, manuscripts, websites, and/or presentations completed using wastewater-based disease surveillance data available to scientific partners such as academic centers.

☒ Required ☐ Optional

9) Evaluate laboratory workflows (Tier 2)

a) Evaluate laboratory analytic workflows

Evaluate laboratory analytic workflows for current surveillance target organisms to improve data quality, assay sensitivity, and inter-lab comparability.

☒ Required ☐ Optional

b) Conduct pilot implementations of lab methods

Conduct pilot implementations of laboratory methods under consideration for inclusion in core NWSS surveillance testing. These assays may include quantification methods for human fecal

markers or potential future surveillance target organisms.

☒ Required ☐ Optional

10) Effective scales of wastewater testing (Tier 2)

a) Develop upstream sampling plans to enhance public health utility of data generated at centralized wastewater treatment plants.

☒ Required ☐ Optional

b) Determine most effective geographic scales

Determine the most effective geographic scale (i.e., treatment plant, sub-sewershed, facility, etc.) and sampling frequency for wastewater testing for different surveillance targets. Considerations can include lab capacity, cost, historic disease trends, and other jurisdictional needs.

☒ Required ☐ Optional

11) Other optional wastewater surveillance strategy (Tier 2)

a) Other Optional Activity.

☐ Required ☒ Optional

Area C: Communication, Coordination, and Partnerships

12) Coordinate &partner to optimize national wastewater surveillance (Tier 1)

a) Communicate data with implementing partners

Facilitate timely and complete communications, sample collection, wastewater testing, and data sharing among implementing partners through the identified NWSS coordinator(s).

☒ Required ☐ Optional

b) Coordinate utility participation

Coordinate utility participation in wastewater surveillance, including, but not limited to,

communications, data sharing, and provision of funding support for sample collection.

☒ Required ☐ Optional

13) Public health communication (Tier 2)

a) Develop communications packages

Develop communications packages to communicate appropriate public health information with public health leadership, civic leadership, and the public.

a) These tools should use wastewater surveillance data at different scales of sampling (e.g., centralized treatment plants, upstream sampling locations, and facility-level testing) to ensure each group has sufficient information to enable them to act.

☒ Required ☐ Optional

b) Identify effective communication strategies

Conduct message testing to identify the most effective communication strategies to 1) ensure the implementing partners receive and understand the information and 2) be prepared to use this information to act.

☒ Required ☐ Optional

14) Improve wastewater utility data collection and sharing (Tier 2)

Improve wastewater data collection and sharing

Work with wastewater utilities and the Water Environment Federation (WEF) to identify effective, efficient, and timely ways to capture and share wastewater treatment plant and wastewater collection metadata with health departments.

☒ Required ☐ Optional

Wastewater utility retention

Engage with wastewater utilities to understand emerging needs and improve utility retention.

☒ Required ☐ Optional

Collaborations:

a. With CDC-Funded Programs

National Wastewater Surveillance System Centers of Excellence (CoEs), National Center for State, Tribal, Local, and Territorial Public Health Infrastructure and Workforce cooperative agreement recipients (Tribes and regional tribally designated organizations) Infrastructure Grant Overview | CDC

b. With Organizations External to CDC

Including, but not limited to: the Association of Public Health Laboratories, Council of State and Territorial Epidemiologists, U.S. Environmental Protection Agency (EPA), Water Environment Federation (WEF), National Association of County and City Health Officials, and state/local water utility organizations.

Recipients should engage wastewater utility partners as appropriate, to accomplish NWSS program required tasks and activities. This can include providing supplemental funding (but any funding should not be duplicative of other federally funded cooperative agreements).

Populations of Focus:

N/A

Evaluation and Performance Measurement:

Performance measures included here are representative and may not be final at the time of NOFO publication. Please see the CK-24-0002 Performance Measure Guidance document for all final measures and descriptions.

a. ACTIVE Performance Measures

N/A

b. PASSIVE Indicators

Measure 1. Median time (in days) from sample collect date to submission to DCIPHER.

Measure 2. Number of data quality control flags in DCIPHER.

Measure 2. Total number of wastewater sampling sites.

Measure 3. Total number of wastewater samples collected.

Project F: Emerging Issues

Program Activity Contact Information:

Jason Snow; Email: JNSnow@cdc.gov

Funding Opportunity Description:

a. Overview

The CDC's Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases (ELC) Cooperative Agreement aims to help health departments strengthen core capacity needed to respond to a variety of emerging infectious diseases. This includes the potential provision of additional funding to increase epidemiology, laboratory, and health information systems support to meet needs during a local, regional, or national infectious disease emergency.

b. Health Equity

N/A

c. Healthy People

N/A

d. Local Health Department and Tribal Engagement

N/A

e. Other National Public Health Priorities and Strategies

N/A

CDC Project Description:

a. Problem Statement

The world of public health is in some state of preparedness or preparation for a variety of outbreaks such as threats related to novel influenza A, expanding arboviral disease vectors, foodborne pathogens, etc. Other types of novel outbreaks (e.g., SARS in 2002/2003 and fungal meningitis in 2012, SARS-CoV-2/COVID-19) are more challenging to anticipate but will also be addressed in this section. However, one commonality between most disease threats is resources available to mitigate them often only become available after the outbreak event occurs and becomes a public health emergency. Due to the unpredictable nature of these infectious disease emergencies and the lag in resources, recipients need a ready mechanism to provide support for a range of infectious disease emergencies.

b. Purpose

The potential funding under *Project F: Emerging Issues* is intended to provide additional epidemiologic, laboratory, and/or health information systems capacity. This project provides financial support necessary for enhanced surveillance due to factors such as technology change and expanding disease boundaries; or response efforts associated with new or emerging infections including outbreak scenarios.

c. Outcomes

State, local, and territorial health departments prepared to respond to new surveillance and response needs (including outbreaks) with timely and efficient efforts for detection, investigation, and implementation of control measures.

Funding Strategy:

Total availability of funds for *Project F: Emerging Issues* is unknown at the start of the budget period. The purpose of this Project is to provide a mechanism for ad-hoc financial assistance throughout the budget period. Applicants are strongly encouraged to apply to Project F: *Emerging Issues* so that surge support can be provided as needs arise.

- Approximate number of awards: TBD
- Approximate average per award: TBD

Please request and have a plan for approximately $3,000,000 per recipient of financial support. Recipients with low populations may request less while recipients with very large populations may request more.

Funds may be available on the condition of a local or national emerging infectious disease and/or emergency. Activities in this section will only be funded should conditions warrant; and funds become available.

Funding may be requested to support (depending on baseline capacity) temporary personnel, laboratory supplies, specimen shipping costs, on-site assessments and trainings, budget items necessary for quarantine and isolation of persons under investigation (PUI), and any other supplies needed for an effective response to an emergency or emerging infectious disease. For State Health Department recipients, inclusion of anticipated financial support that would be needed at the Local Health Department level should also be included.

***Please note:**

1. For State Health Departments (SHDs), when entering budget requests, recipients must use the 'Public Health Allocation' to indicate the portion of financial support going toward 'Local/Regional Health Department (LHD)' support versus staying at the SHD level. This allocation data helps ELC answer inquiries regarding the financial support to LHDs which is crucial given the important role LHDs have in addressing infectious diseases.
2. For Local Health Departments (LHDs), when entering budget requests, please ensure the 'Public Health Allocation' is set to 100% 'Local/Regional Health Department (LHD)' support.
3. For Territorial Health Departments, if you have local/regional jurisdictions, please follow the instructions for State Health Departments in #1.

Required Tasks:

Acceptance of funding conveys acknowledgement and indication that the following requirements will be met. Related strategy/activity noted in parentheses after Required Task.

1. If funds are issued in this section, a post-award call with CDC staff from the program issuing the funds is required within 30 days after the Notice of Award (NOA) is received.

2. Due to the unpredictability of need associated with this project, a revised workplan and budget may be required after the post-award call depending on the nature of the funding and related activities necessary for proper surveillance and/or response activities.
3. Recipients are expected to meet all deadlines for:
    a. Quarterly milestone progress status
    b. Quarterly financial reporting of core funding (expenditures & ULOs)
    c. Performance measure reporting
    d. Submission and/or update of success stories

Strategies and Activities:

0) Strategy to Address Required Tasks

Address Required Tasks in program/project guidance.

☐ Required ☒ Optional

Area A: Surveillance, Detection, and Response

1) Investigation response and reporting

a) Depending upon current baseline capacity, conduct specimen collection, shipping, transmit results to CDC to enhance the ability to rapidly respond to outbreaks.

☐ Required ☒ Optional

2) Laboratory testing for response

a) Depending upon current baseline capacity, enhance the ability of the laboratory to rapidly respond to outbreaks.

☐ Required ☒ Optional

3) Maintain and enhance integrated surveillance information

a) Depending upon current baseline capacity, enhance the ability of the health information system to rapidly respond to outbreaks.

☐ Required ☒ Optional

Area C: Communication, Coordination, and Partnerships

4) Coordinate and engage with partners

a) Foster collaboration among city, county, health districts, state, regional, and federal partners and other external partners to improve outbreak response and the prevention of infectious diseases.

☒ Required ☐ Optional

b) Disseminate relevant information to the public regarding emerging and re-emerging health threats.

☐ Required ☒ Optional

Collaborations:

a. With CDC-Funded Programs

Depending on the specifics of the disease threat, recipients are encouraged to work with respective CDC programs, if technical assistance is needed.

b. With Organizations External to CDC

N/A

Population(s) of Focus:

N/A

Evaluation and Performance Measurement:

Report describing how resources awarded were used to mitigate the disease threat, including activities that were conducted that otherwise would not have been (or conducted faster/more completely).

Performance measures included here are representative and may not be final at the time of NOFO publication. Please see the CK-24-0002 Performance Measure Guidance document for all final measures and descriptions.

a. ACTIVE Performance Measures

N/A

b. PASSIVE Indicators

N/A

Section II: Emerging Infectious Disease Programs

Program G: Enteric, Foodborne, Waterborne, and Zoonotic Diseases: Surveillance, Detection, Response, Reporting, and Prevention

Program Activity Contact Information:

Gwen Biggerstaff: fke8@cdc.gov 404-639-4814; Anna Newton: ivz9@cdc.gov 404-639-2839

General Inquiries: OPSCI@cdc.gov

Funding Opportunity Description:

a. Overview

This program of the Division of Foodborne, Waterborne, and Environmental Diseases, in collaboration with the Division of Viral Diseases and the Division of Parasitic Diseases and Malaria, aims to protect public health through the prevention and control of disease, disability, and death caused by foodborne, enteric, waterborne, and environmentally transmitted infections. This section describes the activities necessary for a comprehensive program in a recipient's jurisdiction for the detection, investigation and response, reporting, and prevention of enteric, foodborne, waterborne, and zoonotic illnesses and outbreaks.

This section is divided into three tiers. Tier 1, Tier 2, and Tier 3 refer to levels of performance by recipients and do not correspond to a predetermined funding award for those levels of performance. Tier 1 strategies and activities cover general surveillance, detection, and response; prevention and intervention; and communications and partnerships. Tier 1 activities apply to nationally notifiable diseases as well as conditions related to enteric, foodborne, waterborne, and zoonotic diseases, using a One Health approach. Activities may contain both epidemiologic and laboratory components. All Tier 1 activities must be addressed before applying for optional activities under Tier 2 or 3.

Tier 2 strategies and activities include expanded capacity for specific components of surveillance, investigation, response, and prevention. These activities are essential to monitor and respond to changes in testing practices; identify sources of sporadic enteric disease; implement methods for improving outbreak detection and response; and improve overall capacity for outbreak detection and response. Tier 3 includes activities for the Integrated Food Safety Centers of Excellence.

Tier 1 includes the following core programs and systems:

CaliciNet: A national network of federal, state, and local public health laboratories established to capture norovirus genotyping data from outbreaks and sporadic samples, which can link geographically different clusters of illness to a common source, e.g., food. Contact calicinet1@cdc.gov for more information.

CryptoNet: CryptoNet is a surveillance program that tracks cryptosporidiosis by regular analysis of merged traditional epidemiology data and subtyping data. Cryptosporidiosis subtyping surveillance is conducted using CryptoNet protocols and will use PulseNet infrastructure to support advancement. CryptoNet hosts monthly calls and optional monthly office hours open to any public health jurisdiction. Additional information about CryptoNet can be found at https://www.cdc.gov/parasites/crypto/cryptonet.html. Contact cryptonet@cdc.gov for more information.

InFORM (Integrated Foodborne Outbreak Response and Management) Conferences and Regional Meetings: InFORM brings together the network of public health officials involved with enteric, foodborne,

waterborne, and zoonotic disease outbreak response. This includes current federal, state, and local public health and environmental health specialists, epidemiologists, health communicators, and laboratory scientists. Held every two years, the national conference will consist of a keynote speaker, plenary and discipline-specific sessions, and poster presentations. On the intervening years, smaller regional meetings will consist of joint and discipline-specific sessions. Contact InFORM@cdc.gov for more information.

National Antimicrobial Resistance Monitoring System (NARMS): The National Antimicrobial Resistance Monitoring System (NARMS) is a collaboration among state and local public health departments and federal agencies. This national public health surveillance system tracks antimicrobial resistance in enteric (intestinal) bacteria that are transmitted through food, the environment, animal contact, and person-to-person (including sexual) contact. The goal of the NARMS program at CDC is to help protect public health by providing information about emerging bacterial resistance, the ways in which resistance is spread, and how resistant infections differ from susceptible infections. Jurisdictions submit clinical isolates from humans to CDC for antimicrobial susceptibility testing (AST) based on the Enteric Diseases Isolate Submission Table guidance https://www.cdc.gov/ncezid/dfwed/edlb/edlb-lab-submission.html or according to additional requests from CDC. Isolates sequenced under PulseNet are analyzed by NARMS to determine predicted resistance based on the presence of resistance genes and mutations. Contact NARMS@cdc.gov for more information.

National Case Surveillance: Collects data from all recipients for nationally notifiable diseases caused by specific bacteria or bacterial toxins, parasites, viruses as well as conditions related to nationally notifiable foodborne, waterborne, and environmentally transmitted diseases. Information is gathered from both laboratory-based and case-based surveillance systems.

National Outbreak Reporting System (NORS): The National Outbreak Reporting System (NORS) captures reports of all waterborne and foodborne disease outbreaks, certain fungal disease outbreaks, and all enteric disease outbreaks transmitted by contact with environmental sources, infected persons or animals, or unknown modes of transmission. Please note, NORS captures environmental fungal disease and legionellosis outbreaks; refer to Project I (Mycotics) and Project P (Legionella) for guidance on reporting environmental fungal disease and legionellosis outbreaks, respectively, through NORS. Additional information about NORS can be found https://www.cdc.gov/nors/index.html. Contact norsadmin@cdc.gov for more information.

One Health Harmful Algal Bloom System (OHHABS): The One Health Harmful Algal Bloom System (OHHABS) receives reports of HAB events and individual human and animal (domestic pets, livestock, and wildlife) cases of HAB-associated illnesses in fresh, brackish, and saltwater settings. OHHABS collects information to help CDC and partners better understand HABs and help prevent illnesses caused by HABs. OHHABS is available to state and territorial public health departments and their designated environmental health or animal health partners. Additional information about OHHABS can be found at https://www.cdc.gov/habs/ohhabs.html. Contact OHHABS@cdc.gov for more information.

Outbreak Detection, Response, and Control: Capacity, processes, and systems to rapidly identify potential outbreaks of enteric, foodborne, waterborne, and zoonotic diseases, gather information about potential sources, and implement timely control measures. Contact outbreakresponse@cdc.gov for general information, and eza@cdc.gov for information specific to enteric zoonoses.

PulseNet: PulseNet is a national laboratory network that connects foodborne, waterborne, and One Health–related illness cases to detect outbreaks. PulseNet uses the DNA fingerprints of bacteria making people sick to detect thousands of local and multistate outbreaks. PulseNet hosts regular 50-state calls, office hours, and communicates information during the InFORM conferences and regional meetings. Contact PulseNet@cdc.gov for more information.

SEDRIC: The System for Enteric Disease Response, Investigation, and Coordination (also known as SEDRIC) is a secure, cloud-based platform for foodborne, waterborne, and animal contact outbreak investigations. SEDRIC hosts monthly office hours and on-demand trainings. Contact SEDRIC@cdc.gov for more information.

Tier 2 includes the following enhanced programs:

CryptoNet Enhanced: CryptoNet Enhanced supports augmented Cryptosporidiosis laboratory activities, including case investigation and reporting, diagnostic/subtyping capacity, and lab surveillance focusing on molecular characterization using CryptoNet protocols for WGS and WGS-MSLT analysis.

***Cyclospora* genotyping**: Conducting amplicon-based multilocus sequence typing approach to provide genotyping information for *Cyclospora cayetanensis* surveillance.

Environmental Microbiology (EM): Conduct environmental sampling and testing of environmental samples for waterborne disease investigations. The most common pathogens for waterborne disease environmental testing include *Cryptosporidium, E. coli*, and norovirus. Tier 2 EM participants work with CDC to develop metrics and participate in the CDC EM Community of Practice. Please note, *Legionella* testing activities are included in Project J: Enhanced Surveillance for Vaccine Preventable Disease (VPD) and Respiratory Diseases. National Wastewater Surveillance System (NWSS) activities are included in Project E.

FoodCORE: FoodCORE is comprised of ten centers that work together to improve the capacity to detect, investigate, respond to, and control multistate outbreaks of foodborne diseases. FoodCORE provides support to improve laboratory, epidemiologic, and environmental health capacity. FoodCORE Centers work with CDC to determine and execute annual program evaluation. FoodCORE hosts monthly calls, annual vision meetings, and ad-hoc site visits. Contact OPSCI@cdc.gov for more information.

FoodNet: FoodNet conducts active surveillance in ten sites aimed at reducing morbidity and mortality due to diseases commonly transmitted by food and understanding the sources of these infections. FoodNet's goals are to provide the knowledge base to inform national-level surveillance and antimicrobial resistance as well as evaluate the effectiveness of regulations and interventions aimed at reducing the burden of select foodborne illnesses. FoodNet hosts monthly calls, an annual vision meeting, and ad-hoc site visits. Contact FoodNet@cdc.gov for more information.

Harmful Algal Bloom (HAB) Surveillance, Response, and Mitigation: Enhanced activities related to surveillance (OHHABS and NORS), public health preparedness and response, and public health mitigation (e.g., risk communication) of harmful algal blooms that occur in fresh, brackish, and saltwater settings. Tier 2 HAB activities involve a One Health approach at state, local, territorial, and national levels. Tier 2 HAB calls and meetings include the monthly One Health HAB Community of Practice, CDC and recipient calls (every 3-6 months) or ad hoc site visits (0–1 annually), and a HAB Tier 2 participant meeting (virtual or in person). For Budget Period 1, applicants should plan to attend a regional or national meeting to increase knowledge related to HABs. This may coincide with the HAB Tier 2 participant meeting. CDC will collaborate with

recipients to highlight HAB activities/accomplishments (e.g., success stories, learning lessons) and share them with others (e.g., web site, fact sheet).

National Respiratory and Enteric Virus Surveillance System (NREVSS) Enhanced: NREVSS Enhanced works to improve clinical laboratory-based surveillance of sporadic cases of norovirus, rotavirus, and adenovirus 40/41 and monitor circulating strains. NREVSS Enhanced hosts bi-monthly calls.

NoroSTAT: A network of sentinel states tasked with improving the timeliness and completeness of reported norovirus outbreaks due to all modes of transmission. NoroSTAT hosts monthly calls.

OutbreakNet Enhanced: Provides epidemiologic support to state and local health departments to improve their capacity to detect, investigate, control, and respond to enteric disease outbreaks. Outbreak Net Enhanced Sites work with CDC to determine and execute annual program evaluation. OutbreakNet Enhanced hosts monthly calls, ad hoc one-on-one calls with CDC, and ad hoc site visits. Contact OPSCI@cdc.gov for more information.

PulseNet Area Labs: The PulseNet Area Labs are seven state PulseNet participating laboratories that provide support to network participants in their regions with troubleshooting, surge capacity for subtyping, training of laboratory and analysis methods, and coordination of regional calls and meetings. PulseNet hosts regular 50-state calls and office hours and participates and communicates information during the InFORM conferences and regional meetings.

PulseNet Metagenomics: PulseNet metagenomic laboratories test and provide feedback on direct-from-sample methods for characterizing PulseNet-monitored and related organisms. Activities may include any portion of a potential metagenomic workflow from sample collection through genomic data analysis and interpretation. PulseNet hosts regular calls (not less than monthly) for participating laboratories to coordinate activities and support troubleshooting.

Tier 3 includes:

Integrated Food Safety Centers of Excellence (Food Safety CoEs): Food Safety CoEs are headquartered at state health departments that have demonstrated excellence in surveillance and investigation of foodborne illness and outbreaks, and each Food Safety CoE must partner with at least one academic institution. Food Safety CoEs develop tools, deliver trainings, support evidence-based investigation and prevention opportunities, develop strategic partnerships to aid the implementation of prevention interventions and provide consultations to public health professionals in other states who conduct surveillance and investigation of foodborne illness and outbreaks. Food Safety CoE applicants may also propose additional activities not listed in this guidance that are compatible with program goals, build on current capacity and public health needs, and do not duplicate other efforts. However, funding cannot and will not be provided through ELC for any research-associated activities. If research activities are described for the purpose of providing program context, please clearly indicate that no ELC funds are requested to support such activities. Additional information about the Food Safety CoEs and the Food Safety Modernization Act (FSMA)-mandated activities can be found at https://www.cdc.gov/foodsafety/centers/index.html. Eligible applicants will have an established relationship between the health department and an academic institution, a documented

history of completing activities described under FSMA, and will excel in epidemiologic and laboratory surveillance as well as outbreak response. Contact FoodSafetyCoE@cdc.gov for more information.

b. Health Equity

Program G recipients should apply health equity principles when developing information resources and communications, engaging partners and communities, and planning and implementing prevention and control measures. Additionally, recipients should collect relevant health equity data elements using best practices and national standards and efforts to improve data completeness, accuracy, and representativeness in order to improve understanding of health disparities and inequities in enteric, foodborne, waterborne, and zoonotic diseases.

c. Healthy People

Healthy People 2030 Goals for Foodborne Illness include reducing the number of infections caused by key pathogens transmitted commonly through food; reducing the number of illnesses due to Shiga toxin-producing *E. coli* (STEC), *Campylobacter, Listeria,* or *Salmonella* (FS-01, FS-02, FS-03, FS-04). https://health.gov/healthypeople/objectives-and-data/browse-objectives/foodborne-illness.

d. Local Health Department and Tribal Engagement

Recipients should engage local, territorial, tribal (or tribal serving) health departments/jurisdictions, as appropriate, to accomplish Program F required tasks and activities. This can include providing supplemental funding (but any funding should not be duplicative of other federally funded activities). When tribes and tribal serving organizations (TSO) are involved in a workplan, please address how they are included in planning and implementation of the workplan. Include relevant documentation of agreement from tribes or TSO relating to partnership and appropriately recognize tribal involvement in all work products.

e. Other National Public Health Priorities and Strategies

- National Strategy for Combating Antibiotic-Resistant Bacteria (CARB) (https://aspe.hhs.gov/reports/national-action-plan-combating-antibiotic-resistant-bacteria-2020-2025)
- CDC's Climate and Health Strategic Framework (https://www.cdc.gov/climateandhealth/climate-health-framework.htm)
- DFWED's Prevention Priorities (https://www.cdc.gov/ncezid/dfwed/prevention-priorities/index.html)
- Public Health Emergency Preparedness and Response Capabilities: National Standards for State Local, Tribal, and Territorial Public Health (https://www.cdc.gov/orr/readiness/phep/orr.htm)
- CDC's Crisis and Emergency Risk Communication (CERC) (https://emergency.cdc.gov/cerc/)
- CDC's Public Health Data Strategy (https://www.cdc.gov/ophdst/public-health-data-strategy/index.html)

CDC Project Description:

a. Problem Statement

Enteric, foodborne, waterborne, and zoonotic disease surveillance and outbreak investigations are essential public health functions. Investigations require close collaboration between state, local, and federal agencies. Changes in society, technology, our environment, and microorganisms themselves are affecting the

occurrence and complexity of enteric, foodborne, waterborne, and zoonotic diseases. Strong national surveillance is key to detecting cases of illness as well as outbreaks. Prompt and effective outbreak investigations and reporting are necessary to identify and remove or mitigate sources of contamination, inform health/risk communication, and focus prevention strategies. Furthermore, antimicrobial resistance is one of our most serious health threats. Surveillance, incorporating when appropriate a One Health framework, is critical to detect the emergence and spread of antibiotic resistance and to inform interventions that reduce resistance among bacteria.

b. Purpose

To support and enhance capacity for detection, investigation, control, and reporting of enteric, foodborne, waterborne, and zoonotic disease cases and outbreaks and implement evidence-based prevention practices through communication, partnerships, policy initiatives, and targeted interventions.

c. Outcomes

1. Conduct timely investigations
2. Conduct surveillance and analyze, compile, and disseminate data
3. Utilize modern laboratory techniques for surveillance, detection, and response
4. Ensure timely, accessible communications and outreach tailored for diverse populations
5. More effective and integrated public health workforce better prepared to respond to infectious disease threats
6. Improved surveillance resulting in:
    a. Improved completeness, accuracy, and representativeness of data
    b. Increased use of data and distribution to public health partners, communities, and other types of partners
7. Rapid detection of cases and outbreaks
8. More timely, complete, and effective investigation efforts to:
    a. Respond to outbreaks
    b. Investigate outbreaks
    c. Implement control measures
9. Improved use of data to:
    a. Inform public health response and control
    b. Develop and implement public health best practices and/or guidelines
    c. Inform program policy development
10. Develop and implement strong public health interventions, tools, and policies using a health equity lens

Funding Strategy:

Total availability of funds for *Program G: Enteric, Foodborne, Waterborne, and Zoonotic Diseases: Surveillance, Detection, Response, Reporting, and Prevention*: $33M

Approximate number of awards: 56-59

Approximate average per award: $575,000; average award depends on the project areas and activities in which a recipient participates.

Funds should be used for:

- Dedicated staff for investigation and reporting
- Resources to transmit surveillance data
- Training of state and local public health staff
- Supplies and equipment to maintain and enhance surveillance and outbreak reporting

Tier 3 Food Safety CoE Funding Note: A portion of the Food Safety CoE budget must be allocated to the academic partner. Detailed justifications must be included in the budget that clearly describe how funds will be spent including a breakdown by salary, travel, supplies, etc. Budgets should be clear that no ELC funds are requested to support research activities; recipients are responsible for ensuring that their partners do not use ELC funds for research purposes.

***Please note:**

1. For State Health Departments (SHDs), when entering budget requests, recipients must use the 'Public Health Allocation' to indicate the portion of financial support going toward 'Local/Regional Health Department (LHD)' support versus staying at the SHD level. This allocation data helps ELC answer inquiries regarding the financial support to LHDs which is crucial given the important role LHDs have in addressing infectious diseases.
2. For Local Health Departments (LHDs), when entering budget requests, please ensure the 'Public Health Allocation' is set to 100% 'Local/Regional Health Department (LHD)' support.
3. For Territorial Health Departments, if you have local/regional jurisdictions, please follow the instructions for State Health Departments in #1.

Required Tasks:

Acceptance of funding conveys acknowledgment and indication that the following requirements will be met.

Administrative

1. Identify at least one designated point of contact(s) for each of the following Tier 1 (and any applicable Tiers 2 and 3) areas: enteric, foodborne, waterborne, and zoonotic disease case surveillance and outbreak response activities.
    a. Key Tier 1 areas include: CaliciNet, CryptoNet, *Cyclospora* genotyping, NARMS laboratory and epidemiology activities, NORS, PulseNet, waterborne epidemiology and laboratory activities, and general outbreak response.
2. Participate in all Tier 1 (and any applicable Tiers 2 and 3) regularly scheduled program calls, conference calls, webinars, office hours, working group calls, community of practice calls, site visits, and vision meetings.
    a. Key participation for Tier 1 includes: PulseNet 50-state calls and Area Lab calls, NARMS partner calls, DFWED Quarterly calls, bi-monthly waterborne disease state partner calls, monthly CryptoNet call, 2025 InFORM Regional Meetings.
    b. Reference Tier 2 project descriptions in the 'Overview' section for specific calls or meetings that are required.

3. Complete, sign, and return Memorandum of Understanding (MOU) and Terms of Reference (TOR) documents for PulseNet, *Cyclospora* genotyping, and CaliciNet and the Rules of Behavior (RoB) and Non-Disclosure Agreement (NDA) documents for SEDRIC.

Workforce capacity

4. Ensure enteric, foodborne, waterborne, and zoonotic disease staff capacity through relevant key positions, trainings, and certifications.
    a. Key positions include: PulseNet laboratorian(s), enteric disease epidemiologist(s), student interviewers, etc.
    b. Key epidemiology trainings, certifications, and skills include: analysis of epidemiologic data for PulseNet and other clusters, participating in SEDRIC trainings and office hours.
    c. Key laboratory trainings, certifications, and tasks include: reading bi-weekly PulseNet Quick Tips, using the PulseNet SharePoint site, ensure PulseNet personnel are lab and/or analysis certified.
5. Ensure staff are cross-trained to build expertise for detection, investigation, control, and reporting of enteric, foodborne, waterborne, and zoonotic disease cases and outbreaks; this includes capacity/infrastructure for data transmission and data management.
6. Maintain supplies, equipment, infrastructure, data entry personnel necessary for surveillance, data and isolate submission, outbreak reporting, specimen delivery, and laboratory diagnostics and subtyping.
7. Travel at least one epidemiologist and one PulseNet laboratorian per recipient jurisdiction to a 2025 InFORM Regional Meeting.
    a. Tier 2 FoodCORE, OutbreakNet Enhanced, PulseNet Area Labs, and Food Safety CoEs are expected to travel more than one representative to the InFORM Regional Meeting.
8. Travel at least one laboratorian per CaliciNet certified laboratory to the annual CaliciNet User Meeting.

Surveillance

9. Conduct epidemiologic surveillance for all nationally notifiable bacterial, viral, and parasitic enteric diseases and electronically submit data to CDC, including data elements from a standard questionnaire, specified in CSTE position statements, and data elements needed to link epidemiology and laboratory data. Paper, faxed, and emailed data will not be accepted (except for cyclosporiasis).
    a. Nationally notifiable bacterial and parasitic diseases include botulism, campylobacteriosis, cholera, *Cronobacter* infection, cryptosporidiosis, cyclosporiasis, giardiasis, listeriosis, salmonellosis, *Salmonella* Typhi infection, *Salmonella* Paratyphi infection, shigellosis, *E. coli* infection (and post-diarrheal HUS for FoodNet), and vibriosis.
10. Work with CDC to respond 24/7 to cases of botulism and free-living ameba to ensure timely treatment and confirmatory testing.

11. Conduct real-time laboratory surveillance and data analysis for all PulseNet and CaliciNet pathogens and electronically submit data to the national database at CDC.
12. Collaborate with Area/Regional/Reference/CDC laboratories for troubleshooting issues and other issues affecting network function.
13. Ensure staff and mechanisms are available for collection and shipment of clinical, animal, and environmental specimens/samples to Regional/Area labs or CDC.
14. Submit samples/isolates to CDC for testing with appropriate documentation.
    a. Includes shipping routine surveillance, outbreak, and special study isolates to CDC for NARMS antimicrobial susceptibility testing according to current guidance or other requests from CDC.
15. Monitor and detect enteric, foodborne, waterborne, and zoonotic disease clusters.
16. Regularly coordinate and share information and apply data-sharing tools among epidemiology, laboratory, and environmental health.
17. Report through NORS all reportable outbreaks as defined in the overview above and in NORS user guidance, including data for environmental health, contributing factors, interventions, and preventative measures.
18. Report harmful algal bloom events (fresh, brackish, marine waters, as applicable) and associated illnesses (human, animal) to the One Health Harmful Algal Bloom System (OHHABS).
19. Collaborate with CDC on data cleaning and closeout activities.

Outbreak Detection, Response, and Control

20. Interview all people with enteric, foodborne, waterborne, and zoonotic infections identified as part of a cluster and/or multistate investigation. This includes conducting hypothesis-generating, focused, and supplemental interviews, conducting or participating in analytic epi investigations (e.g., illness subcluster investigations), and obtaining product or animal information.
    a. In consultation with CDC, interview (or provide exposure history data for) a subset of people ill with reoccurring, emerging, or persisting (REP) strains or other strains of public health concern (e.g., strains with concerning antimicrobial resistance).
21. Collaborate with CDC and other relevant jurisdictions to provide epidemiology and laboratory technical support for multi-jurisdictional investigations, outbreaks, and emergency preparedness activities.
    a. Key tasks include: collecting and sharing case data with CDC (e.g., confirmed case counts, detailed exposure history, demographics including race and ethnicity, food preparation/handling information), participating in multistate analytic epidemiologic investigations, conducting analytic investigations of localized illness sub-clusters, and obtaining other information relevant to identifying traceback and testing opportunities (e.g., shopper card histories or animal purchase receipts, product or animal photographs).

22. Ensure staff/mechanisms are in place to collect and culture samples from animal, pet food, or environmental sources during outbreak investigations, perform whole genome sequencing (WGS), analyze isolate data, and collect a standard set of data elements with the samples.

    a. Key zoonotic specimen collection activities could include: papers lining the boxes used to transport chicks from hatcheries to feed stores to determine which strains of *Salmonella* originate at which hatcheries, fecal samples from puppies of patients with multidrug-resistant *Campylobacter*, fecal samples from ruminants implicated in outbreaks of cryptosporidiosis, or wound biopsies from animals with suspected fungal zoonoses (e.g., *Sporotrichosis brasiliensis*).

23. Implement appropriate control and risk reduction measures based on cluster and outbreak investigations.

24. Collaborate with organizations such as Association of Public Health Laboratories (APHL), U.S. Food and Drug Administration (FDA), U.S. Department of Agriculture (USDA), U.S. Environmental Protection Agency (EPA), U.S. Department of the Interior (DOI), Council of State and Territorial Epidemiologists (CSTE), National Association of State Public Health Veterinarians (NASPHV), United States Animal Health Association (USAHA), American Association of Veterinary Laboratory Diagnosticians (AAVLD), World Health Organization International Food Safety Authorities Network (WHO INFOSAN), PulseNet International, healthcare, agriculture, wildlife, and others as required during investigations of national and international outbreaks and other public health activities.

Prevention and Partnerships

25. Develop and/or disseminate evidence-based health education and promotion materials/messages based on identified health threats and engage in proactive outreach and education to groups disproportionately impacted by enteric, foodborne, waterborne, and zoonotic diseases.

26. Develop and maintain strategic partnerships with diverse partners (including public health, industry, community, institutional, and other prevention partners) to support surveillance, investigations, and collaboratively identify and implement evidence-based interventions to reduce illnesses in high-risk settings (e.g., correctional institutions, long-term care facilities, and daycares) or populations.

Strategies and Activities:

0) Strategy to Address Required Tasks

Program F Required Tasks: Administrative
Program F Required Tasks: Workforce Capacity
Program F Required Tasks: Surveillance
Program F Required Tasks: Outbreak Detection, Response, and Control
Program F Required Tasks: Prevention and Partnerships

☒ Required ☐ Optional

Area A: Surveillance, Detection, and Response

1) Tier 1: Improve epi surveillance, investigation, preparedness, and response

a) Implement model practices to improve interview timeliness and completeness

i) Model practices for case, cluster, and outbreak response and reporting can be found via FoodCORE, Council to Improve Foodborne Outbreak Response (CIFOR), and the Integrated Food Safety Centers of Excellence

☒ Required ☐ Optional

2) Tier 1: Improve lab surveillance, detection, preparedness, and response

a) Improve laboratory activity coordination, workflows, and information flow

i) Model practices for laboratory activities can be found via PulseNet, FoodCORE , and APHL

☒ Required ☐ Optional

b) Transition to PulseNet 2.0 for analysis of molecular subtyping data

☒ Required ☐ Optional

3) Tier 1: Modernize health information systems and electronic data exchange

a) Incorporate generic and condition-specific data elements into data systems

i) Generic elements can be found via the Gen v2 message mapping guide and artifacts: https://ndc.services.cdc.gov/mmgpage/generic-v2-0-message-mapping-guide/

ii) Condition-specific elements (national case surveillance data dictionaries and support materials) can be found via DCIPHER: https://dcipher.cdc.gov/workspace/compass/view/ri.compass.main.folder.d0b345a3-3cb7-44aa-b1f0-e666e9b1cf18

☒ Required ☐ Optional

Area B: Prevention and Intervention

4) Tier 1: Implement public health interventions and tools

a) Identify prevention opportunities using outbreak and case surveillance data

i) Prevention opportunities should include groups disproportionately impacted by enteric, foodborne, waterborne, and zoonotic diseases

ii) Consider behavioral data, culture, and community buy-in/input when designing prevention interventions

☒ Required ☐ Optional

b) Implement model practices/established guidelines into prevention planning

i) Model practices and established guidelines may include: NASPHV Compendia, FDA Food Code, Model Aquatic Health Code, etc.

☒ Required ☐ Optional

Area C: Communication, Coordination, and Partnerships

5) Tier 1: Disseminate relevant public health information

a) Implement outbreak and risk communication principles in public messaging

i) Communication principles include Crisis and Emergency Risk Communication (CERC).

☒ Required ☐ Optional

b) Implement model practices for health promotion communication

i) Model practices for health communication can be found via CDC's Gateway to Health Communication. This includes presenting or disseminating surveillance and/or outbreak summaries to relevant audiences (this includes public webpages, newsletters, conferences, publications) at least once per year.

☒ Required ☐ Optional

Tier 2: CryptoNet Enhanced

While any Tier 2 section is optional for applicants, if a recipient is applying for a Tier 2 project, then all the activities within that project are required.

6) Tier 2 CryptoNet Enhanced: Improve lab testing capacity for *Cryptosporidium*

a) Enhanced public health laboratory surveillance

i) Complete certification CryptoNet surveillance work

ii) Once certified, conduct near real-time subtyping of *Cryptosporidium*-positive stools using CryptoNet protocols and upload subtyping results and associated metadata to CryptoNet using PulseNet infrastructure.

iii) If conducting WGS-based typing in a state public health laboratory is not feasible, ship specimens to the CryptoNet Reference Laboratory at CDC.

☐ Required ☒ Optional

b) Sustain and enhance laboratory diagnostic/subtyping capacity

i) Actively participate in evaluation and/or verification of new methods, testing of new software modules and scripts, adopt improvements to laboratory analysis, and communications processes in a timely fashion.

ii) Provide recommendations and guidance to laboratories within the appropriate region on issues related to laboratory testing or programmatic changes (i.e., WGS).

During outbreak investigations, conduct subtyping for Cryptosporidium clinical/human specimens and for zoonosis-related animal specimens, when available.

☐ Required ☒ Optional

Tier 2: *Cyclospora* Genotyping

While any Tier 2 section is optional for applicants, if a recipient is applying for a Tier 2 project, then all the activities within that project are required.

7) Tier 2 *Cyclospora* Genotyping: Improve surveillance and testing for *Cyclospora*

a) Enhance epidemiologic case investigation response and reporting

i) Improve interviewing timeliness and completeness: this includes attempting to interview all cases of cyclosporiasis with the Cyclosporiasis National Hypothesis Generating Questionnaire (CNHGQ) or state-adapted version, or ad-hoc questionnaire in the case of outbreak-associated cases; with priority given to those patients with samples submitted for genotyping.

ii) Routinely transmit/send CNHGQ/questionnaire data to CDC.

☐ Required ☒ Optional

b) Review exposure data for subtyping clusters in real time

☐ Required ☒ Optional

c) Enhance public health laboratory surveillance

i) If possible, conduct genotyping of *Cyclospora* as part of case or outbreak investigations.

ii) If conducting *Cyclospora* typing in a state public health laboratory is not feasible, ship specimens to CDC or regional laboratory conducting *Cyclospora* genotyping.

☐ Required ☒ Optional

Tier 2: Environmental Microbiology (EM)

While any Tier 2 section is optional for applicants, if a recipient is applying for a Tier 2 project, then all the activities within that project are required.

8) Tier 2 EM: Enhance and sustain a highly skilled, diverse workforce

a) Conduct environmental sample testing for waterborne disease investigations

i) Ensure staff are trained in environmental microbiology with capacity to support waterborne outbreak response. The type of staff required to support an EM response include, but not limited to, EM lead (required), environmental epidemiology, waterborne outbreak coordinator, environmental health/engineering specialist, and waterborne communicator.

ii) Ensure staff/mechanisms (in-house or via partners) are trained and available for collection of environmental samples (e.g., water [small and large volume], soil, surface, and other samples) and shipment of samples to CDC for waterborne disease outbreak response.

iii) Ensure staff are trained in required lab procedures to process and test environmental samples (e.g., water [small and/or large volume], soil, surface, and other samples) for fecal contamination,

etiologic agents, fecal source tracking markers, and physicochemical water quality parameters during waterborne disease investigations.

☐ Required ☒ Optional

9) Tier 2 EM: Improve lab surveillance, detection, preparedness, and response

a) Develop EM response capacity best practices at the state and local level

☐ Required ☒ Optional

b) Develop or maintain capacity to collect and test environmental samples

i) Collect environmental samples (e.g., water [small and/or large volume], soil, surface, and other samples) associated with environmental investigations for fecal contamination, biofilm indicators, etiologic agents, and physicochemical water quality parameters.

ii) Process and test environmental samples (e.g., water [small and/or large volume], soil, surface, and other samples) for fecal contamination, etiologic agents, fecal source tracking markers, and physicochemical water quality parameters during waterborne disease investigations.

☐ Required ☒ Optional

Tier 2: FoodCORE

While any Tier 2 section is optional for applicants, if a recipient is applying for a Tier 2 project, then all the activities within that project are required.

10) Tier 2 FoodCORE: Improve surveillance, investigation, preparedness, and response

a) Implement established FoodCORE activities within recipient jurisdiction

i) For epidemiologic activities this includes attempting to interview all people infected with *Salmonella*, STEC, and *Listeria*, and all other cases with WGS results; reviewing epidemiologic/exposure data for subtyping clusters in real-time; obtaining product information from patients as appropriate; conducting epidemiologic analyses in illness sub-clusters when indicated; and participating in team trainings with state and local staff in outbreak investigation methods.

ii) For environmental health related activities this includes conducting assessments as part of cluster, outbreak, and complaint investigations; and obtaining samples (and associated product information) of implicated and suspect products for testing, as appropriate.

iii) For laboratory activities this includes ensuring routine transport of clinical specimens and specimens from outbreak-associated cases to the public health laboratory; conducting real-time subtyping of *Salmonella*, STEC, and *Listeria*; conducting real-time testing/diagnostics of parasitic identification and calicivirus characterization; and collecting samples from persons with Hepatitis A virus infection linked to a foodborne disease outbreak for molecular characterization.

☐ Required ☒ Optional

b) Participate in FoodCORE strategic planning during BP1

i) Key activities include: identifying at least two participants for strategic planning and describe how they will engage their full FoodCORE team to share updates, solicit feedback to share with CDC, and develop recommendations for updated FoodCORE goals.

☐ Required ☒ Optional

11) Tier 2 FoodCORE: Optional Strategy

a) Optional activity

☐ Required ☒ Optional

b) Optional activity

☐ Required ☒ Optional

c) Optional activity

☐ Required ☒ Optional

Tier 2: FoodNet

While any Tier 2 section is optional for applicants, if a recipient is applying for a Tier 2 project, then all the activities within that project are required.

12) Tier 2 FoodNet: Improve surveillance, investigation, preparedness, and response

a) Enhance epidemiologic interviews and data collection

i) Prioritize epidemiologic interviews and collecting case exposure data.

ii) Complete interviews of patients for standardized demographic, clinical, and travel data elements and data elements associated with antimicrobial resistant infections and case exposure ascertainment.

☐ Required ☒ Optional

13) Tier 2 FoodNet: Improve lab surveillance, detection, and preparedness

a) Enhance lab capacity for reflex culture, sequencing, and other FoodNet work

i) Prioritize sequencing isolates with exposure and antimicrobial use data.

ii) Store/preserve isolates for future characterization.

iii) Store all isolates with exposure and antimicrobial epidemiologic information.

☐ Required ☒ Optional

14) Tier 2 FoodNet: Modernize health information systems and electronic data exchange

a) Align FoodNet surveillance and data transmission with DMI efforts

i) Incorporate FoodNet data elements into the state electronic surveillance system OR ensure elements are mapped into the electronic transmission message to be sent to CDC.

☐ Required ☒ Optional

b) Link laboratory data with FoodNet epidemiologic data

i) Ensure laboratory specimen identifiers for PulseNet sequence information (e.g., PulseNet key, WGS ID) are transmitted to CDC

☐ Required ☒ Optional

Tier 2: Harmful Algal Bloom (HAB) Surveillance, Response, and Mitigation

While any Tier 2 section is optional for applicants, if a recipient is applying for a Tier 2 project, then all the activities within that project are required.

15) Tier 2 HAB: Improve surveillance, investigation, and reporting

a) Enhance HAB event and HAB-associated illness surveillance

i) Enhance surveillance and reporting to national surveillance systems (OHHABS, NORS) for HAB events (inland, coastal [when applicable]) and HAB-associated illness (human, animal) and outbreaks with consideration of data quality, completeness, and use for public health efforts.

☐ Required ☒ Optional

b) Improve collection, submission, and testing of clinical specimens.

i) Develop or continue implementing processes for collection, submission, and testing of human or animal specimens (e.g., necropsy, toxin detection, diagnostic) from humans or animals that have been exposed to HABs. For example, document procedures or update and implement next steps within your jurisdiction.

☐ Required ☒ Optional

16) Tier 2 HAB: Strengthen preparedness, response, and communications capacity

a) Improve public health response and mitigation resources and increase access

i) Improve protocols, trainings, and other public health resources related to public health response and mitigation (e.g., risk communication) of HAB events to address current and emerging issues in your jurisdiction.

ii) Increase access to public health response and mitigation (e.g., risk communications) resources on your jurisdiction's website(s). A set of resources (e.g., a toolkit) might include information such as protocols, response partners, and relevant communications resources (e.g., FAQs, press release templates, etc.).

☐ Required ☒ Optional

b) Provide routine and event-related HAB information to priority audiences

i) Provide new resources or increase access (e.g., post on jurisdictional website) to public health information about HABs and associated illnesses for the general public, human and animal health care providers, or other priority audiences (e.g., populations identified as disproportionately affected by HABs).

ii) Disseminate public-facing health promotion information (e.g., press release, web content, social media, newsletters, onsite signage, etc.) during periods of increased HAB occurrence (e.g., summer months) and HAB events, and support similar efforts by local jurisdictions (e.g., cities), when possible.

☐ Required ☒ Optional

17) Tier 2 HAB: Collaborate with One Health partners

a) Build new or enhanced One Health partnerships

i) Engage with local, state/territorial, federal, Tribal or other One Health partners to establish or strengthen relationships that are supportive of illness prevention in areas such as HAB-associated case and outbreak detection, investigation, response, or reporting, with an emphasis on addressing emerging issues or unmet partnership needs in the jurisdiction.

☐ Required ☒ Optional

b) Participate in a planning a multijurisdictional Tier 2 HAB meeting

i) Identify at least one person to participate in a multijurisdictional Tier 2 HAB meeting (in person or virtual format), including activities such as working with other recipients and CDC to define the timeframe, format, and agenda, along with attending the meeting.

☐ Required ☒ Optional

Tier 2: NoroSTAT

While any Tier 2 section is optional for applicants, if a recipient is applying for a Tier 2 project, then all the activities within that project are required.

18) Tier 2 NoroSTAT: Improve norovirus outbreak surveillance and reporting

a) Report norovirus outbreaks through NORS

i) Include all suspected and confirmed norovirus outbreaks due to any mode of transmission within 7 business days of notification of the outbreak to the state health department.

ii) Provide a minimum set of data elements in the NORS outbreak report (includes: state, date of outbreak, mode of transmission, number ill, suspected or confirmed etiology, and setting).

☐ Required ☒ Optional

b) Upload norovirus outbreak sequences through CaliciNet

i) Report sequences for all laboratory-confirmed norovirus outbreaks due to any mode of transmission to CaliciNet within 7 business days of receipt of outbreak specimens (10 business days if using next generation sequencing).

ii) Include a unique outbreak identifier in CaliciNet reports enabling linkage of those records with the appropriate NORS outbreak report.

☐ Required ☒ Optional

Tier 2: National Respiratory and Enteric Virus Surveillance System (NREVSS) Enhanced

Reporting for norovirus, adenovirus, and rotavirus, and norovirus genotyping activities in this Tier 2 project are required; rotavirus genotyping activities are optional.

19) Tier 2 NREVSS Enhanced: Improve sporadic enteric virus surveillance/testing

a) Improve reporting for norovirus, rotavirus, and adenovirus 40/41 via NREVSS

i) Establish and/or increase participation in clinical laboratory reporting of aggregate diagnostic results for norovirus, rotavirus, and adenovirus 40/41 via the National Respiratory and Enteric Virus Surveillance System (NREVSS), either directly or indirectly through local/state health departments.

☐ Required ☒ Optional

b) Genotype residual norovirus-positive stool specimens

i) Request aliquots/residual stool specimens from patients that test positive for norovirus at clinical laboratories reporting to NREVSS to be sent to the state public health laboratory for confirmation and genotyping.

ii) Upload sequences for genotyped specimens and associated demographic information to CaliciNet

☐ Required ☒ Optional

c) Request residual rotavirus-positive stool specimens

i) Request aliquots/residual stool specimens and associated demographic information from patients that test positive for rotavirus at clinical laboratories reporting to NREVSS.

ii) Forward aliquots/residual stool specimens to CDC for further confirmation and genotyping.

☐ Required ☒ Optional

Tier 2: OutbreakNet Enhanced (OBNE)

While any Tier 2 section is optional for applicants, if a recipient is applying for a Tier 2 project, then all the activities within that project are required.

20) Tier 2 OBNE: Improve surveillance, investigation, preparedness, and response

a) Enhance interviewing timeliness and completeness

i) This includes attempting to interview all cases of *Salmonella*, STEC, and *Listeria* infection and all other cases with WGS testing results, in addition to those associated with multistate and cluster investigations.

☐ Required ☒ Optional

b) Enhance outbreak investigation and response activities

i) This includes real-time review of exposure data, collection/sharing of product information for identified clusters (single and multi-jurisdictional), and when indicated, conducting epidemiologic analyses in illness sub-clusters.

☐ Required ☒ Optional

21) Tier 2 OBNE: Enhance and sustain a highly skilled, diverse workforce

a) Identify and address gaps in surveillance and outbreak response capacity

i) Activities should include implementing workforce development projects (e.g., trainings, exercises) to strengthen surveillance and response capacity. This can include working with or using Food Safety CoE tools and resources.

☒ Required ☐ Optional

Tier 2: PulseNet Area Laboratories

While any Tier 2 section is optional for applicants, if a recipient is applying for a Tier 2 project, then all the activities within that project are required.

22) Tier 2 PulseNet Area Lab: Support regional PulseNet capacity

a) Enhanced outbreak investigation response and reporting

i) Provide recommendations and guidance to laboratories within the appropriate region on issues related to laboratory testing or programmatic changes (i.e., WGS and non-culture-based methods).

ii) Serve as a resource for surge capacity testing and reference capabilities in response to large foodborne outbreaks or potential threats of bioterrorism that might occur locally or nationally.

☐ Required ☒ Optional

b) Sustain and enhance laboratory diagnostic/subtyping capacity

i) Actively participate in evaluation and/or validation of methods that are newly implemented, testing of new software modules and scripts, adopt improvements to laboratory, analysis, and communications processes in a timely fashion.

☐ Required ☒ Optional

23) Tier 2 PulseNet Area Lab: Enhance coordination among lab partners

a) Improve surveillance to drive public health action

i) Activities include: providing laboratory bench training, technical guidance, and scientific expertise to PulseNet participating laboratories within their region.

☐ Required ☒ Optional

24) Tier 2 PulseNet Area Lab: Enhance coordination among epi, lab, and HIS

a) Improve laboratory coordination and information flow between PHLs

i) Coordinate and host PulseNet regional and training meetings.

ii) Serve as representative of laboratories within their areas/region on the PulseNet Steering Committee and the InFORM Regional Meeting and InFORM Conference planning committees.

☐ Required ☒ Optional

Tier 2: PulseNet Metagenomics

While any Tier 2 section is optional for applicants, if a recipient is applying for a Tier 2 project, then all the activities within that project are required.

25) Tier 2 PulseNet Metagenomics: Participate in metagenomic method development

a) Advance PulseNet metagenomics methods

i) This includes actively participating in evaluation and/or validation of newly developed metagenomic methods and testing of related software modules and scripts, adopt improvements to laboratory, analysis, and communications processes in a timely fashion.

☐ Required ☒ Optional

b) Support troubleshooting and feedback cycles on methods in a timely fashion.

☐ Required ☒ Optional

Tier 3: Integrated Food Safety Centers of Excellence (Food Safety CoEs)

While any Tier 3 section is optional for applicants, if a recipient is applying for a Tier 3 project, then all the activities within that project are required.

26) Tier 3 Food Safety CoE: Improve enteric disease activities and programs

a) Conduct evaluations/analyses to inform quality improvement efforts

☐ Required ☒ Optional

b) Develop and disseminate tools and resources

i) Make Food Safety CoE-developed tools and resources publicly available via the Food Safety CoE All Products website (https://foodsafetycoe.org).

ii) Present and promote Food Safety CoE activities and resources, including creating reports, manuscripts, and presentations.

iii) Tools and resources should incorporate health equity principles.

iv) Consider developing tools and resources to improve specific food safety objectives in high-risk settings (e.g., correctional institutions, long-term care facilities, and daycares).

☐ Required ☒ Optional

27) Tier 3: Food Safety CoE: Enhance and sustain a highly skilled, diverse workforce

a) Develop and deliver in-person, virtual, and/or online trainings

☐ Required ☒ Optional

b) Conduct site visits and reverse site visits

☐ Required ☒ Optional

c) Provide consultation to other jurisdictions

☐ Required ☒ Optional

d) Support workforce development activities

i) Activities may include supporting students and projects through internships and other Food Safety CoE projects.

☐ Required ☒ Optional

28) Tier 3 Food Safety CoE: Prevention and Intervention (One Health)

a) Identify/address AR knowledge gaps via expanded surveillance/risk assessments

i) Includes AR pathogens transmitted through animal contact, food, animal feed, water, or environment.

ii) Includes innovative settings/scope for data collection (e.g., vet clinics, environment) and collaboration between CoEs is encouraged.

iii) Enteric AR pathogens could include but are not limited to, *Salmonella*, *Shigella*, Shiga toxin-producing *E. coli*, *Campylobacter*, third-generation cephalosporin-resistant Enterobacterales (ESBL), and carbapenem-resistant Enterobacterales (CRE).

☐ Required ☒ Optional

b) Projects to improve AR pathogen prevention, outbreak response, or surveillance

i) Activities could include developing strategies, materials, tools, or programs Activities can include developing materials, tools, or programs, to address barriers.

ii) Prevention activities could include antimicrobial stewardship projects.

iii) Enteric AR pathogens could include but are not limited to, *Salmonella*, *Shigella*, Shiga toxin-producing *E. coli*, *Campylobacter*, third-generation cephalosporin-resistant Enterobacterales (ESBL), and carbapenem-resistant Enterobacterales (CRE).

☐ Required ☒ Optional

29) Tier 3 Food Safety CoE: Optional Strategy

a) Optional activity: Identify/address barriers to prevention

i) Attend annual calls with the DFWED Prevention Office to share findings.

ii) Work with the DFWED Prevention Office to accelerate prevention solutions.

☐ Required ☒ Optional

30) Tier 3 Food Safety CoE: Emerging Issues Strategy

a) Develop/deliver job aids, trainings, and/or other resources for emerging issues

i) For Budget Period 1, this could include: *Vibrio* surveillance and shellfish traceback investigations; use of non-traditional data sources (e.g., crowd-sourced complaint data)

☐ Required ☒ Optional

b) Emerging Issues Activity (2)

☐ Required ☒ Optional

c) Emerging Issues Activity (3)

☐ Required ☒ Optional

Collaborations:

a. With CDC-Funded Programs

Integrated Food Safety Centers of Excellence (CoEs), CaliciNet, CryptoNet, EHS-Net, FoodCORE, FoodNet, NARMS, NCEH SAFE WATCH/Private Well Initiative, OHHABS, OutbreakNet Enhanced, PulseNet.

b. With Organizations External to CDC

Including, but not limited to: the APHL, CSTE, EPA, U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS), FDA, state drinking water administrator, and state/local water utility organizations.

Populations of Focus:

N/A

Evaluation and Performance Measurement:

Performance measures included here are representative and may not be final at the time of NOFO publication. Please see the CK-24-0002 Performance Measure Guidance document for all final measures and descriptions.

a. ACTIVE Performance Measures

Laboratory Surveillance (PulseNet/NARMS)	
Measure G.1	Total number of isolates and isolate-yielding specimens received in the public health lab
Measure G.2	Culture-Independent Diagnostic Tests (CIDT) measures for *Campylobacter, Salmonella*, *Shigella*, and STEC
CaliciNet	
Measure G.3	Number and percent of outbreaks (≥ 2 specimens) tested for norovirus
Measure G.4	Number and percent of outbreaks (≥ 2 specimens) sequenced for norovirus
Measure G.5	Frequency (e.g., weekly, monthly, quarterly) of meetings between epidemiology and laboratory staff on norovirus outbreaks
Prevention	
Measure G.6	Has your jurisdiction instituted any changes to food safety regulations/statutes in the last calendar year (Y/N)? If yes, describe briefly.
Tier 2 National Respiratory and Enteric Virus Surveillance System (NREVSS) Enhanced	
Measure G.7	Number of clinical laboratories reporting norovirus, rotavirus, and adenovirus 40/41 test data into NREVSS
Measure G.8	Number of clinical laboratories submitting norovirus positive specimens and/or rotavirus positive specimens for further confirmation and genotyping
Measure G.9	Number of norovirus positive specimens submitted to the state laboratory for genotyping and/or rotavirus positive specimens submitted to the state laboratory for forwarding to CDC.
Tier 2 PulseNet Area Laboratories	
Measure G.10	Number of individuals trained by the PulseNet Area Lab from other laboratories in the area for WGS wet lab and/or data analysis
Measure G.11	Number of isolates for which WGS testing was done from other laboratories in your area
Tier 2 Harmful Algal Bloom (HAB) Surveillance, Response, and Mitigation	
Measure G.12	Number of HAB events and associated illnesses investigated
Measure G.13	Number of HAB-associated outbreaks reported to both OHHABS and NORS

Measure G.14	Webpages or other resources made available to support public health surveillance, response, or mitigation of HAB impacts

b. PASSIVE Indicators

Measure G.P1	Proportion of clinical isolates in multistate outbreaks with epidemiologic data submitted
Measure G.P2	Median time (in days) from date of notification to completion using an outbreak-specific questionnaire disseminated by CDC
Measure G.P3	Proportion of clinical isolates in multistate outbreaks with race and ethnicity data submitted to CDC
Measure G.P4	Timeliness and completeness of data reported to CDC surveillance systems for cases of botulism, cholera and vibriosis (COVIS), cryptosporidiosis, listeriosis (*Listeria* Initiative), and *Salmonella* Typhi and Paratyphi infection (NTPFS)
Measure G.P5	Number of outbreak-associated (including zoonotic links/animal involvement) and sporadic *Cryptosporidium* specimens or molecular data submitted to CDC for typing
Measure G.P6	Number and percent of CDC submitted specimens with completed CryptoNet forms submitted to CDC CryptoNet
Measure G.P7	Whole Genome Sequencing (WGS) measures for *E. coli* O157:H7, Non-O157 STEC, *Listeria, Salmonella, Cronobacter, Campylobacter*, *Shigella*, *Vibrio cholerae*, Non-cholerae *Vibrio*
Measure G.P8	Proportion and timeliness of isolates submitted to CDC for NARMS antimicrobial susceptibility testing, with sampling targets based on established guidelines
Measure G.P9	Timeliness and completeness of data reported to OHHABS

Program H: Healthcare-associated Infections, Antimicrobial Resistance, and Antibiotic Stewardship

Program Activity Contact Information:

HAIAR@cdc.gov

Funding Opportunity Description:

a. Overview

The goals of the Healthcare-associated Infection (HAI)/Antimicrobial Resistance (AR) Program are to monitor and prevent HAIs; protect patients and healthcare personnel; advance the detection, response, and containment of AR; train and educate healthcare personnel (HCP); and promote antibiotic stewardship (AS) to ensure safety, quality, and value in healthcare delivery systems. These goals are achieved through support for the HAI/AR Program Network for Response and Prevention, Antimicrobial Resistance Laboratory Network (AR Lab Network), Antibiotic Stewardship, the National Healthcare Safety Network (NHSN), and the National Training Collaborative for Healthcare Infection Prevention and Control (Project Firstline).

HAI/AR Program activities have relevance anywhere healthcare is delivered and across all healthcare settings. Epidemiologic activities are described here in H: Healthcare-associated Infections, Antimicrobial Resistance, and Antibiotic Stewardship, while laboratory activities are described in Program I: Antimicrobial Resistance Laboratory Network (AR Lab Network).

The base tasks and activities described in this guidance (H and I) are complementary to the tasks and activities described in the recent Strengthening HAI & AR Program Capacity (SHARP) awards (1 and 2). Since the project periods for these awards may overlap, care must be taken to assure that expenditures are not duplicative.

b. Health Equity

HAI/AR Programs have an important role in promoting equitable quality of care for all people, especially those living in under-resourced communities. Recipients are encouraged to identify, address, and monitor HAI/AR-related health disparities in implementing tasks and activities, prioritizing approaches that will advance health equity. For example, HAI/AR activities can and should include partnership with local health departments and organizations representing or serving disproportionately affected populations or underserved (e.g., rural) areas. Equitable approaches should be incorporated in outreach to healthcare facilities across the recipients' jurisdictions with a focus on identifying facilities that are under-resourced, located in communities with high social vulnerability, or have populations at higher risk of HAI/AR. Plans to deploy HAI/AR training and education should account for equitable dissemination (e.g., cultural appropriateness, health literacy considerations, language translations), and workforce capacity building efforts should be inclusive, with particular consideration for historically underserved and underrepresented populations.

c. Healthy People

Aligning with U.S. Department of Health and Human Services (HHS) Healthy People 2030 core objectives, HAI/AR objectives prioritize activities that are evidence based and focus on reducing health inequities in HAIs/AR. The HAI objectives for Healthy People 2030 reflect HHS's commitment to reduce HAIs and prevent spread of AR. The 2030 hospital targets include reductions of *Clostridioides difficile* infection (CDI) (HAI-01) and invasive methicillin-resistant Staphylococcus aureus (MRSA) infections (HAI-02). There is also a developmental objective to reduce inappropriate antibiotic use in outpatient settings (HAI-D01). Another

objective (CKD-08) aims to reduce the proportion of adult hemodialysis patients who use catheters as the only mode of vascular access in order to decrease the risk of bloodstream infections.

d. Local Health Department and Tribal Engagement

Recipients are encouraged to support and engage with local health departments and tribal governments, where applicable, to build local capacity in HAI/AR and to expand HAI/AR infection prevention, control, and outbreak response activities.

e. Other National Public Health Priorities and Strategies

Detecting and preventing HAIs and AR is a cross-cutting federal priority. The National Action Plan to Prevent Health Care-Associated Infections: Road Map to Elimination (HAI Action Plan) identifies priorities related to the prevention of HAIs across healthcare settings, while the National Strategy for Combating Antibiotic-Resistant Bacteria and companion National Action Plan articulate national goals, priorities, objectives, milestones, and reduction targets to provide an overarching framework for federal investments aimed at combating antimicrobial resistant bacteria. Key strategies include addressing emerging threats from antimicrobial-resistant organisms, detecting, and responding to outbreaks that are related to healthcare delivery, promoting surveillance through NHSN, and expanding prevention efforts through collaborations and innovative approaches. Recipient activities should reflect these strategies and be informed by the work of the CDC/Council of State and Territorial Epidemiologists (CSTE) Antimicrobial Resistance Surveillance Task Force (ARSTF) and the Council for Outbreak Response: HAIs and Antimicrobial Resistant Pathogens (CORHA).

CDC Project Description:

a. Problem Statement

Health departments have an essential role in preventing and controlling HAI/AR threats and improving safety across the healthcare spectrum. However, the wide range of activities (including surveillance, training, outbreak response, improving antibiotic use, and laboratory capacities) needed to achieve these broad aims depends on federal support in the forms of technical expertise, funding, and other resources.

b. Purpose

These funds are broadly intended to provide critical resources to improve public health, patient safety, and health equity by supporting and enhancing the epidemiologic capacity of local, territorial, and state health departments to detect, prevent, and respond to HAIs; limit the spread of emerging AR; and improve use of antibiotics. This includes healthcare infection prevention and control (IPC) activities; epidemiologic surveillance activities to detect, monitor, mitigate, and prevent the spread of novel and emerging pathogens (e.g., SARS-CoV-2/COVID-19); reducing inappropriate antibiotic use; and training and educational activities to improve HAI/AR, IPC, and AS knowledge and practices among HCP. HAI/AR Program laboratory activities are addressed through the AR Lab Network (Program I).

c. Outcomes

1. Rapid detection, identification, and response to novel or high-concern resistance
2. Timely and effective response to HAI/AR outbreaks
3. Reduction in HAI/AR to protect HCP and improve patient safety across all healthcare settings
4. Improved infection control capacity and practices in all healthcare settings, including detection and monitoring of HAI/AR using NHSN

5. Improved antibiotic stewardship (AS) practices in healthcare settings, including implementation of AS core elements
6. Improved coordination and information sharing with epidemiology, laboratory, and prevention partners to support outbreak response and prevention efforts
7. Demonstrated progress towards identifying and reducing HAI/AR inequities/disparities
8. Strengthened HAI/AR expertise and capacity available throughout the jurisdiction

Funding Strategy:

Supplemental ELC funds like the Strengthening HAI & AR Program Capacity awards (i.e., SHARP 1 and 2) may have the scope to support tasks and activities similar to those described in this guidance. In those cases, funded work and expenditures can be complementary across awards but must not be duplicative. If required tasks and activities in this guidance are being supported by other funding (e.g., SHARP 1 and 2), recipients should indicate this in work plans and budgets. The required tasks and activities listed in this guidance are foundational and should be considered priorities even when supported by supplemental funds.

Recipients should utilize funds for personnel, travel, supplies, equipment, and contractual or other support for proposed activities. Mechanisms could include direct hires, fellowships, contracts, or agreements with local/regional health departments, experts, or other partnering organizations (e.g., academic).

In general, in-state travel for response activities, onsite assessment of infection control and prevention practices, providing training or other onsite technical assistance will be prioritized over other travel. With the exception of required travel to national and/or regional HAI/AR Recipients' meetings and the CSTE Annual Conference HAI/AR Sunday Workshop, in-state travel will be prioritized over out-of-state travel.

Recipients should make clear in their budget requests which strategies, activities, and tasks will be supported by the requested funding, as well as the justification for why funding is needed; as a reminder, laboratory expenses should be covered under Program I. Distribution of funding for each activity will be dependent on recipient needs, the quality and composition of the application, progress during the prior ELC funding cycle, as well as the availability of funds and agency priorities.

Available funding will be prioritized first to support key personnel roles (see item 2 under Required Tasks), and next for infrastructure (including other personnel) to carry out required tasks and required activities.

Total availability of funds for *H: Healthcare-associated Infections, Antimicrobial Resistance, and Antibiotic Stewardship*: $15,400,000

- Approximate number of awards: 65
- Approximate average per award: $260,000

***Please note:**

1. For State Health Departments (SHDs), when entering budget requests, recipients must use the 'Public Health Allocation' to indicate the portion of financial support going toward 'Local/Regional Health Department (LHD)' support versus staying at the SHD level. This allocation data helps ELC answer inquiries regarding the financial support to LHDs which is crucial given the important role LHDs have in addressing infectious diseases.
2. For Local Health Departments (LHDs), when entering budget requests, please ensure the 'Public Health Allocation' is set to 100% 'Local/Regional Health Department (LHD)' support.

3. For Territorial Health Departments, if you have local/regional jurisdictions, please follow the instructions for State Health Departments in #1.

Required Tasks:

Acceptance of funding conveys acknowledgement that the following requirements will be met. As a condition of funding under this project, recipients must attach a letter of commitment from health department leadership (e.g., state epidemiologist, state health official) to support the HAI/AR Program goals.

HAI/AR Program Management

1) **Update the recipient's HAI/AR Plan as necessary**. There is no standard format; recipients can organize the plan as appropriate. Recipients should ensure this plan is coordinated with their MDRO Prevention Workplan, Containment Plan, and Epi-Lab Coordination Plan. Recipients are encouraged to make HAI/AR Plans available on their respective health department websites with an email contact for HAI/AR inquiries.
2) **Workforce Capacity**
    a. Designate one HAI/AR Program Manager who will serve as the HAI/AR Program's primary point of contact to CDC. The manager is typically responsible for providing leadership, oversight, and direction for implementation of CDC-funded HAI/AR activities described in core ELC (H) and supplemental funding guidance. This work should be done in coordination with AR Lab Network lead(s). At a minimum, the HAI/AR Program Manager is in a leadership position within the program, knowledgeable about program activities, and can ensure CDC communications reach the appropriate program areas. This includes regularly checking ELC CAMP to maintain awareness and inform award administration. The HAI/AR Program Manager should actively work with the ELC governance committee on HAI/AR priorities, including identifying cross-cutting activities across the ELC portfolio. Given the variation in program structure, some programs may designate more than one CDC point of contact. The HAI/AR Program Manager title applies to how CDC refers to the functional position and is meant to better reflect the significantly expanded responsibility that this position holds. CDC understands that each jurisdiction has their own official job titles and classifications that may differ and will continue to be used (e.g., Program Director, Program Coordinator, Program Lead).

    b. Maintain HAI/AR expertise through key positions located centrally or regionally, including:

        a) HAI Outbreak Lead

        b) HAI and/or AR Epidemiologist(s)

        c) AS Expert(s)

        d) Infection prevention and control expert(s)

        e) Other positions to sustain program capacity may include: administrative staff, industrial hygienists, health educators, data analysts, setting specific experts (e.g., dialysis expert), health equity experts

c. Provide training and support for HAI/AR Program staff at the state, regional, territorial, or local levels to build or sustain capacity in conducting investigations and prevention activities in healthcare settings, including for the control of targeted MDROs and the prevention of HAIs.

3) **CDC-led meetings and CSTE HAI/AR Sunday Workshop** Attendance at in-person, CDC-led meetings (in Atlanta or hosted regionally) and the CSTE Annual Conference HAI/AR Sunday workshop is expected, with representation that includes the HAI/AR Program Manager or their designee as well as other personnel to represent relevant program areas/projects.

4) **Program Management Reporting**
   a. Update the DHQP HAI/AR Program Staffing Directory at least quarterly, by the last day of the quarter (October 31, January 31, April 30, and July 31).
      a) Document additions and revisions to HAI/AR program staff contacts.
      b) Document vacancies for ELC-funded positions
      c) Identify staff contacts for removal
   b. Submit data on activity implementation to the following HAI/AR REDCap projects annually:
      a) HAI/AR Response & Prevention Reporting System
      b) HAI/AR Antibiotic Stewardship Reporting System
      c) HAI/AR Project Firstline Reporting System

      *The BP1 reporting deadline will be January 31, 2025, for the performance period August through December 2024. For the subsequent budget periods, the period of performance will be the previous 12 months. Reporting criteria including definitions and periods of performance will be described in the HAI/AR Reporting Guide
   c. Provide an annual update on health equity-focused HAI/AR activities.
   d. Submit annual HAI/AR Program Annual Response and Prevention Survey within 90 days of the start of the budget period. CDC will provide a template.
   e. Participate in CDC site visits, as requested, either in-person or virtually.
   f. CDC may require recipients to develop annual progress reports (APRs). CDC will provide APR guidance and optional templates should they be required.

HAI/AR Response

5) Implement **timely detection and response to targeted organisms or resistance mechanisms**, and other HAI/AR outbreaks and risks. Monitor response actions and their timeliness, and report them through the HAI/AR Response & Prevention Reporting System (REDCap). For targeted organisms or resistance mechanisms, initiate investigation within 1 business day of receiving an alert value from the AR Lab Network; for tier 1-3 organisms, a response plan should be developed and initiated within 7 days.
6) **Facilitate coordinated response among interconnected facilities**. This includes but is not limited to

sharing data, such as laboratory testing results, for situational awareness and action.

7) **Report potential medical product contamination and medical tourism outbreaks** Report concerns for intrinsic contamination of a widely distributed medical product or potential outbreak stemming from medical tourism to CDC/DHQP.

8) **Conduct response-driven onsite infection control assessments** at facilities where targeted organisms or resistance mechanisms have been identified, and where potential outbreaks are being investigated. Assessments may require direct observation and ongoing monitoring of infection prevention practices in affected areas/units. Provide or arrange for continued assistance until infection control gaps have been addressed. Ensure the response driven assessments are reported to the HAI/AR Response & Prevention Reporting System (REDCap).

9) **Conduct or facilitate colonization screenings** when recommended by CDC guidance and continue until spread is controlled. Facilitate timely sharing of colonization screening results and incorporate findings in recommendations to affected healthcare facilities and providers. Ensure colonization screening activities are reported to the HAI/AR Response & Prevention Reporting System (REDCap).

10) **Write or update the recipient's Containment Plan as necessary**. Guidance is available on the HAI/AR Program SharePoint Site. As long as CDC guidance is addressed, this plan can be separate or combined with the HAI/AR Plan and Epi-Lab Coordination Plan.

11) Use tracking of **response requests and actions to inform future response and prevention** efforts.

12) **Facilitate timely sharing of laboratory results** and incorporate findings in recommendations to affected healthcare facilities and providers.

Epi-Lab Coordination (for complementary elements directed toward public health laboratories, see the separate Program I guidance for the AR Lab Network)

13) Facilitate **connections between facilities or clinical laboratories and public health labs** to ensure appropriate isolates are forwarded to the regional AR laboratory for targeted surveillance activities, with a particular focus on engaging facilities and clinical laboratories that serve communities that have historically been or currently are underserved, that serve populations at higher risk for illness related to HAI/AR threats, and that have limited resources for detection of emerging HAI/AR threats.

14) **Write or update the recipient's Epi-Lab Coordination Plan as necessary**. Guidance is available on the HAI/AR Program SharePoint Site. As long as CDC guidance is addressed, this plan can be separate or combined with the HAI/AR Plan and Containment Plan.

Data-Driven Detection and Prevention

15) **Use NHSN data to identify high HAI/AR burden** Use NHSN and state/local data to identify healthcare facilities, regions, or populations with disproportionate or high HAI/AR burden to facilitate prevention.

16) **Conduct analyses to assess health disparities related to HAI/AR** and use the results to implement targeted prevention and response activities to improve health equity.

17) **Use available data to detect emerging MDROs within the jurisdiction** and to define local and regional epidemiology. This could include working to develop a network of representative facilities/labs to conduct surveillance or could include a broader collection of isolates throughout the jurisdiction. Update MDRO Prevention Workplan as needed.

Antibiotic Stewardship

18) Facilitate **Core Elements of Antibiotic Stewardship implementation in designated settings**. Core elements should be applied to the setting for which they were designed.

19) Participate each year in **CDC's U.S. Antibiotic Awareness Week observance**.

20) **Distribute CDC's Core Elements and materials** from Be Antibiotics Aware: Smart Use, Best Care to local partners, providers, healthcare systems, and the general public (year-round).

21) **Provide access to antibiotic stewardship education and expertise** across the spectrum of healthcare, particularly to settings and populations with limited access to AS expertise or where stewardship and/or antibiotic use inequities exist.

Communication, Coordination, and Partnerships

22) **Convene HAI/AR advisory committee**. The committee should include representatives from across the spectrum of healthcare delivery and should include, at a minimum, representatives from the state and/or regional public health laboratories, local/regional/tribal health departments, state survey agency, hospital/emergency preparedness, patient and community representatives, and healthcare provider groups (e.g., academic medical centers, hospital and/or long-term care associations). The committee should seek perspectives from a broad range of facility types (e.g., dialysis) and groups/communities that have historically been under-resourced and/or face a disproportionate burden of HAI/AR. The committee is expected to convene (virtually or in person) at least twice per year.

23) Maintain, and update as needed, an **inventory of all healthcare settings in the recipient's jurisdiction**. Use this inventory to guide outreach for surveillance, education, AR containment, response, stewardship, and other prevention activities.

24) **Share surveillance data and findings in EIP catchment area** Recipients with Emerging Infections Program (EIP) catchment areas, especially those with active Healthcare Associated Infections—Community Interface (HAIC) projects: Establish plans to share data and findings related to surveillance activities, projects, and outbreaks. Funding requests should be of sufficient detail to demonstrate there is no overlap with EIP-funded activities and that ELC funds will not be used for research purposes.

Strategies and Activities:

Recipients are expected to address all of the Required Strategies and Activities listed below. Recipients without an established HAI/AR Program, who have not historically been funded under ELC H ("HAI/AR Focal Points" / U.S. Affiliates and Territories) do not need to address all of the Required Strategies and Activities

listed below. CDC is available to collaborate with these recipients to customize strategies depending on priorities and capacities in their jurisdiction.

0) Maintain organizational capacity to complete Required Tasks

Recipients must maintain the organizational capacity and technical expertise required to support a well-functioning HAI/AR Program. Budget line items (BLIs) needed to support Required Tasks should be requested under this activity. Minimal implementation plans are acceptable, e.g., "We will maintain capacity to complete the listed Required Tasks." Recommended milestone: Identify capacities to complete Required Tasks by October 31, 2024.

☒ Required ☐ Optional

Area A: Surveillance, Detection, and Response

1) Support response related to novel/high-concern AR organisms and HAI risks. Support rapid response to control novel or high-concern antimicrobial-resistant organisms and newly identified healthcare-associated infection risks.

a) ***Implement MDRO responses*** for timely detection of and response to novel and targeted MDROs or mechanisms. Response activities must include related required tasks. Strong implementation plans will address how the recipients will: (1) provide technical and epidemiologic consultation to public health laboratories in the AR Lab Network to guide recruitment of clinical laboratories; (2) provide outreach and technical assistance to clinical microbiology laboratories and infection prevention networks to improve the detection of targeted organisms, case reporting, and response; and (3) advise clinical laboratories on which specimens to send for testing, promote local, state, and regional laboratory support, and facilitate isolate submission for testing.

☒ Required ☐ Optional

b) ***Support rapid response to HAIs and AR risks*** not described in 1.a, including clusters, sentinel cases or serious infection control breaches. Response activities must include related required tasks. Strong implementation plans will: (1) describe how the recipient will facilitate coordination of response activities with local/regional/tribal health departments, state survey agencies, licensing/professional boards, and (2) describe how lessons learned from response activities are informing development of response-driven prevention activities.

☒ Required ☐ Optional

Area B: Prevention and Intervention

Implement data-driven HAI/AR prevention strategies.

a) ***Conduct activities to prevent the spread of novel and targeted MDROs*** (gram negatives and C. auris) in long length-of-stay high-acuity facilities (such as LTACHs, vSNFs or other facilities that provide ventilator care), and other facility types in line with the recipient's MDRO Prevention Plan. This must include educational activities for healthcare workers about targeted resistance or common infection control gaps that contribute to spread of novel resistance in the region; activities to improve IPC practices; and activities to facilitate communication between public health and facilities and/or between facilities that share patients. Prevention-based colonization screening can also be included; if included, strategies for screening [e.g., facilities targeted, types

of screening (PPS vs. admission screening), and screening frequencies] should be described. Strong implementation plans will: (1) provide the rationale for selected activities; (2) identify specific settings and facilities; and (3) include at least one activity to improve interfacility communication.

☒ Required ☐ Optional

b) ***Conduct ongoing prevention-based assessments and gap mitigation*** for HAI/AR risks not addressed in 2.a in nursing homes/skilled nursing facilities, long length-of-stay high-acuity facilities (such as LTACHs or other facilities that provide ventilator care [e.g., vSNFs]), and other facility types (based on identified jurisdictional priorities and needs). Assessments will require direct observation. Strong implementation plans will: (1) provide the rationale (e.g., previous outbreak experience, inequities, under-resourced facilities) for selected settings and specific facilities; (2) set numerical targets; and (3) describe steps for gap mitigation.

☒ Required ☐ Optional

c) ***Address health disparities related to HAI/AR*** by developing priorities for focused prevention and response. Strong implementation plans will describe how the recipient will: (1) develop a better understanding of health inequities for HAI/AR through collection, analysis, and reporting of data and (2) use these findings to implement focused interventions to benefit the population(s) or setting(s) identified as disproportionally affected or historically underserved.

☒ Required ☐ Optional

Implement Antibiotic Stewardship Efforts

c) ***Improve and maintain Antibiotic Stewardship capacity*** by monitoring jurisdiction-level antibiotic use in different healthcare settings (e.g., inpatient, outpatient, long-term care, or other settings such as dialysis or telehealth) and use of selected antibiotic classes (e.g., fluoroquinolones). Strong implementation plans will describe how monitoring efforts and assessment of the impact of related required tasks will inform implementation of focused stewardship interventions (e.g., dissemination strategies and collaborative partnerships).

☒ Required ☐ Optional

Area C: Communication, Coordination, and Partnerships

HAI/AR Program Workforce Capacity Building

d) ***Ensure that public health HAI/AR response and prevention expertise is widely and rapidly available*** to provide support across the entirety of the jurisdiction (i.e., at regional or local levels) and for a range of healthcare facility types, including, specifically, dialysis and nursing homes/skilled nursing facilities. Strong implementation plans will: (1) describe steps to establish or maintain clearly defined workforce roles; (2) describe steps to develop or reinforce mechanisms for oversight, training, education, and technical assistance; and (3) describe challenges to establishment of workforce capacity, if applicable.

☒ Required ☐ Optional

HAI/AR Education and Training

e) ***Provide education/training on infection control for healthcare facilities and personnel*** on prevention of HAIs and control of targeted MDROs in a manner that leverages and complements Project Firstline. Promote Project Firstline, leveraging capacity to educate, train, and communicate with frontline healthcare workers. Strong implementation plans will: (1) describe steps to disseminate and conduct trainings with Project Firstline materials and (2) describe how trainings will be tailored to specific audiences.

☒ Required ☐ Optional

Coordination and Partnerships

f) ***Identify and engage with partners*****.** Recipients should collaborate with public health partners (state, county, city, local), other agencies (e.g., regulatory/licensing), Centers for Medicare & Medicaid Services-funded networks [e.g., End Stage Renal Disease (ESRD) networks, Quality Innovation Network – Quality Improvement Organizations (QIN-QIOs)], Public Health Emergency and/or Hospital Preparedness Programs, clinical laboratories, healthcare facilities, hospital and long-term care associations, academic partners [e.g., Epicenters, EIP], and others to maximize overall effectiveness, reduce duplication of effort, and make progress towards achieving the desired program outcomes (see Funding Opportunity Description, section 'c. Outcomes'). Strong implementation plans will: (1) identify specific partners, roles, and responsibilities, and (2) describe intersections with HAI/AR advisory committee activities (see Required Task #22).

☒ Required ☐ Optional

Collaborations:

a. With CDC-Funded Programs

Given the complementary nature of the HAI/AR Program and the AR Lab Network, recipients are expected to coordinate planning, execution, and management of Program H activities with their local/state/territorial and regional AR Lab Network laboratories (Program I). Recipients are also expected to collaborate and ensure alignment with other relevant ELC-funded programs (e.g., National Wastewater Surveillance System; Mycotics, for containment of *Candida auris*), as well as CDC-funded EIP sites and Prevention Epicenters, where applicable.

b. With Organizations External to CDC

In addition to engaging with their HAI/AR advisory committee (Required Task #22) and partners described under Activity 6, recipients are expected to actively engage with the CSTE HAI/AR Subcommittee and regularly be represented at monthly subcommittee calls. Other relevant national organizations may include National Association of County and City Health Officials (NACCHO), Association of State and Territorial Health Officials (ASTHO), Association for Professionals in Infection Control and Epidemiology (APIC), and Society for Healthcare Epidemiology of America (SHEA).

Populations of Focus:

Recipients should consider populations, facilities, and communities at greatest risk for adverse outcomes related to HAI/AR and inappropriate antibiotic use. Recipients should assess health disparities related to HAI/AR and develop priorities for targeted prevention and response activities to reduce identified disparities.

Evaluation and Performance Measurement:

a. ACTIVE Performance Measures

1. Status of updates to the HAI/AR Response & Prevention Reporting System (REDCap) for activities conducted during August through December 2024:

A. Novel and targeted multidrug-resistant organism (nMDRO) responses [Complete, Partially complete, Not complete]
B. Other HAI/AR responses [Complete, Partially complete, Not complete]
C. Prevention-based activities (infection control assessments and point prevalence surveys) in healthcare facilities [Complete, Partially complete, Not complete]
D. Response and prevention focused health equity activities [Complete, Partially complete, Not complete]

2. HAI/AR Antibiotic Stewardship Reporting System (REDCap) completed, with all required data elements by the established deadline

3. HAI/AR Project Firstline Reporting System (REDCap) completed, with all required data elements by the established deadline

*Starting in BP1, the HAI/AR period of performance for performance measures will change from budget period to calendar year. For BP1 reporting, the period of performance will include August through December 2024. For subsequent years, the period of performance will include the previous 12 months (January–December).

b. PASSIVE Indicators

CDC will use the following metrics to assess recipient progress toward outcomes. CDC will pull these metrics from data reported by recipients through the HAI/AR REDCap reporting projects.

1. # of HAI/AR responses in healthcare facilities
2. # of prevention-based IPC assessments in healthcare facilities
3. # of healthcare facilities engaged to facilitate implementation of antibiotic stewardship activities
4. # of individuals trained via Project Firstline
5. Total reach of promotional activities conducted for Project Firstline (email, social media, and website)
6. # and % of staff with an updated profile in the Staffing Directory
7. # of recipients that have provided an annual update on health equity-focused HAI/AR activities, to include HAI/AR Response and Prevention, Antibiotic Stewardship, and/or Project Firstline

Program I: Antimicrobial Resistance Laboratory Network (AR Lab Network)

Program Activity Contact Information:

ARLN@cdc.gov

Funding Opportunity Description:

a. Overview

CDC's Antimicrobial Resistance Laboratory Network (AR Lab Network), established in 2016, provides nationwide laboratory capacity to rapidly detect antimicrobial resistance and inform local responses to prevent spread and protect people from AR threats, including healthcare-associated infections (HAIs), *Candida* species, *Neisseria gonorrhoeae*, *Mycobacterium tuberculosis* (Mtb), *Streptococcus pneumoniae*, *Aspergillus fumigatus*, *Haemophilus influenzae, Clostridioides difficile*, etc. The AR Lab Network bridges the gap between local capabilities and the data needed to combat antimicrobial resistance by providing:

- Comprehensive laboratory capacity and infrastructure to identify antimicrobial-resistant bacterial and fungal pathogens
- Cutting-edge technology, like DNA sequencing
- Data to drive response and prevent infections

This funding opportunity supports increased public health infrastructure for early detection and response to stop transmission of antimicrobial-resistant bacterial and fungal pathogens. With support from CDC's Healthcare-associated Infections and Antimicrobial Resistance (HAI/AR) Program (ELC Program H) and other AR Lab Network Programs, participating health departments contribute to a national network that can more rapidly detect resistance, respond to outbreaks, and help control antimicrobial resistance.

This capacity can, and should, be leveraged to provide early detection of antimicrobial-resistant pathogens to areas and populations that are historically underserved and would be unable to test for these public health threats otherwise. Additionally, infrastructure for testing and data transmission created by this funding opportunity contributes to national surveillance of antimicrobial-resistant pathogens with goals of monitoring and preventing their spread within the U.S., identifying populations at increased risk, and understanding associated inequities.

The base tasks and activities described in this guidance are complementary to the tasks and activities described in the recent Strengthening HAI & AR Program Capacity (SHARP) awards (1 and 2). Since the project periods for these awards may overlap, care must be taken to assure that expenditures are not duplicative.

b. Health Equity

By fostering partnerships with entities that serve disproportionately affected populations, improving the ability to identify inequities in laboratory resource availability, and providing direct support to facilities with fewer testing resources but at higher risk for antimicrobial resistance (AR) among individuals with healthcare-associated infections (HAIs) and/or community infections, the AR Lab Network incorporates an equity-centered approach across all strategies and activities.

c. Healthy People

Objectives for antimicrobial-resistant bacterial and fungal pathogens causing HAIs and community infections have been established for Healthy People 2030 (HP2030) that reflect the commitment of the U.S. Department of Health and Human Services (HHS) to prevent and reduce AR. Aligning with HP2030 core objectives, our objectives prioritize activities that are evidence-based and address health disparities while focusing on reducing health inequities in AR.

d. Local Health Department and Tribal Engagement

Early detection of new resistance requires significant resources in laboratory testing capabilities and expertise which may not be available in all areas. State, tribal, local, and territorial public health laboratories play an important role in providing resources and expertise for early detection of AR threats for all people and communities, especially those communities that have historically and currently been marginalized. These communities may include rural areas, economically disadvantaged areas, areas with higher proportion of people who are uninsured/underinsured, etc. As a result, we strongly recommend all recipients foster partnerships with local health departments and tribal governments to enhance laboratory capacity to detect AR threats.

e. Other National Public Health Priorities and Strategies

Detecting and preventing antimicrobial-resistant bacterial and fungal pathogens causing HAIs and community infections are cross-cutting federal priorities. The National Strategy for Combating Antibiotic-Resistant Bacteria and companion National Action Plan articulate national goals, priorities, objectives, milestones, and reduction targets that provide an overarching framework for federal investments aimed at combating antimicrobial-resistant bacteria and fungi, and *Clostridioides difficile* infections. Key strategies include detecting and responding to emerging threats from antimicrobial-resistant organisms and containing outbreaks within healthcare facilities and in communities.

As part of the American Rescue Plan (ARP) Act of 2021, ELC awarded program-initiated component supplemental funding under CK19-1904, in project called 'Strengthening HAI/AR Program (SHARP) Capacity' . This funding provides additional critical epidemiology, laboratory, and informatics support to recipients for resources to support healthcare infection prevention activities to detect, monitor, mitigate and prevent the spread of SARS-CoV-2, HAIs and AR in healthcare settings.

CDC Project Description:

a. Problem Statement

Annually, AR is linked to more than 2.8 million illnesses and 35,000 deaths in the U.S. Combating AR requires early detection of new resistance and robust prevention efforts, including early outbreak detection and response. Creating state and regional laboratory capacity to detect antimicrobial-resistant bacteria and fungi will improve the ability to implement timely local prevention efforts and to develop national strategies that limit transmission of resistant pathogens and prevent infections. Some AR threats, like carbapenem-resistant Enterobacterales (CRE), are resistant to nearly all available therapeutic agents and require enhanced detection and infection control measures to prevent the spread of infections. For other pathogens, like antimicrobial-resistant *Neisseria gonorrhoeae*, *Haemophilus influenzae*, and *Candida* species, detecting resistance is challenging because antimicrobial susceptibility testing (AST) is not routinely performed in hospitals or other laboratories. In these cases, resistance data are needed to identify outbreaks and prevention measures, as well as to develop treatment guidelines. *Streptococcus pneumoniae* infections are

decreasing because of effective vaccines, but new resistant serotypes may emerge for which patients are not protected by the current vaccine. Early detection of these serotypes will help keep vaccines up to date. Detecting resistance in slow-growing bacteria like *Mycobacterium tuberculosis* (Mtb) requires implementing new rapid methods, like whole genome sequencing (WGS), to identify resistance and provide molecular typing data for tracking transmissions during outbreaks and for ongoing surveillance.

b. Purpose

The AR Lab Network builds capacity to rapidly detect AR in healthcare settings and the community, inform local response to prevent spread, and protect people, especially those living in marginalized communities, from AR threats. The AR Lab Network includes public health laboratories in all 50 states and Puerto Rico, including seven regional laboratories and the National Tuberculosis Molecular Surveillance Center (National TB Center). State and local laboratories will build or sustain capacity to detect and support responses to concerning resistance. Health department partners work with the AR Lab Network to implement a wide range of activities to track changes in bacterial and fungal resistance patterns and identify and respond to outbreaks faster and more effectively .

c. Outcomes

Implementation of AR Lab Network activities will result in:

1. Increased state, local, and regional public health laboratory capacity to detect and confirm bacterial and fungal AR using CDC-recommended methods
2. Rapid identification and containment of AR threats including novel resistance, especially in facilities lacking in resources (in the form of laboratory testing capacity and/or expertise) or serving historically and currently marginalized communities
3. Timely and effective response to AR outbreaks that occur in healthcare and community settings
4. Improved coordination and information sharing with epidemiology, laboratory, and prevention partners to support outbreak response and prevention efforts
5. Improved test results and data reporting to partners including public health epidemiologists, laboratorians, healthcare partners, and CDC to inform surveillance efforts and outbreak response
6. Enhanced molecular surveillance of AR threats
7. Enhanced capacity for detection of outbreaks and transmission of Mtb
8. Improved surveillance of AR Threats: Improved completeness, accuracy, and representativeness of data
9. Enhanced understanding of health disparities among individuals with bacterial and fungal antimicrobial-resistant pathogens in healthcare and community settings

Funding Strategy:

Supplemental ELC funds like the Strengthening HAI & AR Program Capacity awards (i.e., SHARP 1 and 2) may have the scope to support tasks and activities similarto those described in this guidance. In those cases, funded work and expenditures can be complementary across awards but must not be duplicative.

Distribution of funding for each activity will be dependent on recipient needs, the quality and composition of the application, progress during the prior ELC funding cycle, as well as the availability of funds and agency

priorities, which center on equitably protecting health, safety, and security for all communities. *(CDC Mission, Role, and Pledge*).

All applicants are eligible to apply for Tier II activities. Priority for funding Tier II activities will be given to applicants who demonstrated progress during the prior ELC funding cycle, as reported by progress made toward desired outcomes, performance measures, and semi-annual updates to CDC; propose feasible plans that reflect the program's capacity and explain how performance measures will be addressed and reported.

Tier 1: Basic funding for minimum required activities as described in guidance. All activities under Tier 1 are required for all applicants.

- Approximate total availability of funds: $3,500,000
- Approximate number of awards: 56
- Approximate average per award: $62,500

Tier 2: Enhanced laboratory capacity (non-regional laboratories). Applying for Tier 2 is optional. Note that the average award may vary depending on number of awards given.

Tier 3: AR Lab Network regional laboratories. CDC will fund up to 7 regional laboratories to support AR Lab Network activities within regions (). Candidates for regional laboratory funding are not limited to laboratories that previously received funding for regional laboratory activities.

- Approximate total availability of funds: $10,000,000
- Approximate number of awards: 7
- Approximate average per award: $1,430,000

Applicants should make clear in their budget requests which strategies and activities will be supported by the requested funding, as well as providing justification for why these activities are needed; failure to do so may result in a reduced funding award. Recipients should be aware that future funding decisions will be based on measurable progress, as reported by progress made toward desired outcomes, performance measures, and regular updates to CDC.

Applicants should also delineate use of funds for personnel, supplies, equipment, contractual support, or travel for proposed activities. Shipping costs for AR Lab Network activities are funded by CDC separately. If funding is requested for shipping supplies or the use of a courier service, please provide details and/or justification.

National TB Molecular Surveillance Center: CDC will fund continuation of one public health laboratory to provide WGS for all Mtb isolates from culture-confirmed cases of TB in the U.S. for surveillance of resistance determinants, transmission, and development of a CLIA-compliant WGS assay for the prediction of drug resistance in Mtb. Approximately 8,000 Mtb complex isolates will be submitted from public health laboratories from all 50 states and U.S. territories with a possible reduction in submission with each subsequent year of the project. In subsequent years, CDC intends to fund up to three regional laboratories to provide CLIA-compliant WGS testing of Mtb isolates for the prediction of antibiotic resistance and surveillance.

Applying to be the National TB Molecular Surveillance Center is optional (Strategy 7). Estimated total availability of funds:

- Estimated number of awards: 1
- Estimated average per award: $1,800,000

***Please note:**

1. For State Health Departments (SHDs), when entering budget requests, recipients must use the 'Public Health Allocation' to indicate the portion of financial support going toward 'Local/Regional Health Department (LHD)' support versus staying at the SHD level. This allocation data helps ELC answer inquiries regarding the financial support to LHDs which is crucial given the important role LHDs have in addressing infectious diseases.
2. For Local Health Departments (LHDs), when entering budget requests, please ensure the 'Public Health Allocation' is set to 100% 'Local/Regional Health Department (LHD)' support.
3. For Territorial Health Departments, if you have local/regional jurisdictions, please follow the instructions for State Health Departments in #1.

Required Tasks:

Acceptance of funding conveys acknowledgement and indication that the following requirements will be met.

Tier 1/2/3

1. Perform CLIA-validated identification, mechanism testing, and antimicrobial susceptibility testing on all targeted organisms within five working days of isolate receipt.
2. Report CLIA-validated testing results to submitting clinical laboratory within two working days of testing completion. Any test results returned to submitters for individual patient management must be CLIA-validated or contain appropriate disclaimers, as determined by the jurisdiction's CLIA director.
3. Store isolates for a minimum of two years. Transport isolates of interest (as defined or specifically requested by CDC) to the AR Lab Network regional laboratory and/or to CDC for further characterization or to CDC for deposit into a CDC repository. These isolates of interest may include historic isolates of scientific merit as defined by CDC.
4. Update test order forms, LIMS, and other data systems to include variables that can be used to understand and address health equity.
5. Submit all testing results data routinely per CDC program requirements. This includes using HL7 2.5.1 messages or DHQP CSV upload, at least biweekly, to CDC via APHL Informatics Messaging Services platform (AIMS) to Data for Action on Antibiotic Resistance Threats (DAART) or submission of data via Redcap for those projects not available in AIMS/ DAART. Participate in data reconciliation confirmation of counts and data quality assessments. Communicate any test results defined as an "alert" by CDC (e.g., novel, or high-concern resistance), within one business day to CDC and the state/local epidemiologist(s) that work on antimicrobial-resistant bacterial and fungal pathogens. States should actively plan to transition to HL7 transmissions for all AR Lab Network reporting.
6. Implement AR-related consultations and results interpretation for facilities, designated outbreak prevention program staff, and partners, and other network clinical or public health laboratories with a

focus on entities that are within or serve communities that have historically and /or currently been underserved.

7. Update the methods tracking portal annually to assist in cataloging the AR Lab Network test library and facilitate peer-to-peer technical assistance.
8. Participate in regularly scheduled conference calls with CDC to discuss AR concerns, emerging issues, protocol plans, health equity related topics, etc.
9. Submit at least one success story about how the AR Lab Network made a positive impact in the jurisdiction through the CDC's AR Lab Network Success Story Dashboard in SharePoint.
10. Laboratories need to track the usage of the CDC AR Lab Network FedEx account and report usage to CDC per direction.

Tier 3

11. Sustain/implement specimen storage and isolate transport per CDC guidance or upon request (e.g., isolates which harbor new or unusual resistance, a subset of isolates including representative isolates from outbreaks) for additional characterization and potential inclusion in CDC specimen repositories.
12. Submit all testing results (isolate testing, colonization, screening target surveillance) in standardized HL7 2.5.1 messages to CDC via APHL Informatics Messaging Services (AIMS) platform in DAART to improve on timeliness and completeness of data. Actively check DAART for any failed messages and resolve issues on a weekly basis to ensure data are being sent. Participate in data reconciliation confirmation of counts and data quality. Report all colonization screening and Expanded Antimicrobial Susceptibility Testing (ExAST) results to submitters within one day of testing completion, as well as report results to CDC by REDCap. Report all testing results conducted for other jurisdictions in timely manner and electronic format if possible.
13. Demonstrate surge capacity. Accept specimens for testing from outside of the region when CDC determines that a public health need exists, and alternative testing capacity is limited or unavailable. The testing volume and turn-around time will be determined in collaboration with CDC.
14. Implement AR-related consultations and results interpretation for facilities, designated outbreak and prevention program staff, partners, and other network clinical or public health laboratories.
15. As needed or requested, provide expertise, training, and guidance for laboratory personnel conducting AR testing in regional, state, or local AR Lab Network-funded public health laboratories.
16. Host or participate in a regional partnership meeting for state epidemiology prevention programs and public health laboratories that work on bacterial and fungal antimicrobial-resistant pathogens within the region.
17. Participate in regularly scheduled conference calls with CDC to discuss AR concerns, emerging issues, protocol plans, etc.

For laboratories supporting laboratory capacity for *N. gonorrhoeae* resistance surveillance

18. Funded laboratories will participate in regular communication outreach with CDC and sites contributing *N. gonorrhoeae* isolates.
19. AR Lab Network laboratory staff will participate in semi-annual agar dilution external quality assessments (EQA) and a semi-annual WGS EQA administered by CDC.
20. Sequencing priorities will be set by CDC based on requested surveillance activities and in support of epidemiologic investigations. Priority isolates must be sequenced (WGS) and data transmitted to CDC within one month of AST data generation; CDC will perform all analyses using WGS data to detect and

characterize isolates with unique antibiotic susceptibility patterns and to strengthen epidemiologic investigations through sexual network analysis.

21. Funded laboratories must store *N. gonorrhoeae* isolates for at least 2 years and transport all isolates to CDC for further characterization and/or to deposit in a CDC biorepository.

Strategies and Activities:

0) Strategy to Address Required Tasks

a) Address Required Tasks in program guidance.

☐ Required ☒ Optional

Area A: Surveillance, Detection, and Response

Tier 1 activities are for all recipients applying for AR Lab Network funding. Tier 2 activities are optional enhanced laboratory capacity activities intended for non-regional laboratories.

Tier 3 activities are intended for regional laboratories only. Applying to be an AR Lab Network regional laboratory is optional, but for those that apply, note that all activities except those under Strategy 6 and Strategy 10 are required. Applying to be the National TB Molecular Surveillance Center (Strategy 7) is optional, but some activities under this strategy are required for those that apply.

1) Enhance and sustain laboratory testing for surveillance and reporting (Tier 1)

a) ***Perform CLIA-compliant organism identification on CRE/CRPA/CRAB***. Increase or sustain laboratory capacity to perform CLIA-compliant organism identification and carbapenemase production testing on CRE, including at least *E. coli*, *Enterobacter*, and *Klebsiella*, carbapenem-resistant *Pseudomonas aeruginosa* (CRPA), and carbapenem-resistant *Acinetobacter baumannii* (CRAB) isolates, as recommended by CDC.

☒ Required ☐ Optional

b) ***Perform CLIA-compliant carbapenem-resistance mechanism testing on CRE/CRPA/CRAB.*** Increase or sustain laboratory capacity to perform CLIA-compliant carbapenem-resistance mechanism testing on CRE (at least *E. coli, Enterobacter, and Klebsiella*), CRPA, and CRAB isolates for specific resistance mechanisms targeted for detection (e.g., PCR-based detection of KPC, NDM, VIM, OXA-48-like, IMP) as recommended and updated annually by CDC.

☒ Required ☐ Optional

c) ***Perform CLIA-compliant routine confirmatory AST on CRE/CRPA/CRAB***. Increase or sustain laboratory capacity to perform CLIA-compliant routine confirmatory AST on CRE, CRPA, and CRAB isolates, in accordance with CDC guidance. This testing is in addition to the organism identification, carbapenemase production testing and carbapenem-resistance mechanism testing described above.

☒ Required ☐ Optional

d) ***Perform CLIA-compliant routine organism identification for yeast***. Increase or sustain laboratory capacity to perform CLIA-compliant routine organism identification for yeast from clinical sites in accordance with CDC guidance. (e.g., MALDI-TOF based detection of yeast represented in current

FDA approved libraries). This does not include molds or unique yeast that may require further sequencing to identify.

☒ Required ☐ Optional

2) Sustain AR capacity to implement AR Lab Network Activities (Tier 1)

a) ***Quality Management System for CPOs***. Develop, maintain, or incorporate AR Lab Network-related testing into a quality management system (QMS), ensuring highly reliable and accurate laboratory results. The QMS should include:

i) Proficiency testing (PT) and/or alternative performance assessment(s) for each test performed as part of the AR Lab Network program performed at least twice per year. If more than one test method is used for the same purpose (e.g., mCIM and CarbaNP; CarbaR and CDC PCR), the laboratory should demonstrate method correlation at least twice per year.

ii) Completed and approved validations (or verifications for unmodified FDA-approved assays) for all new methods prior to the initiation of patient testing. Note: CDC-developed assays, unless explicitly stated, are not FDA-approved and require full validation in the jurisdiction laboratory.

iii) At least monthly reviews of testing data, including quality control data, for performance, trends, accuracy, and the identification of novel mechanisms and/or emerging outbreaks.

☒ Required ☐ Optional

3) Expand and sustain AR Lab testing and reporting (Tier 2)

a) ***Conduct CLIA-Compliant Susceptibility Testing of Candida spp***. Perform CDC-recommended antifungal susceptibility testing methods to characterize *Candida* spp. isolates submitted for reference testing or enhanced surveillance. Submit data to CDC via REDCap at least monthly or per CDC guidance. Labs should work with CDC towards HL7 reporting for all AR Lab Network testing.

☐ Required ☒ Optional

b) ***Conduct Enhanced Yeast Surveillance.*** Conduct enhanced yeast surveillance for species identification using MALDI-TOF or DNA-based methods in accordance with CDC guidance. Enhanced yeast surveillance may include active surveillance related to specific topics or pathogens of interest and will include recruitment of isolates from clinical laboratories, commercial laboratories, or other relevant submitters in the jurisdiction (perhaps through development of a local sentinel surveillance network). Submit data to CDC at least monthly.

☐ Required ☒ Optional

c) ***Conduct WGS for Carbapenemase-Producing Organisms (CPOs)***. Non-regional public health laboratories may receive funding to conduct WGS for CPOs (e.g., CRE, CRAB, CRPA) in coordination with the CDC to support AR Lab Network priorities and epidemiologic investigations

in their state. These laboratories should demonstrate sequencing capacity, use, or make progress toward using the CDC-developed PHoeNIx (Portable Healthcare Nextgen Informatics) pipeline or comparable bioinformatics tools, and follow CDC guidance and training. CDC determines sequencing priorities based on emerging threats, AR Lab Network data, and current WGS capacities. Upon request, CDC will provide resources and bioinformatics support for WGS analysis. Laboratories must post publicly data and associated isolate metadata to the HAI-Seq Umbrella BioProject on NCBI in a deidentified manner and update relevant alert records with WGS and NCBI identifiers. This should occur in accordance with the latest guidance established by CDC and all applicable regulations. When WGS data are used for individual patient management, laboratories must ensure that WGS processes (data generation and analysis) are CLIA-validated or include appropriate disclaimers, as determined by their CLIA director. Labs must report WGS results (i.e., WGS identifiers, NCBI identifiers, etc.) to CDC.

☐ Required ☒ Optional

d) ***Conduct WGS for C. auris Isolates****.* Non-regional public health laboratories performing *Candida* identification and colonization screening, may receive funding to perform WGS and bioinformatic analyses for C. auris isolates to identify new introductions, support epidemiological investigations, and identify resistance-conferring mutations. In accordance with CDC guidance, laboratories will:

i) Perform WGS on prioritized isolates and use bioinformatics tools and pipelines suitable for analysis. Sequencing analysis will include single nucleotide polymorphism (SNP) analysis, phylogenetic tree-building, phylogenetic tree visualizations, and identification resistance-conferring mutations (e.g., FKS1). For sequencing analysis, laboratories must use or make progress toward using the CDC-developed pipeline, MycoSNP-nf, or comparable bioinformatics tools that have been validated by CDC.

ii) Share relatedness analyses with coordinating epidemiologists at state health departments in a timely manner to support investigations. WGS data reported at an individual level to submitters for patient management must be CLIA-validated or contain appropriate disclaimers, as determined by each public health laboratory's CLIA director.

iii) Post sequence data and associated isolate data to the *C. auris* WGS Umbrella BioProject on NCBI in a deidentified manner, within timelines established by CDC, and in accordance with all applicable regulations.

iv) Report WGS results to CDC (i.e., including WGS identifiers, NCBI identifiers, etc.)

☐ Required ☒ Optional

4) Expand and sustain AR lab testing and reporting for surveillance (Tier 3)

a) ***Provide CLIA-Compliant Detection of CPO Mechanisms.*** In collaboration with CDC, provide CLIA-compliant organism identification, AST, carbapenemase production testing, and molecular detection (e.g., PCR, WGS) of resistance mechanisms for new, unusual, or emerging AR threats, including isolates suspected of carrying novel resistance mechanisms sent from state and local laboratories within the region. Guidance for required mechanism testing directory will be set by CDC.

☒ Required ☐ Optional

b) ***Perform Surveillance for CPOs.*** Perform targeted surveillance for emerging or changing AR threats (e.g., carbapenemase genes), as directed by CDC, using laboratory testing to fill gaps in detection and containment.

i) Laboratory will perform coordinated public health surveillance for CDC-targeted CPOs. This surveillance will involve CDC-directed collection of isolates, swabs, or remnant clinical specimens from a network of collaborating clinical laboratories throughout the recipient's jurisdiction, with results shared with submitting laboratories and CDC. Some specified isolates will be shared with CDC for additional characterization. Techniques may include isolation of bacterial isolates from swabs or other clinical specimens, bacterial identification, AST, and molecular characterization (e.g., PCR, WGS).

☒ Required ☐ Optional

c) ***Conduct CLIA-Compliant Susceptibility Testing of Candida spp.*** Perform CDC-recommended antifungal susceptibility testing methods to characterize *Candida* spp. isolates originally submitted for reference testing or enhanced surveillance. Regional laboratories will test isolates collected from hospitals and healthcare settings in their state or submitted from other jurisdictions in the region. Results should be sent to CDC using HL7 data via AIMS to DAART or per CDC guidance.

☒ Required ☐ Optional

d) ***Conduct Enhanced Yeast Surveillance.*** Conduct enhanced yeast surveillance through the submission of yeast isolates for species identification using CLIA-compliant MALDI-TOF or DNA-based methods in accordance with CDC guidance. Enhanced yeast surveillance may include active surveillance related to specific pathogens of interest according to CDC guidance and will include recruitment of isolates from clinical laboratories (perhaps through development of regional sentinel surveillance network). Submit data to CDC at least monthly.

☒ Required ☐ Optional

5) Expand and sustain AR lab testing for response (Tier 3)

a) ***Sustain Expanded Antimicrobial Susceptibility Testing*****.** Implement or sustain CDC-directed reference AST to new antimicrobial agents of highly resistant bacteria through the ExAST Program. Laboratories will validate testing and establish capacity to test up to 150 isolates per year. Testing and reporting results to submitters and CDC will be timely, providing results within 3 days.

☒ Required ☐ Optional

b) ***Perform WGS for CPOs****.* Perform WGS for CPOs (e.g., CRE, CRAB, CRPA) to support national AR containment priorities in the region. Laboratories should demonstrate sequencing capacity, use, or make progress toward using CDC's PHoeNIx (Portable Healthcare Nextgen Informatics) pipeline

or comparable bioinformatics tools and follow CDC guidance and training recommendations. CDC determines sequencing priorities based on emerging threats, evidence from AR Lab Network data, and current WGS capacities. Upon request, CDC will provide resources and bioinformatics support for WGS analysis. Laboratories must publicly post WGS data and associated isolate metadata to the HAI-Seq Umbrella BioProject on NCBI in a deidentified manner and update relevant alert records with appropriate WGS and NCBI identifiers. This should occur in accordance with the latest guidelines established by CDC and all applicable regulations. When WGS data are used for individual patient management, laboratories must ensure that WGS processes (data generation and analysis) are CLIA-validated or include appropriate disclaimers, as determined by their CLIA director. Labs must report WGS results (i.e., WGS identifiers, NCBI identifiers, etc.) to CDC.

☒ Required ☐ Optional

c) ***Perform WGS for C. auris Isolates.*** Perform WGS and bioinformatic analyses for *C. auris* isolates to identify new introductions, support epidemiological investigations, and identify resistance-conferring mutations (up to 7 regional laboratories). In accordance with CDC guidance, laboratories will:

i) Perform WGS on prioritized isolates and use bioinformatics tools and pipelines suitable for analysis. Sequencing analysis will include single nucleotide polymorphism (SNP) analysis, phylogenetic tree-building, phylogenetic tree visualizations, and identification resistance-conferring mutations (e.g., FKS1). For sequencing analysis, laboratories must use or make progress toward using the CDC-developed pipeline, MycoSNP-nf, or comparable bioinformatics tools that have been validated by CDC.

ii) Share relatedness analyses with coordinating epidemiologists at state health departments in a timely manner to support investigations. WGS data reported at an individual level to submitters for patient management must be CLIA-validated or contain appropriate disclaimers, as determined by each public health laboratory's CLIA director.

iii) Post sequence data and associated isolate data to the *C. auris* WGS Umbrella BioProject on NCBI in a deidentified manner, within timelines established by CDC, and in accordance with all applicable regulations.

iv) Report WGS results to CDC (including WGS identifiers, NCBI identifiers, etc.)

☒ Required ☐ Optional

6) Implement or maintain additional laboratory capacity (some regional laboratories) (Tier 3)

a) ***Surveillance for Aspergillus fumigatus.*** Perform testing for surveillance of azole-resistant *Aspergillus fumigatus* at the direction of CDC, laboratories will perform testing for surveillance of azole-resistant *Aspergillus fumigatus* (up to 2 regional laboratories). AR Lab Network regional laboratories will:

i) Perform CLIA-compliant species identification and testing for azole resistant *A. fumigatus* and report results to the jurisdictional public health department and submitting healthcare facility as appropriate in timeframe consistent with CDC guidance.

ii) Work with state public health department and healthcare facilities to solicit isolates, arrange transport of materials needed, and provide guidance on transport of specimens in accordance with CDC guidance.

iii) Forward any isolate requiring additional/confirmation testing to CDC and submit testing data to CDC at least monthly.

iv) In consultation with CDC, perform WGS on select *A. fumigatus* isolates to assess relatedness and track resistance markers (e.g., CYP51 mutations).

☐ Required ☒ Optional

b) ***Sustain Laboratory Capacity for N. gonorrhoeae*****.** Laboratories will establish or sustain laboratory capacity for N. gonorrhoeae resistance surveillance by performing AST on up to 5,000 isolates and WGS for up to 1,750 isolates per laboratory annually (four regional laboratories).

i) Preference will be given to laboratories that have demonstrated proficiency in AST *of N. gonorrhoeae* using agar dilution and beta-lactamase testing in accordance with methods recommended by CDC's Division of Sexually Transmitted Disease Prevention (DSTDP), and those with capacity to manage data and report results as required by project protocols.

ii) AST will consist of agar dilution for ceftriaxone, cefixime, azithromycin, ciprofloxacin, penicillin, tetracycline, gentamicin, doxycycline, and zoliflodacin, as well as Etest for ertapenem.

iii) Funded laboratories must comply with CDC's GC AR surveillance data reporting, data quality management, and specimen submission protocols.

iv) Work plan must address/describe processes for ensuring timely AST, WGS, and maintaining data integrity (data QC-check) at all stages. CDC supports implementation of Lab Web Portal for uploading shipping manifests and test requests from submitters into LIMS to ensure data entry accuracy.

v) Testing will be done on isolates sent from clinic sites and state or other public health laboratories participating in DSTDP surveillance, rapid detection, and response programs (e.g., Combating Antimicrobial Resistant Gonorrhea and other Sexually Transmitted Infections (CARGOS)). Isolates may also be sent for confirmatory agar dilution testing from AR Lab Network laboratories conducting gradient strip AST for clinical management of gonorrhea.

vi) Funded regional laboratories must complete AST and communicate non-alert AST results to submitters or designates within 3 weeks of submission or as otherwise directed by CDC.

☐ Required ☒ Optional

c) ***Establish GC Reference Laboratory Capacity.*** Establish reference laboratory capacity for *N. gonorrhoeae* gradient strip AST using Etest (BioMerieux) for suspected treatment failure patient samples. Laboratories funded for GC Etest activities under SHARP may not apply for this activity.

i) Implement CLIA-compliant procedures to recover GC isolates from genital and extragenital specimens including pharyngeal specimens and conduct Etest for azithromycin, ceftriaxone, cefixime, and ciprofloxacin on GC isolates recovered from these specimens in accordance with CDC guidance.

ii) Provide specimen collection and/or transport materials (e.g., InTray) to submitters based on the acceptable specimen types in their validated protocols.

iii) Enroll and participate in the semi-annual Proficiency Test program provided by the Wisconsin State Laboratory of Hygiene (WSLH).

iv) Work with CDC to develop a plan for soliciting specimens.

v) Report Etest AST results/reports back to submitters with a turn-around-time of 7 to 10 days and submit summary data to CDC at least monthly. Notify CDC of ceftriaxone and/or cefixime alert MICs within 24 hours.

vi) With the goal of building state and local capacity for this testing, the funded laboratory will develop guidance documents for conducting internal validation of Etest SOPs and maintaining a CDC-approved validation panel of *N. gonorrhoeae* isolates to be shared with external laboratories for Etest capacity development. Provide outreach and technical assistance to support these jurisdictions in bringing on this testing under SHARP and DSTDP GC surveillance, rapid detection, and response programs (e.g., CARGOS).

☐ Required ☒ Optional

d) ***AST and serotyping of Streptococcus pneumoniae.*** AST and serotyping of *Streptococcus pneumoniae* (up to 500 isolates per year). Funded laboratories (two regional laboratories) will perform conventional AST and WGS/PCR-based serotyping for up to 500 isolates per funded laboratory annually. The WGS/PCR-based methods will be used to identify the serotypes of *S. pneumoniae* isolates while AST will be performed to detect unique antibiotic susceptibility patterns. Confirmed identification and serotyping results will be shared with submitting facilities within 7 to 10 business days.

☐ Required ☒ Optional

e) ***Implement C. difficile Culture Capacity.*** Perform CDC-directed and coordinated public health assessments of emerging or changing epidemiology of *Clostridioides difficile* by implementing culture capacity for clinical specimens and environmental specimens. As directed by CDC, apply advanced molecular detection testing, such as typing of isolated bacteria and metagenomics. (One regional laboratory)

☐ Required ☒ Optional

f) ***Surveillance of Antimicrobial Resistant Dermatophytes.*** At direction of CDC, laboratories will perform testing to support surveillance of antimicrobial-resistant dermatophytes (up to 3 regional laboratories if funding is available). AR Lab Network regional laboratories will:

i) Perform CLIA-compliant species identification for dermatophytes (e.g., *Trichophyton* [including *T. indotineae*/*T. mentagrophytes* genotype VIII], *Epidermophyton*, *Microsporum*) and report results to the jurisdictional public health department and submitting healthcare facility in timeframe consistent with CDC guidance.

ii) Perform CLIA-compliant antifungal susceptibility testing for dermatophytes (e.g., *Trichophyton* [including *T. indotineae*/*T. mentagrophytes* genotype VIII], *Epidermophyton*, *Microsporum*) and report results to the jurisdictional public health department and submitting healthcare facility in timeframe consistent with CDC guidance.

iii) Perform genomic sequencing (including WGS) on select dermatophyte isolates to support tracking of antimicrobial-resistant isolates (e.g., *T. indotineae/T. mentagrophytes genotype VIII)* and for identifying outbreaks.

iv) Work with state public health department and healthcare facilities to solicit isolates, arrange transport of materials needed, and provide guidance on transport of specimens in accordance with CDC guidance.

v) Forward any isolate to CDC upon request or as appropriate per guidance and submit testing data to CDC at least monthly.

☐ Required ☒ Optional

g) ***Establish laboratory capacity for H. influenzae***. Establish laboratory capacity for *H. influenzae* antimicrobial resistance surveillance by performing AST on up to 500 isolates (up to 2 regional laboratories if funding is available).

i) Participating laboratories will perform broth microdilution for AST, either in accordance with guidance provided by CDC or in accordance with CLIA requirements and regulations and include all appropriate QC strains and procedures.

ii) Antimicrobial resistance testing should include the following antibiotics, at a minimum: rifampin, ampicillin, amoxicillin-clavulanate, chloramphenicol, cefotaxime, ceftriaxone, cefuroxime, clarithromycin, levofloxacin, meropenem, tetracycline, and trimethoprim-sulfamethoxazole.

iii) Work with CDC to establish a plan for isolate submission from state and local public health laboratories.

iv) Funded regional laboratories must complete AST and communicate non-urgent AST results to submitters or designates within 3 weeks of submission or as otherwise directed by CDC.

v) Antimicrobial susceptibility testing priorities may be requested by CDC in support of epidemiologic investigations. Priority isolates must be tested by regional laboratories and results transmitted to CDC within 2 weeks of priority notification; CDC may request prioritized shipment (within 1 week) of these same isolates to perform WGS analysis for characterization of unique antibiotic susceptibility patterns or for epidemiologic investigation.

vi) Routine antimicrobial susceptibility testing results will be reported to CDC on a quarterly basis.

vii) Funded laboratories must store *H. influenzae* isolates for at least 2 years and transport all isolates to CDC for further characterization and/or deposit in a CDC Biorepository within 1 year of receipt.

☐ Required ☒ Optional

h) ***Surveillance of Antimicrobial Resistant Mycoplasma genitalium.*** At direction of CDC and in partnership with participating sexually transmitted infection (STI) clinics, laboratories will perform testing to support surveillance of M. genitalium and macrolide and fluoroquinolone resistance associated mutations in specimens positive for M. genitalium (up to four regional laboratories if funding is available). Selected AR Lab Network regional laboratories will:

i) Perform nucleic acid amplification testing (NAAT) to identify *M. genitalium* in remnant Hologic Aptima Combo2 urogenital, urine, or rectal specimens using Hologic's Aptima *Mycoplasma genitalium* (AMG) assay.

ii) Perform molecular testing to identify macrolide and/or fluoroquinolone resistance associated mutations in all *M. genitalium*-positive specimens.

iii) Work closely with participating state/local health departments (HDs) and STI clinics to solicit clinical specimens (i.e., NAATS), arrange transport of materials needed, and provide guidance on transport of specimens in accordance with CDC guidance.

iv) Forward any clinical specimen/isolate to CDC upon request or as appropriate per guidance.

v) Collect line-listed laboratory, clinical, and demographic data elements associated with each submitted specimen.

vi) Electronically submit line-listed data to participating state/local HDs, STI clinics, and to CDC following project protocols and, in a timeframe, (such as monthly) consistent with CDC guidance.

☐ Required ☒ Optional

7) Sustain workforce capacity to implement AR Lab Network regional laboratories (Tier 3)

a) ***Sustain WGS of Mycobacterium tuberculosis (Mtb***). Sustain WGS of Mycobacterium tuberculosis (Mtb) by sequencing approximately 8,000 isolates in total annually submitted from public health laboratories from all 50 states and U.S. territories with a possible reduction in submitted samples with each subsequent year of the project. The NextSeq sequencer is the preferred platform for this work. Preference will be given to laboratories that have demonstrated proficiency in WGS testing of Mtb in accordance with methods recommended by CDC's Division of TB Elimination. The laboratory should transmit the WGS FASTQ files to CDC within two weeks of receiving the isolate.

☒ Required ☐ Optional

b) ***Maintain Mtb Sample Inventory Storage System.*** Prepare subcultures of all submitted isolates and provide transport to CDC within four months of submission for long term storage.

☒ Required ☐ Optional

c) ***Implement CLIA-Compliant Testing for Use of WGS Mtb Data.*** Implement CLIA-compliant testing for use of WGS data for the prediction of antibiotic resistance in *M. tuberculosis*.

☐ Required ☒ Optional

d) ***Implement or Sustain Electronic Test Ordering.*** Work with CDC and APHL to implement or sustain electronic test ordering and reporting for the clinical application of using WGS data for the prediction of antibiotic resistance using APHL Informatics Messaging Services (AIMS) platform and Lab Web Portal version 2 or higher, or similar platform.

☐ Required ☒ Optional

e) ***Provide CLIA-Compliant Testing for Use of WGS Mtb Data.*** In collaboration with CDC, provide CLIA-compliant testing for use of WGS data for the prediction of antibiotic resistance in *M. tuberculosis*.

☐ Required ☒ Optional

Area B: Prevention and Intervention:

Tier 2 activities are optional enhanced laboratory capacity activities intended for non-regional laboratories.

Tier 3 activities are intended for regional laboratories. Applying to be an AR Lab Network regional laboratory is optional, but for those that apply, note that all activities except those under Strategy 6 and Strategy 10 are required.

8) Expand and sustain AR Lab testing and reporting (Tier 2)

a) Perform C. auris colonization screening testing. Non-regional laboratories may be funded to increase laboratory capacity to perform C. auris colonization screening testing to support surveillance activities and outbreak investigations occurring within their state or local jurisdiction in accordance with CDC guidance. This testing will be in collaboration with CDC and the AR Lab Network regional laboratory and preference may be given to those laboratories in high burden areas.

i) Coordinate with state or local programs that work on antimicrobial-resistant pathogens to transport collection swabs to healthcare facilities where swabbing for colonization testing will take place

ii) Provide advice to healthcare facility laboratories on the collection and transportation of specimens

iii) Test and report results to the recipient public health department and submitting healthcare facility in timeframe consistent with CDC guidance

iv) Submit colonization testing data to CDC at least monthly. Programs submitting data to REDCap should work with CDC to develop a timeline for implementation of HL7 reporting via AIMS to DAART.

☐ Required ☒ Optional

9) Expand and sustain AR lab testing for response (Tier 3)

a) ***Support State-Led Epidemiologic Investigations.*** Provide regional laboratory support for state-led epidemiologic investigations and AR prevention efforts focused on important healthcare pathogens by performing molecular tests to detect colonization for targeted AR threats (e.g., CPOs, pan-resistant organisms, vancomycin resistant *Staphylococcus aureus*). Regional laboratories will work

with state/local epidemiologists or programs that work on antimicrobial-resistant pathogens to facilitate collection and transportation of specimens for colonization testing to ensure timely testing of specimens (e.g., ≤ two working days' time to reporting molecular results). AR Lab Network regional laboratories will:

i) Work with state programs that work on antimicrobial-resistant pathogens to transport collection kits to healthcare facilities where swabbing for colonization testing will take place

ii) Provide advice to healthcare facilities and personnel on the collection and transportation of specimens,

iii) Have specimens collected at healthcare facilities sent directly from healthcare facilities to the regional laboratory

iv) Test and report result to the jurisdictional public health department and submitting healthcare facility within two working days of specimen receipt and submit colonization testing data to CDC, via AIMS, at least monthly.

☒ Required ☐ Optional

b) ***Perform C. auris Colonization Screening Testing.*** At the direction of CDC, laboratories will perform *C. auris* colonization screening testing to support surveillance activities and outbreak investigations occurring within the region. AR Lab Network regional laboratories will:

i) Work with state programs that work on antimicrobial-resistant pathogens to transport collection swabs to healthcare facilities where swabbing for colonization testing will take place.

ii) Provide advice to healthcare facility laboratories on the collection and transportation of specimens.

iii) Have specimens collected at healthcare facilities sent directly from healthcare facilities to the regional laboratory.

iv) Test and report result to the jurisdictional public health department and laboratory and submitting healthcare facility in timeframe consistent with CDC guidance and submit colonization testing data to CDC, using HL7 via AIMS to DAART.

☒ Required ☐ Optional

10) Implement or maintain additional laboratory capacity (some regional laboratories) (Tier 3)

a) ***CRE and CRPA in Companion Animals.*** Establish or maintain laboratory capacity for CRE and CRPA antimicrobial susceptibility testing, carbapenemase production testing, genetic mechanism testing and WGS on specimens from companion animals (i.e., dogs, cats), consistent with scientifically accepted laboratory methods. Participating regional labs (up to 2 regional laboratories if funding is available) will:

i) Prioritize testing of companion animal samples when colonized or infected companion animals might be a potential public health risk or serve as ongoing sources of transmission,

and when the requesting public health jurisdiction has the capacity to investigate or respond to identification of CP-CRE and CP-CRPA in companion animals. Colonization testing in companion animals should be limited and reserved for containing outbreaks or mitigating public health risk.

ii) Work with state and local AR and zoonotic disease programs and CDC to establish procedures for companion animal isolate submission and sampling, prioritization of testing, reporting, and responses to CP-CRE and CP-CRPA detections in companion animals. Funded regional labs may process samples originating from outside of their AR Lab Network region.

iii) Work with CDC to establish and maintain data flows for companion animal test and WGS results that ensures clear and easy delineation of human and animal results and case counts. Reporting procedures are expected to evolve as the activity matures.

☐ Required ☒ Optional

b) ***Evaluate Wastewater Surveillance.*** Evaluate wastewater surveillance as a supplement to colonization screening in long-term care facilities (LTCFs).

i) Develop or enhance partnership(s) with an established wastewater surveillance program(s). Expectations for the AR Lab Network Regional Lab (up to 2 regional laboratories if funding is available):

a. Partner with an established wastewater surveillance program within their State or Region; coordinate colonization screenings of residents or patients with the LTCF; manage the administrative aspects for the transport of final samples, wastewater concentrate and/or extract and colonization swabs to the regional laboratories (e.g., payment and paperwork for any transport or shipment); and additional responsibilities detailed below.

b. Expectations for the selected wastewater surveillance program* partner: Conduct wastewater collection at the LTCF; concentrate and extract wastewater samples; transfer a final concentrate and/or extract to the Regional AR Lab, in accordance with CDC guidance. Partners may be one or more of the following: state or local laboratory, academic institution, hospital, corporate partners, or a multi-partner program of such entities.

**An established wastewater surveillance program clearly demonstrates, at a minimum:*

c. On-going or previous wastewater surveillance program, project, or study at a LTCF, where evidence of peer-reviewed publications, an externally facing public dashboard, or participation in the National Wastewater Surveillance System may be provided to support the qualification of "established".

d. Existing field capacity to collect wastewater at a skilled nursing facility (SNF) and/or long-term acute care hospital (LTACH), in accordance with CDC guidance.

e. Existing laboratory capacity for concentrating wastewater, extracting DNA, and transferring final wastewater concentrates and/or extracts, in accordance with CDC guidance.

ii) Provide one or more AR Lab Network Regional Lab contacts to the CDC, who will participate in monthly calls with the CDC.

iii) AR Lab Network Regional lab will coordinate with the wastewater surveillance program and the selected LTCF to collect, on the same day at a minimum of 6 times in a calendar year with at least 4 weeks between samples, wastewater samples directly from the facility (on the property) and colonization swabs directly from residents/patients in the facility on that same day.

iv) AR Lab Network Regional lab will test final wastewater concentrates/lysates/extracts (transferred from partner to the designated regional AR Lab Network lab) and resident/patient colonization swabs for *C. auris* and/or carbapenemases (*bla*KPC, *bla*NDM, *bla*VIM, *bla*IMP, *bla*OXA-48) and the organisms carrying them, assuring side-by-side analysis using CDC CLIA approved assays.

v) AR Lab Network Regional lab will coordinate data management, record keeping and reporting for wastewater and colonization swab testing to produce reliable and high-quality data for public health action, including additional data variables to be collected and shared in accordance with CDC guidance.

☐ Required ☒ Optional

Area C: Communication, Coordination, and Partnerships

Tier 1 activities are for all recipients applying for AR Lab Network funding

Tier 3 activities are intended for regional laboratories. Applying to be an AR Lab Network regional laboratory is optional, but for those that apply, note that all activities except those under Strategy 6 and Strategy 10 are required.

11) Sustain AR capacity to implement AR Lab Network Activities (Tier 1)

a) ***Identify AR Lab Expert. Designate, hire, or train a dedicated AR Lab Expert for the jurisdiction***. Note: This position is separate from AR Lab Coordinator position under SHARP.

The AR Lab Expert should:

i) Demonstrate extensive knowledge of the goals, purposes, and methods of the AR Lab Network program

ii) Have, or gain, a thorough understanding of the principles, methodologies, and quality control elements essential for the performance of CLIA-compliant bacterial and fungal organism identification, carbapenemase production testing, carbapenemase mechanism testing, and bacterial and fungal AST

iii) Have knowledge of resources available at the AR Lab Network regional laboratory and how and when to access that testing

iv) Facilitate submission of isolates and other specimens to the local, state, and/or regional laboratory

In the absence of an AR Lab Coordinator, the AR Lab Expert shall also:

v) Ensure coordination between state and local programs that work on bacterial and fungal antimicrobial-resistant pathogens and the AR Lab Network regional laboratory
vi) Facilitate submission of testing data to CDC
vii) Serve as primary point of contact for AR Lab Network communications with CDC

☒ Required ☐ Optional

12) Improve laboratory and epidemiology coordination and outreach (Tier 1)

a) ***Coordinate epidemiology and laboratory functions.*** In collaboration with the AR Lab Coordinator (funded under SHARP), and the HAI/AR Program (for AR issues related to healthcare settings), coordinate epidemiology and laboratory functions at state, city, county, and local levels, as well as with the AR Lab Network regional laboratory.

☒ Required ☐ Optional

b) ***Collaborate with programs that work on antimicrobial-resistant pathogens***. Using guidance provided by CDC, collaborate with other ELC-funded programs that work on antimicrobial-resistant pathogens to develop and update coordinated Work Plans (e.g., HAI/AR Plan, MDRO Prevention and Containment Plans). These plans should include a list of prioritized bacterial and fungal antimicrobial-resistant organisms and mechanisms and should be based on the epidemiology of the recipient's jurisdiction. States that participate in the Emerging Infections Program (EIP), should demonstrate efforts to enhance relationships and collaboration with EIP staff, especially in the context of Healthcare-Associated Infections Community Interface (HAIC) and other programs within the EIP that have a focus on bacterial and fungal antimicrobial-resistant pathogens.

☒ Required ☐ Optional

c) ***Solicit bacterial and fungal isolates from clinical laboratories.*** Develop strong connections with clinical laboratories in the jurisdiction. Solicit and coordinate the submission of bacterial and fungal isolates from the clinical laboratory to the state/jurisdictional public health lab or AR Lab Network regional laboratory, as requested. Focus should be placed on those laboratories that serve short stay acute care hospitals and high-acuity post-acute care facilities or as defined by CDC.

☒ Required ☐ Optional

d) ***Provide outreach and technical assistance to clinical microbiology laboratories.*** Provide outreach and technical assistance to clinical microbiology laboratories to improve knowledge of AR threats, methods for the detection of targeted organisms, and situational awareness of program goals/initiatives, including timely submission and reporting of results.

☒ Required ☐ Optional

e) ***Engaging facilities.*** Using preexisting knowledge of inequities in testing resources and/or health risks and outcomes within the jurisdiction, identify and engage entities (healthcare facilities, clinical laboratories, etc.) that:

i) Serve communities that have historically and/or currently been underserved
ii) Serve populations at a higher risk for illness related to AR threats
iii) And/or have limited resources for detection of emerging AR threats

☒ Required ☐ Optional

13) Advance electronic information exchange implementation (Tier 1)

a) ***Develop protocols per CDC guidance.*** Develop testing, communication protocols, reporting processes, and IT infrastructure, per CDC guidance and specifications, to ensure timely testing and reporting of results to submitting laboratories, state prevention epidemiologists, jurisdictional public health laboratories, and CDC.

☒ Required ☐ Optional

b) ***Work with APHL to implement or sustain HL7 reporting.*** Work with APHL to implement or sustain HL7 reporting via the AIMS platform to DAART. Work with CDC programs and APHL to ensure reporting per required implementation guidelines for all programs reporting to DAART and respond to issues or updates to ensure high quality data submissions. This includes collecting and reporting all required demographic and testing data to DAART and working towards expanding the available data elements that can be reported to CDC as additional data elements are implemented.

☒ Required ☐ Optional

14) Sustain workforce capacity to implement AR Lab Network regional laboratory activities (Tier 3)

a) ***Train Personnel to Perform all AR Tests.*** Regional laboratories will train laboratory personnel to demonstrate competency and proficiency for performing all AR tests (e.g., AST, detection of resistance mechanisms, and advanced molecular techniques, such as WGS), to detect resistance and address the genetic relatedness of bacterial and fungal isolates in accordance with protocols and/or guidelines established by CDC available in their test directory.

☒ Required ☐ Optional

15) Improve laboratory and epidemiology coordination and outreach (Tier 3)

a) ***Collaborate with Public Health Communicable Disease Partners.*** Regional AR Lab Network staff should work closely with HAI/AR Programs and other relevant public health communicable disease staff (e.g., mycotics, STD) including epidemiologists and laboratorians to collaborate on work related to bacterial and fungal antimicrobial-resistant pathogens, such as recruiting and coordinating sample submissions and testing and use of data for containment and prevention activities applying strategies and guidance provided by CDC.

☒ Required ☐ Optional

b) ***Plan for Collection of Specimens***. In collaboration with CDC programs, establish a project plan and protocol for collection of bacterial and fungal specimens and/or isolates from healthcare facilities, clinical microbiology laboratories, or other clinical settings for:

i) Clinical isolates requiring specialized testing (e.g., CRE, CRPA, CRAB, *Candida* spp., and *Streptococcus pneumoniae* for AR Lab Network regional laboratories conducting this testing)

☒ Required ☐ Optional

16) Advance electronic information exchange implementation (Tier 3)

a) ***Sustain IT Infrastructure per CDC Guidance.*** Develop or sustain the processes and IT infrastructure, per CDC guidance and specifications, for timely reporting to submitting facilities, state or local public health laboratories, epidemiologists, regional AR prevention partners, and CDC for the following:

i) Clinical isolates requiring specialized testing (e.g., pan-resistant organisms, CPOs, and *Candida* spp.)

ii) Outbreak detection requested through state or local health authorities for (CPOs, *C. auris*, and other pathogens, as needed and resources permit)

iii) Representative sets of isolates to describe estimates of scope and magnitude of specific AR threats and mechanisms for resistance (*N. gonorrhoeae*, *Candida* spp., and *Streptococcus pneumoniae* for regional laboratories conducting this testing)

☒ Required ☐ Optional

b) ***Sustain Reporting through AIMS to DAART.*** Sustain reporting using APHL Informatics Messaging Services (AIMS) to DAART. Laboratories will work with APHL to implement or sustain reporting using APHL Informatics Messaging Services (AIMS) platform. Additionally, labs should implement an electronic testing and reporting system (ETOR) for submission and reporting to submitters, with preference for or equivalent capabilities to APHL supported Lab Web Portal version 2 or higher for applicable testing. Timely reporting will include sharing results in acceptable manner as well as addressing special "alert" notification needs.

☒ Required ☐ Optional

Collaborations:

a. With CDC-Funded Programs

Collaboration with CDC programs is expected to ensure implementation of approved or recommended methods and protocols that support national data needs. To ensure that efforts and activities are complimentary and minimize the burden on clinical laboratories, sites should coordinate their activities with:

- Other ELC-funded Antimicrobial Resistance Lab Network programs and initiatives
- ELC-funded HAI/AR Programs (Program H)
- Emerging Infections Program (EIP) sites and initiatives if present in their state or jurisdiction
- APHL AIMS program implementation team collaborations

- Prevention Epicenters and partnering collaborations

b. With Organizations External to CDC

Recipients should collaborate with other state or public health laboratories, clinical laboratories, and medical and/or public health academic centers to assure that efforts are being maximized while avoiding duplication.

Populations of Focus:

N/A

Evaluation and Performance Measurement:

CDC's AR Lab Network program evaluation is focused on the five core performance measures (PMs) (e.g., G2.1-G2.5 three enhanced capacity measures (e.g., G 2.6-2.8) and thirteen regional laboratory measures (e.g., G 2.8-G2.21) that are captured by recipients using a standardized form in a secure web-based application for building and managing online surveys and databases called ELC CAMP hosted by the CDC.

Performance measurement is an ongoing process that monitors and reports on a program's progress and accomplishments leveraging data between what was planned and intended. It also helps identify the conditions under which a program is doing well or poorly, solicit improvement strategies, and assess success of remedial actions. A linear model of the relationship between our inputs, activities and intended effects are available in the AR Lab Network's logic model below. Ongoing monitoring of milestones and PMs will be utilized to gauge progress toward successful completion of priority activities. PMs are used by CDC and recipients to help.

- Support continuous monitoring and examine opportunities to improve the program or project, and implementation of activities,
- Demonstrate accountability to partners (partners are defined as individuals or organization that are involved in the AR Lab Network and could include: funders, the public, recipients, etc.)
- Clarify program or project expectations and priorities.

However, there are limitations to PMs to solely evaluate a program. For example, measures do not always fully represent program success or impacts. Other sources of data are often used to measure program information to help fully demonstrate its progress which may include workplan updates, progress reporting, success stories, and site visits.

Performance measures included here are representative and may not be final at the time of NOFO publication. Please see the CK-24-0002 Performance Measure Guidance document for all final measures and descriptions.

a. ACTIVE Performance Measures

Performance measure details will be communicated to recipients in a separate document. An abbreviated list is included below:

I.1- Routine Testing by Genera in Jurisdiction

I.2- Expanded Drug Susceptibility Testing (ExAST) in Jurisdiction

I.3- *Candida* Species Identification in Jurisdiction

I.4 - HAI/AR Whole Genome Sequencing (WGS) of Gram-Negative AR Threats in Jurisdiction

I.5 – *C. auris* Whole Genome Sequencing (WGS) in Jurisdiction

I.6- Carbapenemase-Producing Organism (CPO) Screening in Jurisdiction

I.7- Azole Resistance in Clinical *Aspergillus Fumigatus* Isolates

I.8- *N. Gonorrhoeae* Whole Genome Sequencing (WGS)

I.9- Gonococcal (GC) Antimicrobial Susceptibility Testing (AST) in Jurisdiction

I.10- Whole Genome Sequencing (WGS) of *S. Pneumoniae*

I.11- *Clostridioides Difficile* (*C. Difficile*) Testing in Jurisdiction

I.12- Antifungal Resistant Tinea/Dermatophytes

I.13- Antimicrobial Susceptibility Testing (AST) of H*. Influenzae* in Jurisdiction

I.14- *Mycoplasma Gentalium* (MG)

I.15- Molecular Mtb Testing

I.16- *C. auris* Colonization Screening in Jurisdiction

I.17- Monitoring CRE/CRPA in Companion Animals to/from Humans

I.18- Healthcare Wastewater-Based Surveillance

I.19- Communication and Coordination of Actionable Epi Lab Data

I.20- Characterization of the Clinical Laboratory Network in Jurisdiction

b. PASSIVE Indicators

N/A

Program J: Enhanced Surveillance for Vaccine-Preventable Disease (VPD) and Respiratory Diseases

Program Activity Contact Information:

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a. Overview

The overall goal of the ELC Cooperative Agreement for Enhanced Vaccine-Preventable (VPD) and Respiratory Disease Surveillance and Coordination (Program I) is to strengthen and coordinate case, disease, laboratory, and outbreak surveillance for VPDs and respiratory diseases. This support builds upon established surveillance systems, to provide more accurate, timely, complete, and representative data to monitor the impact of these pathogens. Five required activity areas (Tier 1) for this cooperative agreement include (1) VPD surveillance coordination; (2) respiratory virus surveillance and coordination (including but not limited to influenza, Respiratory Syncytial Virus (RSV), and Coronavirus disease (COVID)); and enhanced surveillance specifically for (3) meningococcal disease, (4) varicella, and (5) acute flaccid myelitis (AFM). In addition, optional activity areas (Tier 2) include opportunities for applicants to request support for additional enhanced surveillance activities. Current guidelines for VPD surveillance can be found in the *Manual for the Surveillance of Vaccine-Preventable Diseases* (Manual for the Surveillance of Vaccine-Preventable Diseases | CDC). Additional guidance/guidelines referenced throughout this document can be found on CDC disease-specific websites.

b. Health Equity

Health outcomes are improved with enhancing public health inquiry, surveillance, and implementation science efforts to shift toward identifying and addressing the drivers of health disparities (Health Equity - Office of Health Equity - CDC).Activities to address health equity include, but are not limited to, improved educational awareness through engagement with diverse groups of health care providers, community institutions, and other public health partners. Improved surveillance data quality and completeness for data elements such as vaccine history, importation status, race, and ethnicity provide information to address these issues.

Supported activities align with the CDC 2022-2027 Strategic Plan: Advancing Science & Health Equity by increasing capacity for rapid outbreak response (Advancing Science & Health Equity (cdc.gov)).

c. Healthy People

The Immunization and Infectious Diseases 2030 Objectives include: “Maintain the elimination of measles, rubella, congenital rubella syndrome, and polio” (IID-01) and “Reduce cases of pertussis among infants” (IID-05). Infectious Disease - Healthy People 2030 | health.gov

The Respiratory Disease 2030 Objectives include: “Reduce the rate of hospital admissions for pneumonia among older adults” (OA-06). Respiratory Disease - Healthy People 2030 | health.gov

The Public Health Infrastructure 2030 Objectives include: “Increase the proportion of state public health labs that provide services to support emerging issues” (PHI-D04) and “Increase the proportion of state public health labs that use emerging technology to provide enhanced services” (PHI-D05). Public Health Infrastructure - Healthy People 2030 | health.gov

In addition, the 2030 Objectives include “Enhance the use and capabilities of informatics in public health” (PHI-R06) and “Increase the proportion of people with vaccination records in an information system” (IID-D02). Public Health Infrastructure - Healthy People 2030 | health.gov

d. Local Health Department and Tribal Engagement

Applicants should consider how to leverage local health departments’ and tribes’ networks of partners, connections to the local communities, and understanding of community context and trusted sources of information toward common goals.

Engagement with local health departments and tribal entities will enhance and modernize data and surveillance infrastructure to support national public health priorities.

The CDC Public Health Data Strategy calls for improving the timeliness, quality, and completeness of surveillance data available to CDC programs; state, tribal, local, and territorial (STLT) agencies; and other stakeholders Public Health Surveillance and Data | CDC.

The U.S. influenza surveillance system is a collaborative effort between CDC and its many partners in state, local, and territorial health departments, public health and clinical laboratories, vital statistics offices, healthcare providers, clinics, and emergency departments U.S. Influenza Surveillance: Purpose and Methods | CDC.

e. Other National Public Health Priorities and Strategies

The National Notifiable Disease Surveillance System (NNDSS) is based on local and tribal disease surveillance systems that monitor, control, and prevent around 120 nationally notifiable diseases/conditions. (National Notifiable Diseases Surveillance System | CDC) The list of nationally notifiable diseases/conditions is determined by Counsel of State and Territorial Epidemiologists (CSTE) About CSTE | Council of State and Territorial Epidemiologists. Engagement with local health departments and tribal entities will enhance and modernize data and surveillance infrastructure to support national public health priorities. Data Modernization Initiative | CDC.

The Public Health Laboratory Interoperability Project (PHLIP) is a mechanism currently utilized by all state and some larger local public health laboratories to electronically report specimen level testing results to CDC for influenza and SARS-CoV-2. Some public health laboratories also report other viral pathogen test results using PHLIP. PHLIP one-pager (aphl.org)

FLU View is a weekly influenza surveillance report prepared by the Influenza Division at CDC and FluView Interactive is an online module that allows for deeper exploration of influenza surveillance data. Weekly U.S. Influenza Surveillance Report | CDC

COVID data tracker provides updates on the most recent and detailed data for hospitalizations, deaths, emergency department visits, and vaccinations. CDC COVID Data Tracker: Home

The National Respiratory and Enteric Virus Surveillance System (NREVSS) is a laboratory-based system that monitors the seasons trends and circulation patterns for a variety of viruses. National Respiratory and Enteric Virus Surveillance System | CDC

The Strategic Direction of Healthy and Safe Community Environments, as part of the National Prevention Strategy, strengthens surveillance and laboratory capacity, enhancing health departments' capacity to identify communities at greatest risk, detect infectious diseases, and respond to outbreaks. CDC - Healthy Places - National Prevention Strategy Report

CDC Project Description:

a. Problem Statement

A comprehensive plan for detecting, measuring, and reducing the impact of VPDs and respiratory diseases is critical. Various surveillance methods are used to collect public health data, depending on disease incidence, specificity of clinical presentation, available laboratory testing, control strategies, public health goals, and structure of vaccination program. Case reporting (data collection by jurisdictions) and notification (data submission to CDC) are dependent on many factors (National Notifiable Disease Surveillance System - case reporting and notification). Variations in reporting/notification may be due to differences in disease/condition characteristics (e.g., symptoms, incidence, severity), availability of laboratory diagnostics, patient/provider awareness, jurisdiction attributes (e.g., laws, regulations), disease transmission setting, and capacity for electronic data exchange (Manual for the Surveillance of Vaccine-Preventable Diseases). Interpretation of incomplete and untimely data for any of these reasons poses challenges for measuring disease burden and vaccine program impact. These challenges negatively impact decision making and public health action. Specific challenges within each of the activity areas are described below:

Surveillance Coordination for VPDs and Respiratory Viruses supports collection, assessment, and application of surveillance data to evaluate epidemiologic trends and inform public health action. However, NNDSS data has known limitations (e.g., missing data for key variables) and has not been sufficient to fully assess the impact of vaccine programs. Support for VPD surveillance coordination and respiratory virus surveillance coordination, in addition to support specifically for enhanced meningococcal disease, varicella, and AFM surveillance, will help address the problems in case reporting and notification.

Acute Flaccid Myelitis (AFM) is characterized by flaccid limb weakness and abnormalities of the spinal cord gray matter on magnetic resonance imaging (MRI) scan. Acute Flaccid Paralysis (AFP) has numerous etiologies including viruses, genetic conditions, and environmental toxins and can prove diagnostically challenging. Anterior horn cell disease, or AFM, is a subset of AFP, and is caused by poliovirus, West Nile virus, and other viruses including non-polio enteroviruses. CDC developed a passive laboratory-based surveillance system, the National Enterovirus Surveillance System (NESS), to track the epidemiology of enteroviruses and parechoviruses in the United States (National Enterovirus Surveillance System (NESS) | CDC). Since the widespread implementation of polio vaccination worldwide, AFM due to poliovirus has decreased substantially and had been eliminated in the United States, but not yet eradicated globally. AFM is not nationally notifiable, however, there is a standardized case definition and AFM may be reportable within specific recipient jurisdictions. Although surveillance for AFP is not routinely conducted in the United States,

surveillance for AFM is an important tool to help ensure that imported and indigenously acquired poliomyelitis cases are detected in the U.S. Interpreting any apparent increase in AFM had been challenging in the absence of baseline incidence of AFP (Acute Flaccid Myelitis in the United States, August-December 2014: Results of Nationwide Surveillance - PubMed (nih.gov)), but data accumulated since implementation of AFM surveillance in 2015 informed the national understanding of AFM epidemiology (National Surveillance for Acute Flaccid Myelitis — United States, 2018–2020 | MMWR (cdc.gov)). Additional information about investigations of AFM and guidance for clinicians and health departments can be found on the CDCs AFM webpage (Acute Flaccid Myelitis (AFM) | CDC).

Meningococcal Disease is a serious bacterial infection that can lead to severe long-term sequelae or death. Serogroups B, C, and Y are the major causes of meningococcal disease in the United States. Meningococcal conjugate vaccines protect against serogroups C and Y and are routinely recommended for adolescents. Serogroup B meningococcal vaccines have also recently been licensed in the United States. With the incidence of disease at historic lows, surveillance and vaccine program evaluations through established systems are challenging. High quality surveillance data and collection of circulating isolates from a broad and representative population are key for following disease trends, making vaccine program policy recommendations, and monitoring vaccine program impact. Recent outbreaks among special populations (e.g., college students, homeless, men who have sex with men (MSM)) reinforce the need for particular emphasis on high quality and complete surveillance data and *N. meningitidis* isolates.

Respiratory Virus Surveillance: Respiratory viruses cause a large burden of illness each year, including severe lower respiratory tract infections. Viruses of particular public health importance include influenza, SARS-coronavirus-2 (the virus that causes COVID), respiratory syncytial virus (RSV), human metapneumovirus, parainfluenza viruses, rhinoviruses, enteroviruses, coronaviruses, and adenoviruses, as well as re-emergent and novel viruses such as adenovirus type 14, Enterovirus-D68, Middle East Respiratory Syndrome coronavirus (MERS-CoV), and novel influenza A viruses. Identification of these viruses and appropriate public health response measures have been critical in mitigating their spread. For instance, surveillance for newly emerging viruses often requires ruling out common etiologies of severe pneumonia, and not all states currently have the capacity to detect some of the common respiratory viruses using the most sensitive molecular techniques. To track the epidemiology of these viruses on a national level, CDC uses several surveillance systems including: the National Respiratory and Enteric Virus Surveillance System (NREVSS), the National Adenovirus Type Reporting System (NATRS), U.S. WHO Collaborating Laboratories System, U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet), Pediatric Influenza A Mortality Reporting, RESP-LENS, and the National Vital Statistics System. These systems track the seasonality of virus activity, details about the specific viruses circulating and may help identify outbreaks across recipients' jurisdictions. Due to the disruption in typical circulation of most respiratory viruses during the pandemic, monitoring seasonal patterns more closely is warranted. CDC relies on health departments and laboratories with the capacity to test for these viruses to report results to these systems and to help CDC collect data from clinical, academic, and reference laboratories within their jurisdiction. Additional details regarding several common respiratory viruses are described below.

Influenza is an acute respiratory disease caused by infection with influenza viruses. Influenza types A and B viruses are responsible for epidemics of respiratory illness that occur almost every winter in temperate climates and are often associated with large numbers of illnesses, medically attended visits, hospitalizations and deaths. The timing, amount of illness, and age groups most affected can vary substantially from one

influenza season to the next, depending, in part, on the characteristics of the circulating influenza virus strains. Therefore, CDC maintains a multi-component surveillance system that collects information from multiple data sources in order to find out when and where influenza activity is occurring, track influenza-related illness, determine what influenza viruses are circulating, detect changes in influenza viruses, measure the impact influenza is having on hospitalizations and deaths and provide inputs to inform estimates of influenza burden (U.S. Influenza Surveillance: Purpose and Methods | CDC). CDC's Influenza Division continuously works to make improvements to each of the components of the U.S. Influenza Surveillance System and expand surveillance capacity to fill gaps including focusing efforts on enhancing the system to provide data needed to better quantify the contribution of influenza virus infection to respiratory virus activity, to identify the severity of illness associated with influenza viruses tested at public health laboratories (PHL), and to calculate rates of outpatient influenza like illness (ILI). In addition to maintaining the multi-component traditional national influenza surveillance system, there is a need for CDC and public health partners to implement and maintain a comprehensive plan for detecting, measuring, and reducing the impact of influenza.

RSV is a common respiratory virus that usually causes mild, cold-like symptoms; however, infants, older adults, and people with certain chronic conditions are at particular risk for severe outcomes due to RSV infection, and RSV is the most common cause of bronchiolitis and pneumonia in children under 1 year of age in the United States. There are several immunization products under development, or newly licensed, to prevent RSV infections, so it is increasingly important to have current baseline measures of severe morbidity and mortality associated with RSV to identify populations at risk and to monitor the success of public health treatments and interventions going forward (RSV (Respiratory Syncytial Virus) | CDC).

SARS-CoV-2 is the virus that caused the Coronavirus Disease 2019 (COVID) pandemic. Although COVID no longer poses the societal emergency that it did when it first emerged in late 2019, COVID remains an ongoing public health challenge. Despite the availability of vaccines and therapeutics, approximately 1,000 COVID-associated weekly deaths were reported in early April 2023. In addition, Post-COVID Conditions and Long COVID are contributing to long term health impacts and warrant improved clinical awareness and surveillance (Long COVID or Post-COVID Conditions | CDC). Monitoring the impact of COVID and the effectiveness of prevention and control strategies continues to be a public health priority during the transition from the emergency phase of the COVID response to routine public health practice. As part of this transition, CDC is stiving to establish COVID prevention goals within a sustainable and integrated surveillance strategy that monitors other circulating respiratory viruses and prevention measures, including vaccination, to provide timely and comprehensive situational awareness (Surveillance & Data Analytics (cdc.gov)).

Varicella (chickenpox) is a febrile rash illness from primary infection with the varicella-zoster virus (VZV). Varicella was added to the list of nationally notifiable conditions in 2003 and is reportable in 40 states as of 2021. In 2007, routine two-dose varicella vaccination was recommended for children, primarily in response to outbreaks of varicella in populations with high 1-dose coverage. Data from the first 5 years of the 2-dose varicella vaccination program demonstrated reductions in the number and size of outbreaks. Comparing surveillance data from 1995-1998 to 2016-2019 data shows outbreak duration and size have declined. Varicella outbreak surveillance supports assessment of vaccine program impact and informs public health interventions. Case-based surveillance is the only data source currently available to monitor trends in varicella incidence. Improving varicella surveillance by increasing reporting completeness for varicella specific clinical and epidemiologic variables of reported cases, including severe cases (e.g., hospitalizations), will allow

monitoring for the impact of the 2-dose varicella vaccine program and identify changes in varicella epidemiology.

b. Purpose

The purpose for providing resources for Vaccine Preventable Disease (VPD) and respiratory disease surveillance (including coordination) is to build and maintain capacity for detection, investigation and reporting of the relevant pathogens to inform prevention activities. Resources also enhance and strengthen case-based, laboratory-based, and outbreak surveillance for VPDs, respiratory viruses, and related conditions, allowing public health agencies to effectively collect and provide timely and complete surveillance data to inform public health action. The Enhanced VPD and Respiratory Virus Surveillance Program within the ELC Cooperative Agreement will provide funding and technical support and build on established epidemiology, laboratory, immunization, health information, and surveillance systems (e.g., NNDSS, NREVSS, ILINet) and capacities. In addition to VPD surveillance coordination, this section of the cooperative agreement will focus on respiratory virus surveillance and enhancing surveillance specifically for meningococcal disease, varicella, and acute flaccid myelitis. Recipients may also choose to participate in optional activities to further enhance VPD surveillance.

c. Outcomes

Outcomes for Required Tier 1 Activities (VPD) Surveillance Coordination, respiratory virus surveillance and coordination, enhanced surveillance for meningococcal disease, varicella, and AFM):

- Improved coordination and exchange of surveillance data and information across recipients'
- programs and partners
- Improved surveillance data quality and completeness (e.g., vaccine history, importation, sociodemographic data)
- Improved timeliness of case notifications (e.g., NNDSS, NREVSS, ILINet) and reporting (e.g., NREVSS, ILINet) to CDC
- Improved timeliness of detection, investigation, and response to cases, outbreaks, and deaths
- Increased support for and utilization of surveillance data assessments to inform public health practice
- Improved linkages between epidemiology, immunization, laboratory, and health information partners to support surveillance-related activities and resources
- Improved educational awareness through engagement with diverse groups of health care providers, community institutions, and other public health partners
- Enhanced support for laboratory testing as appropriate for monitoring, investigation, and control
- Enhanced standardization, harmonization, interoperability, and use of surveillance information systems by recipient and CDC
- Enhanced workforce (e.g., program management, epidemiology, laboratory, and informatics) to support surveillance activities and methods (e.g., virus detection, typing, and subtyping; VPD surveillance coordination)

Outcomes for Optional Tier 2 Activities:

Enhance surveillance for severe cases of varicella:

- Improved completeness of data collected for severe (e.g., hospitalized) cases of varicella (e.g., vaccination history, clinical presentation, reason for hospitalization) to monitor severe varicella disease during the mature varicella vaccination era

Enhance pertussis surveillance:

- Enhanced monitoring for molecular changes in pertussis through submission of isolates to CDC
- More complete and timely surveillance data (e.g., vaccination history, clinical presentation, laboratory results) to monitor the incidence and epidemiology of pertussis
- Increased notification of suspected pertussis-related deaths
- Collect isolates (and data, if available) for other *Bordetella* species associated with reported cases and submit to CDC

Enhance invasive *Haemophilus influenzae* disease surveillance:

- More complete and timely surveillance data to monitor the incidence and epidemiology of *H. influenzae*, with particular focus on children < 5 years of age
- Availability of isolates sent to CDC for *H. influenzae* serotyping

Enhance Invasive Pneumococcal Disease (IPD) surveillance:

- More complete and timely surveillance data to monitor the incidence and epidemiology of IPD to inform vaccine policy decisions
- Enhanced monitoring of changes in serotypes and antibiotic susceptibility in IPD through testing of appropriate sterile site isolates

Enhance invasive and non-invasive group A Streptococcus (GAS) surveillance:

- More complete and timely surveillance data to monitor the incidence and epidemiology of invasive, non-invasive GAS infections (e.g., pharyngitis, scarlet fever and skin infections) and their sequelae (e.g., acute rheumatic fever and acute post-streptococcal glomerulonephritis)
- Enhanced availability of representative sequence typing (emm type), whole genome sequencing and antibiotic susceptibility data through testing of appropriate sterile and non-sterile site isolates

Enhance measles surveillance:

- Surveillance data used to identify populations at risk
- Enhanced evidence-based interventions addressing the specific needs of populations at increased risk for measles cases and outbreaks

Enhance mumps surveillance:

- Surveillance data used to identify risk factors responsible for increased number of mumps cases and outbreaks
- Enhanced characterization of mumps cases (e.g., in high 2-dose vaccination coverage settings, in outbreak settings) through improved completeness of clinical, laboratory, and epidemiologic data
- Improved molecular surveillance for mumps

Enhance measles, mumps, rubella (MMR) case and community surveillance of vaccine uptake and coverage related factors:

- Enhanced recipient partnerships (e.g., epidemiology, immunization program, schools, Department of Education) to improve data describing factors impacting vaccine uptake and coverage
- Improved surveillance data and other resources to analyze and describe cases and community factors impacting MMR vaccine uptake and coverage
- Increased analyses of measles case surveillance and other related data to describe possible interventions to improve MMR uptake and coverage and to describe potential impact on public health
- Strengthen collaboration between jurisdictional and federal partners through participation in CDC held quarterly meetings by jurisdictional representatives from the immunization services and vaccine preventable diseases departments

Enhance AFM surveillance and follow-up of AFM cases:

- Increased recipient capacity to provide awareness for AFM among healthcare providers
- Increased number of recipients reporting AFM patients under investigation (PUIs) to CDC (NOTE: A suspected AFM case is considered a PUI when the patient summary form is received by CDC)
- Increased completeness and timeliness of surveillance data submitted and used to monitor AFM PUIs and cases
- Increased timeliness of laboratory specimens sent to CDC laboratories for etiologic testing
- Improved data describing AFM outcomes through follow-up of confirmed and probable cases
- Increased recipient capacity for typing enteroviruses and reporting to CDC through the National Enterovirus Surveillance System (NESS)

Enhance MIS-C (Multisystem Inflammatory Syndrome in Children) surveillance:

- Increased recipient capacity to provide awareness of and technical assistance for MIS-C through communications and partnerships
- Increased completeness and timeliness of surveillance data submitted and used to monitor cases
- Increased syndromic surveillance data to inform epidemiologic and programmatic decisions related to MIS-C surveillance practice
- Increased implementation of technical improvements that modernize surveillance activities and improve data completeness, quality, and timeliness of case notification to CDC

Enhance collection and use of Industry and Occupation (I/O) surveillance data:

- Increase awareness regarding the importance of collecting I/O data for VPDs and respiratory diseases
- Improve completeness and timeliness of surveillance data collected, submitted, and used to monitor VPDs and respiratory diseases
- Improve surveillance data analysis to inform possible clustering of VPDs and respiratory diseases in and across workplaces

Enhance respiratory virus surveillance (including, but not limited to influenza, RSV, and SARS-CoV-2):

- Improve disease burden estimation and provide a fuller picture of respiratory virus impact across illness severity
- Determine the proportion of acute respiratory illness that is due to infection with a specific respiratory virus
- Identify the severity of illness associated with influenza and SARS-CoV-2 viruses tested at the public health laboratory
- Estimate population-based rates of outpatient acute respiratory illness
- Improve health department laboratory capacity to detect respiratory viruses such as human metapneumovirus, parainfluenza viruses, rhinoviruses, enteroviruses, coronaviruses, and adenoviruses.

Enhance awareness and coordination of post-COVID conditions (PCC):

- Increase recipient engagement to expand awareness of PCC and surveillance activities including increasing engagement with providers.
- Identify areas of surveillance for PCC and assess completeness and timeliness of approach to inform other activities.
- Review and apply surveillance data to inform epidemiologic and programmatic decisions related to PCC surveillance practice.

Enhance surveillance for other VPDs, respiratory diseases, and related conditions:

- If optional activities for other VPDs, respiratory diseases, and related conditions are proposed, outcomes should be defined in collaboration with CDC programs to improve surveillance and public health response

Enhance capacity for Legionnaires' disease (LD) surveillance, outbreak response, testing, reporting, and prevention:

- Improve timeliness, completeness of LD case interviews, and number of LD cases reported with exposure information
- More rapid detection of clusters and outbreaks
- More timely, efficient, and coordinated outbreak investigation, response, and control measure implementation
- Improved coordination across public health teams and jurisdictions for outbreak response
- Improved communication with persons and communities at increased risk for LD
- Ensure trained public health workforce to better respond to LD cases and outbreaks

Funding Strategy:

Tier 1 funds should be used for personnel such as VPD Surveillance Coordinator, influenza surveillance coordinator, epidemiologist(s), laboratorian(s), respiratory virus laboratory reagents and supplies, and storage/shipping of specimens and isolates.

The total funded amount for Tier 1 activities per award is expected to include funding for approximately one full-time person specified as the VPD Surveillance Coordinator for the recipient. Funding will also prioritize personnel needed to address other Tier 1 disease-specific activities (i.e., meningococcal disease, varicella, and AFM). In addition, funding is expected to support a minimum of 0.5 FTE personnel to conduct influenza surveillance and a minimum of 0.5 FTE personnel to conduct influenza diagnostic testing. These positions serve as the CDC point of contact for influenza surveillance and laboratory diagnostics, respectively. If available, respiratory virus funds will also support the purchase of laboratory supplies and reagents needed for influenza surveillance and not provided through the International Reagent Resource (IRR), activities related to determining and achieving the optimal volume of influenza laboratory testing for surveillance purposes (e.g., shipping supplies and transport costs) as outlined in the CDC-Association of Public Health Laboratories (APHL) Influenza Virologic Surveillance Right Size Road Map, and other activities related to respiratory virus surveillance.

Total availability of funds for *Program I: Name*: $16.7 million

- Approximate number of awards: 60
- Approximate average per award: $277,500

For Tier 2 Legionnaires' disease (LD) activities: Core Capacity, Enhanced Capacity, and Centers of Excellence

LD activities are divided into three categories: LD Core Capacity, LD Enhanced Capacity, and LD Center of Excellence (CoE). LD Core Capacity activities cover core capacity for LD epidemiology and laboratory activities. LD Enhanced Capacity activities cover enhanced capacity-building for specific components of LD prevention,

surveillance, investigation, testing, and/or outbreak response. LD CoE activities cover the new LD CoE to be established in the first budget period of this cooperative agreement (pending availability of funds).

Applicants for LD Enhanced Capacity and/or LD CoE activity funding do not also need to apply for LD Core Capacity activity funding. However, all LD Core Capacity required activities must be addressed through existing capacity or proposed LD Core Capacity workplans before applying for activities under LD Enhanced Capacity or LD CoE.

Funding may support personnel, laboratory or office supplies, training and communications materials, specimen storage and shipping costs, environmental sample collection and shipping costs, travel for educational or outbreak response purposes, conference attendance, and other resources needed for capacity building and/or an effective response to a situation involving LD or the implementation of *Legionella* control strategies. While future year funding is not guaranteed, whenever possible, Core Capacity activities will be supported for the full Notice of Finding Opportunity (NOFO) period.

Due to changes in the structure and scope of the ELC Legionnaires' disease work, environmental health-focused activities and projects will be de-prioritized and are unlikely to receive funding under this cooperative agreement. Other CDC funding opportunities such as the Strengthening Environmental Health Capacity (EHC) cooperative agreement may be able to provide support for water-related environmental health work.

Core Capacity awards will be prioritized according to demonstrated need to address gaps in core capacity. Please note that some activities related to laboratory core capacity are listed in Enhanced Capacity. Placement in Enhanced Capacity ensures that recipients can apply for laboratory funding without submitting workplans for LD Core Capacity activities, although LD Core Capacity requirements must be met by the recipient.

If available, funding for LD Enhanced Capacity proposals will be prioritized for recipients that are able to complete activities within a single budget period. It is desirable that activities have potential for public health impact beyond recipient's jurisdiction.

One LD Center of Excellence (CoE) will be funded to support public health professionals in other jurisdictions that conduct surveillance, investigate, test, and promote primary prevention of LD cases and outbreaks. The LD CoE must partner with at least one academic institution.

A substantial portion of the CoE budget should be allocated to support academic and public health collaboration for LD activities. Detailed justifications must be included in the budget that clearly describe how funds will be spent including a breakdown by salary, travel, supplies, etc. Budgets should be clear that no ELC funds are requested to support research activities; recipients are responsible for ensuring that their partners do not use ELC funds for research purposes. LD CoE activities are required to have public health impact beyond the recipient's jurisdiction and should result in capacity to support a variety of recipients nationwide.

Funding estimates for Tier 2 Legionnaires' Disease activities

- Total: $1.5M–2.5M
- Approximate number of awards:
    - Core Capacity: 8–10
    - Enhanced Capacity: 1–5
    - Center of Excellence: 1

- Approximate average per award:
  - Core: $50,000–$200,000
  - Enhanced: $50,000–$250,000
  - CoE: $200,000–$400,000

***Please note:**

1. For State Health Departments (SHDs), when entering budget requests, recipients must use the 'Public Health Allocation' to indicate the portion of financial support going toward 'Local/Regional Health Department (LHD)' support versus staying at the SHD level. This allocation data helps ELC answer inquiries regarding the financial support to LHDs which is crucial given the important role LHDs have in addressing infectious diseases.
2. For Local Health Departments (LHDs, when entering budget requests, please ensure the 'Public Health Allocation' is set to 100% 'Local/Regional Health Department (LHD support.
3. For Territorial Health Departments, if you have local/regional jurisdictions, please follow the instructions for State Health Departments in #1.

Required Tasks:

Acceptance of funding conveys acknowledgement and indication that the following requirements will be met for the program activities. Related strategy/activity noted in parentheses after Required Task.

1. Notify of staff changes for Vaccine Preventable Disease (VPD) surveillance coordinator and influenza surveillance coordinator positions (Strategy 1)
2. Participate on quarterly All-Jurisdiction VPD Surveillance Calls and other Tier 1-specific calls (Strategy 1)
3. Submit Tier 1 activity summaries, reports, and/or other requirements (Strategy 1)

For Tier 2 **influenza related activities** the following tasks are required if applicant is awarded funding:

1. Collect specimens from patients with viral respiratory illness seen in an outpatient or emergency department setting regardless of clinical suspicion for a particular pathogen. Test specimens at the PHL using an influenza/SC2 multiplex assay or, at the discretion of the health department, a broader respiratory virus panel, and transmit specimen level results to CDC via PHLIP indicating that the specimen was collected as part of this activity.
2. Enhance virologic surveillance by reporting level of care (inpatient or outpatient) for patients with specimens tested for influenza at the public health lab (PHL)and transmitting specimen-level data containing this information to CDC via Public Health Laboratory Interoperability Project (PHLIP).
3. Enhance ILINet surveillance by recruiting ILINet providers that will, in addition to reporting influenza-like illness (ILI) patient visits to ILINet, estimate the population served annually.

For Tier 2 **Legionnaires' disease (LD) related activities** the following tasks are required if applicant is awarded funding:

All Tier 2 Legionnaires' disease funding recipients (Strategy 8, Activities r–t)

1. Report all legionellosis cases to the Supplemental Legionnaires' Disease Surveillance System (SLDSS) [N/A for local public health jurisdictions]
2. Report all outbreaks to the National Outbreak Reporting System
3. Submit LD outbreak response protocol to CDC Legionella Program Team
4. Share available communication materials with the LD Center of Excellence (CoE)
5. Participate in Technical Advisor and group calls scheduled throughout the budget period
6. Applicant key staff must travel to meetings and/or conferences as deemed necessary by CDC, where applicant may use cooperative agreement funding for travel
7. Review case and outbreak data to identify jurisdiction-specific inequities
8. Report the number of legionellosis outbreaks or clusters detected that meet the National Outbreak Reporting System (NORS) reporting criteria (2 or more cases associated with the same facility or device within 12 months) for calendar year 2024
9. Report the number of legionellosis outbreaks/clusters/single cases meeting CDC criteria for a full investigation for calendar year 2024
10. Report the number of confirmed and suspect legionellosis cases for which case or proxy interviews were conducted for exposure history for calendar year 2024

Legionnaires' disease (LD) Enhanced Capacity (Strategy 8, Activity s):

11. Complete, sign, and return Non-Disclosure Agreements (NDA), Rules of Behavior (RoB), and other documents, as required.
12. Collaborate with the LD Center of Excellence (CoE)
13. Present funded activities during group call(s)

Legionnaires' disease (LD) Center of Excellence (CoE) (Strategy 8, Activity t):

14. Identify one or more points of contact as LD CoE coordinators
15. Complete, sign, and return Non-Disclosure Agreement (NDA), Rules of Behavior (RoB), and other documents, as required.
16. Present funded activities during group call(s)
17. Collaborate with LD Enhanced Capacity participants regarding activities and dissemination of findings
18. Participate in annual vision meeting and other meetings, as requested.

Strategies and Activities:

Applicants must address the five **required** Tier 1 activity areas for this project in their applications:

1. Coordinate NNDSS surveillance for Vaccine Preventable Diseases (VPD), respiratory diseases, and related conditions (Strategies 1, 2, 3, 4, 5, 6, 7, 9, 10)
2. Support respiratory virus surveillance and coordination (Strategies 1, 2, 3, 4, 5, 6, 9)
3. Enhance surveillance for meningococcal disease (Strategies 1, 2, 3, 4, 5, 6, 10)
4. Enhance surveillance for varicella (Strategies 1, 2, 4, 5, 6, 10)
5. Support/establish surveillance for AFM (Strategies 1, 2, 4, 5, 10)

In addition to the required Tier 1 outcomes and strategies/activities listed above, applicants may select one or more additional pathogen-specific activities from those listed below as OPTIONAL. Applicants may select from among the optional Tier 2 activities (Strategy 8) that a) expand and enhance current surveillance infrastructure based on the priorities and public health needs of their jurisdiction, and b) will make progress toward the outcomes defined in the "Outcomes" section of this guidance.

Area A: Surveillance, Detection, and Response

1) Enhance and coordinate investigation and outbreak response

a) Maintain VPD surveillance coordinator(s) & influenza surveillance coordinator.

i) VPD surveillance coordinator will support surveillance for VPDs, respiratory diseases, and related conditions, including, but not limited to, measles, mumps, rubella, congenital rubella syndrome, varicella, pertussis, *H. influenzae*, meningococcal disease, tetanus, diphtheria, invasive pneumococcal disease (IPD), paralytic poliomyelitis, non-paralytic poliovirus infection, acute flaccid myelitis (AFM), and congenital cytomegalovirus (cCMV) and will serve as the point(s) of contact for this work within ELC Program I.

ii) Influenza surveillance coordinator will support surveillance for influenza and may, depending on the jurisdiction and/or funding availability, support surveillance for a wider array of respiratory viruses, including, but not limited to, respiratory syncytial virus (RSV), and COVID and will serve as the point of contact for this work within ELC Program I.

Ensure the use and implementation of standard investigative questionnaires, data collection/sharing tools, (e.g., *VPD Surveillance Manual* worksheets, influenza-associated pediatric death, novel influenza A case report forms), and methods.

Lead/assist in the timely investigations of and data submission for cases, clusters, and outbreaks.

Support high quality data to measure, monitor, and analyze health impact and equity.

☒ Required ☐ Optional

b) Collect case data on key and enhanced variables, as described in CDC guidance

☒ Required ☐ Optional

c) Provide surveillance data for evaluation of response to meningococcal disease

i) As appropriate, collect data regarding risk factors for meningococcal disease, serogroup B meningococcal vaccine effectiveness, retrospective record review to identify cases among the same household.

☒ Required ☐ Optional

d) Ensure reporting sources apply recipient requirements for varicella outbreaks

i) For jurisdictions where varicella is not a reportable condition, but outbreaks of all etiologies are reportable, processes should be put into place to facilitate reporting of varicella outbreaks.

☒ Required ☐ Optional

e) Participate in outbreak investigations of respiratory viruses and VPDs

☒ Required ☐ Optional

2) Improve surveillance and reporting

a) Develop, implement, and maintain surveillance systems.

i) For VPDs and respiratory diseases, apply recommendations found in the *Manual for the Surveillance of Vaccine-Preventable Diseases,* the Council for State and Territorial Epidemiologists (CSTE), the Association for Public Health Laboratories (APHL), and additional CDC guidance documents.

ii) For influenza and, if feasible, other respiratory viruses, such as but not limited to SC2 and RSV, develop, implement, and maintain the components of the U.S. surveillance systems by recruiting, retaining, and encouraging timely reporting from laboratories, health care providers, and other data providers.

☒ Required ☐ Optional

b) Evaluate and enhance surveillance systems based on CDC guidelines.

i) For VPDs and respiratory diseases, apply recommendations found in the *Manual for the Surveillance of Vaccine-Preventable Diseases* and additional CDC guidance documents.

ii) Maintain the number of providers (e.g., laboratories, physicians) reporting results and other surveillance data

☒ Required ☐ Optional

c) *Improve completeness, timeliness, and quality of data submitted to CDC.*

i. Conduct regular assessment of surveillance data and implement enhanced processes.

ii. Review surveillance indicator reports at least annually (e.g., provisional, final) to identify areas for improvement (e.g., electronic, programmatic).

iii. Review surveillance data regularly (e.g., weekly, quarterly) to identify areas for improvement (e.g., electronic, programmatic).

iv. For meningococcal disease: check immunization information system (IIS) for vaccination information for cases; check HIV registry for HIV status for cases (if feasible in accordance with recipient policies and procedures), check previous sexually transmitted infections (STI) investigations for MSM status, follow-up with providers and/or parents regarding clinical presentation.

v. For varicella cases in jurisdictions where varicella is a reportable condition: check IIS for vaccination information for cases, check databases for varicella-related

hospitalizations, follow-up with providers and/or parents regarding clinical presentation.

vi. For influenza surveillance, identify and maintain an influenza surveillance coordinator to facilitate the improvement of influenza surveillance as recommended by CSTE and CDC. Collect, analyze, and disseminate influenza surveillance data weekly. Depending on the recipient jurisdictions and/or funding availability, this individual or a similar individual within the recipient jurisdictions will provide similar activities for other respiratory viruses including, but not limited to SC2 and RSV.

☒ Required ☐ Optional

d) Enhance and facilitate coordination/exchange of surveillance data with CDC.

i) For meningococcal disease, support collection of enhanced variables for confirmed and probable meningococcal disease cases and provide case notifications and other surveillance data reports to CDC with complete information.

ii) For varicella, enhance cluster and outbreak-related case data and submit to CDC quarterly, including the number of varicella clusters and outbreaks reported to the jurisdiction.

iii) In recipient jurisdictions where varicella is a reportable condition and varicella case-based surveillance is in progress, enhance established case notification processes for submitting case-based varicella data to CDC.

iv) In recipient jurisdictions where varicella is a reportable condition and varicella case-based surveillance is in progress, enhance varicella-related variables collected, the data completeness for those variables, and provide annual summaries to CDC.

v) In recipient jurisdictions where AFM cases are reported to the local/state health department and specimens are submitted, enhance surveillance for AFM and notify/report to CDC suspect cases (https://www.cdc.gov/acute-flaccid-myelitis/index.html).

vi) Investigate deaths associated with VPDs and respiratory virus infection among children and adults, as outlined in CDC guidance (e.g., influenza-associated pediatric deaths).

☒ Required ☐ Optional

3) Enhance laboratory testing for surveillance and reporting

a) Support availability of appropriate surveillance testing capacity

i) For each disease/condition, support testing (e.g., culture, serotyping/serogrouping, molecular sequencing, real-time RT-PCR) within recipient jurisdictions public health laboratories and/or VPD Reference Centers (RCs).

ii) Submit specimens to CDC or associated reference laboratory for additional characterization as requested in CDC guidance .

☒ Required ☐ Optional

b) Use modern techniques for influenza virus testing

i) *For influenza, utilize typing and subtyping/lineage testing, including detection of novel influenza viruses, year-round.*

☒ Required ☐ Optional

c) Implement flexible plan for acquisition of laboratory supplies and testing

i) For VPDs and respiratory diseases, apply recommendations found in the Manual for the Surveillance of Vaccine-Preventable Diseases and additional CDC guidance documents, to address changing needs/purposes for each disease/condition.

ii) For influenza surveillance, identify and maintain personnel proficient in using modern techniques for diagnostic testing (e.g., PCR methods for influenza virus detection, typing, and subtyping). Depending on the recipient and/or funding availability, this individual or a similar individual within the jurisdiction will provide similar activities for other respiratory viruses including, but not limited to SC2 and RSV.

☒ Required ☐ Optional

4) Collect isolates from meningococcal **disease** cases

i) For meningococcal disease, collect isolates from confirmed and probable cases and test for serogroup and additional molecular characterization.

☒ Required ☐ Optional

5) Improve laboratory coordination and outreach to increase efficiency

a) Support linkage of laboratory data with epidemiologic and clinical case data

ii) For VPDs and respiratory diseases apply recommendations found in the Manual for the Surveillance of Vaccine-Preventable Diseases and additional CDC guidance documents, including linkage of laboratory specimens, isolates, and results with other data.

iii) For influenza surveillance, assess, and if necessary, improve capacity for achieving the guidance and goals within the Influenza Virologic Surveillance Right Size Roadmap by evaluating and updating implementation plans to achieve the objectives.

☒ Required ☐ Optional

b) Coordinate activities to increase access to specimens and isolates

i) Ensure that laboratory data are available to inform surveillance activities.

☒ Required ☐ Optional

6) Enhance epi-lab-HIT (Health Information Technology) partner coordination

a) Implement and maintain electronic data

i) Collaborate with CDC for electronic data transfers from public health laboratories to CDC, including laboratory results, epidemiologic data, and clinical data.

b) Support and integrate epidemiology, laboratory, immunization, and HIT

ii) Foster collaboration between epidemiology and laboratory functions of state and local level VPD program, respiratory virus surveillance programs, immunization programs, and other public health programs (e.g., STI) to facilitate collection of key and enhanced variables for confirmed and probable meningococcal disease cases.

iii) Ensure coordination between partners (e.g., immunization, epidemiology, health information) to facilitate access to Immunization Information System (IIS) data for immunization history of VPDs (i.e., meningococcal disease, varicella, AFM) in accordance with guidance in the Manual for the Surveillance of Vaccine-Preventable Diseases, the Council for State and Territorial Epidemiologists (CSTE), the Association for Public Health Laboratories (APHL), and additional CDC guidance documents.

iv) Link and use traditional and non-traditional data sources to measure, monitor, and analyze health impact and equity.

v) Ensure coordination between epidemiology and public health laboratory functions to support the exchange of public health information between jurisdictions and CDC, including but not limited to transmitting specimen level data to CDC for influenza and SC2 each week via the Public Health Laboratory Interoperability Project (PHLIP) and maintaining timely reporting (e.g., weekly reporting of influenza testing results by U.S. World Health Organization (WHO) collaborating laboratories).

vi) Enhance collaboration and relationship-building among city, county, state, territorial, federal partners, and other external partners (e.g., CSTE, APHL).

☒ Required ☐ Optional

7) Improve and/or sustain enhanced information systems

a) Coordinate epidemiology, lab, immunization, and health information systems

i) Enhance surveillance for VPDs, respiratory diseases, and related conditions through coordination (e.g., NNDSS, IIS, electronic lab reports (ELR), electronic case reports (eCR), Health Level 7 (HL7) messages) to enhance use and exchange of electronic data files

ii) Advance meaningful public health use of electronic health records, including exploring the availability and utility of existing sources of electronic morbidity and mortality data (e.g., influenza hospitalization data).

☒ Required ☐ Optional

8) Enhance data available for public health action

a) Support collection, use, and reporting of actionable data.

i) Ensure collection of complete sociodemographic data (e.g., race and ethnicity, location/residence, industry and occupation) to advance health equity.

☒ Required ☐ Optional

9) Engage in targeted optional surveillance activities

a) Enhance surveillance for severe cases of varicella

i) Improve completeness of data collected for severe (e.g., hospitalized) cases of varicella, including reason for hospitalization, clinical presentation, vaccine history, and other epidemiologically relevant data elements, in sites where varicella is reportable and case-based surveillance is conducted.

ii) Submit hospitalization data to CDC annually.

☐ Required ☒ Optional

b) Enhance pertussis surveillance

i) Collect complete data on key and enhanced variables (e.g., clinical course of infection, vaccination history, maternal Tdap history for infant cases aged <1 year, laboratory testing) for cases of pertussis.

ii) Notify CDC of suspected pertussis-related deaths via e-mail for non-reportable cases or via NNDSS for cases meeting the public health case definition for nationally notifiable conditions.

iii) Collect isolates of Bordetella pertussis, when available, and routinely ship to CDC for further laboratory characterization (NOTE: if the optional pertussis activity is proposed, the plan must include collection and shipment of isolates to CDC).

iv) Utilize IIS to obtain/verify pertussis vaccination history.

v) Collect isolates of other Bordetella species, when available, and ship to CDC for further laboratory characterization. When isolates are available to be shipped, also provide data for key variables (e.g., clinical course of infection, pertussis vaccination history, laboratory testing).

☐ Required ☒ Optional

c) Enhance invasive H. influenzae disease surveillance

i) Collect complete data on key and enhanced variables (e.g., serotype, outcome) for cases of H. influenzae.

ii) Enhance existing surveillance systems and submit *H. influenzae* case data to CDC.

iii) Collect isolates from cases of *H. influenzae* for serotype confirmation.

☐ Required ☒ Optional

d) Enhance IPD surveillance

i) Establish/support surveillance for IPD (e.g., all ages, among children <5 years of age) and submit case data to CDC.

ii) Collect complete data on key and enhanced demographic and clinical variables (e.g., date of birth, sex, race, ethnicity, underlying medial conditions, risk factors) and pneumococcal vaccination history (e.g., vaccination status, dates of vaccine

administration, vaccine product) for cases of IPD (e.g., all ages, among children <5 years of ages).

iii) Evaluate completeness of case ascertainment.

iv) Identify laboratories capable of isolating Streptococcus pneumoniae within the jurisdiction.

v) Collect sterile-site isolates of *S. pneumoniae* from all children <5 years old (or all ages if feasible) and submit isolates to CDC's Streptococcus Laboratory or VPD Reference Centers (e.g., Minnesota Department of Health, Wisconsin Department of Health) for serotyping and antimicrobial resistance testing.

vi) Implement surveillance among targeted at-risk populations; however, if this activity is proposed, planning should be done in collaboration with CDC.

☐ Required ☒ Optional

e) Enhance invasive and non-invasive group A Streptococcus (GAS) surveillance

i) Establish/Enhance surveillance for GAS and submit case data to CDC.

ii) Collect complete data on key and enhanced variables (e.g., age, race, ethnicity, underlying health conditions risk factors, place of residence, clinical outcomes, post-infection sequelae) for cases of GAS.

iii) Evaluate completeness of case ascertainment.

iv) Identify laboratories capable of isolating GAS and/or whole genome sequencing within the jurisdiction.

v) Collect specimens for molecular surveillance and antimicrobial resistance testing and submit in accordance with CDC guidelines.

vi) Implement surveillance among targeted at-risk populations; however, if this activity is proposed, planning should be done in collaboration with CDC.

vii) Use epidemiologic (including molecular epidemiology) and surveillance data to: 1) describe frequency, extent, and impact of GAS outbreaks, 2) design appropriate interventions and outbreak resources, 3) assess impact of these interventions (e.g., antibiotic treatment and prophylaxis, contact screening, enhanced infection prevention and control measures), and 4) identify risk factors responsible for increased number of GAS cases and outbreaks.

☐ Required ☒ Optional

f) Enhance measles surveillance

i) Collect complete data for key and enhanced variables (e.g., number of contacts, rates of transmission) for all cases of measles.

ii) Use epidemiologic and surveillance data to: 1) describe impact of measles outbreaks, 2) plan for appropriate interventions for prevention and control, and 3) describe impact of those interventions (e.g., isolation, quarantine, post-exposure prophylaxis, infection control).

☐ Required ☒ Optional

g) Enhance mumps surveillance

i) Collect and submit complete data on key and enhanced variables (e.g., symptoms, complications, vaccination, outbreak information, transmission setting, laboratory results) for cases of mumps.

ii) Use epidemiologic and surveillance data to 1) describe impact of mumps outbreaks, 2) plan for appropriate interventions, 3) describe impact of those interventions (e.g., isolation, quarantine, prevention, and outbreak control measures), and 4) identify risk factors responsible for increased number of mumps cases and outbreaks.

iii) Describe mumps outbreaks, establish mumps outbreak resources, and provide input regarding existing or new communication and outbreak response resources.

iv) Collect specimens for molecular surveillance and submit for testing in accordance with CDC guidelines, to better capture circulating genotypes of mumps virus and outbreak strains.

☐ Required ☒ Optional

h) Enhance MMR case/ community surveillance of vaccine uptake and coverage

i) Enhance recipient partnerships (e.g., epidemiology, immunization program, schools, Department of Education) to improve data describing factors impacting vaccine uptake and coverage.

ii) Improve surveillance data and other resources to analyze and describe cases and community factors related to *measles, mumps, rubella* (MMR) vaccine uptake and coverage.

iii) Analyze measles case surveillance and other related data to describe possible interventions to improve MMR uptake and coverage and to describe potential impacts on public health.

☐ Required ☒ Optional

i) Enhance AFM surveillance

i) Ensure timely and appropriate collaborations with pediatric hospitals and tertiary referral centers to enhance AFM awareness, data completeness, case reporting, and laboratory testing.

ii) Establish and maintain processes to reduce the interval between symptom onset and clinical specimen collection.

iii) Establish and maintain processes to improve the timeliness between symptom onset and submission of AFM case report form to the CDC.

iv) Establish and maintain processes to ensure complete information about the acute phase of illness (e.g., history and physical notes, infectious disease and neurology consult notes, follow-up neurology consult notes, MRI reports, laboratory test results, vaccination registry data, and discharge summary) for confirmed and probable AFM cases are collected and submitted to CDC within 60 days after onset of limb weakness.

v) Establish or maintain laboratory capacity to perform typing for enterovirus positive specimens.

vi) Report appropriate type-specific enterovirus results from public health laboratories to CDC via the National Enterovirus Surveillance System (NESS).

☐ Required ☒ Optional

j) Enhance long-term follow-up for AFM cases

i) Establish and maintain processes to improve timeliness for collecting information about long-term clinical outcome data for all AFM persons under investigation (PUIs) at, or as close as possible to, 60 days after initial onset of limb weakness.

ii) Ensure long-term clinical outcome data are complete and submitted to CDC in a timely manner (e.g., as close to 60 days after initial onset of limb weakness) for all AFM PUIs.

☐ Required ☒ Optional

k) Address emerging AFM issues

i) Engage health care providers (e.g., neurologists) to conduct hospital-specific outreach with their infectious diseases, pediatric primary care clinicians, and ER/emergency care practitioners (e.g., using CDC educational materials).

ii) Conduct enhanced surveillance at tertiary care hospitals or pediatric centers in the area by connecting with neurology, infectious diseases, or hospital infection prevention/control specialists to conduct weekly searches for possible patients with AFM-active surveillance.

iii) Ensure that AFP and AFM are included in syndromic surveillance projects with state-based hospital information systems, to improve data describing the burden of disease for both entities.

iv) Conduct wastewater testing for EV-D68 and other non-polio enteroviruses to help provide a possible early warning signal for increases in these viruses and AFM. Ensure that wastewater testing is coupled with clinical surveillance to better understand circulation.

☐ Required ☒ Optional

l) Enhance MIS-C surveillance

i) Engage clinicians who care for children with MIS-C, including pediatric critical care specialists, pediatric hospitalists, pediatric infectious disease specialists, pediatric rheumatologists, and pediatric cardiologists to conduct searches for possible MIS-C patients.

ii) Conduct active surveillance at select tertiary care hospitals and/or pediatric centers to identify possible patients with MIS-C, and strengthen collaborations between health departments and hospital infection prevention/reporting clinicians.

iii) Ensure review and application of syndromic surveillance data to inform epidemiologic and programmatic decisions related to MIS-C surveillance practice.

iv) Implement technical improvements to modernize surveillance activities (e.g., enhance electronic information exchange, train staff to use interactive dashboards).

☐ Required ☒ Optional

m) Enhance collection and use of Industry and Occupation (I/O) surveillance data

i) Engage public health practitioners and others regarding the importance of I/O data collection for VPDs and respiratory diseases.

ii) Conduct I/O surveillance to improve completeness and timeliness of data collected, submitted, and used to monitor VPDs and respiratory diseases.

iii) Ensure review, analysis, and application of surveillance data to monitor for clustering of VPDs and respiratory diseases in and across workplaces.

☐ Required ☒ Optional

n) Enhance influenza, COVID, RSV, & respiratory virus surveillance and reporting

i) Collect specimens from patients with viral respiratory illness seen in an outpatient or emergency department setting regardless of clinical suspicion for a particular pathogen. Test specimens at the PHL using an influenza/SC2 multiplex assay or, at the discretion of the health department, a broader respiratory virus panel, and transmit specimen level results to CDC via PHLIP indicating that the specimen was collected as part of this activity.

ii) Enhance virologic surveillance by reporting level of care (inpatient or outpatient) for patients with specimens tested for influenza, and if possible other respiratory viruses, at the PHL and transmitting specimen level data containing this information to CDC via PHLIP.

iii) Enhance ILINet surveillance by recruiting ILINet providers that will, in addition to reporting ILI patient visits to ILINet, estimate the population served annually.

iv) Report laboratory test data to NREVSS on behalf of clinical, reference, or academic laboratories within one's jurisdiction using the pass-through report feature.

v) Expand and enhance diagnostic testing and genotyping for non-influenza respiratory viruses in eligible ELC public health state and local laboratories.

vi) Expand and enhance investigations of deaths associated with RSV and COVID among children and adolescents less than eighteen years of age.

vii) Expand and enhance type-specific respiratory virus results from public health laboratories to CDC via the National Adenovirus Type Reporting System (NATRS).

☐ Required ☒ Optional

o) Enhance post-COVID conditions (PCC) surveillance

i) Increase engagement of clinicians who care for children and adults with long-COVID or PCC, including critical care specialist, hospitalists, infectious disease specialists, rheumatologists, and cardiologists.

ii) Identify areas of surveillance for PCC across a variety of health care settings, primary care clinicians, clinical specialists, rehabilitation clinics, or tertiary care hospitals to identify surveillance methods and approaches.

iii) Implement, review, and apply surveillance data to inform epidemiologic and programmatic decisions related to PCC surveillance practice.

☐ Required ☒ Optional

p) Enhance congenital cytomegalovirus (cCMV) surveillance

i) Conduct jurisdiction-wide or sentinel surveillance to identify infants with cCMV infection and/or disease (see CSTE standardized case definition).

ii) Enhance completeness and timeliness of cCMV surveillance data collected (e.g., birth outcomes and clinical signs, long-term outcomes, maternal information, laboratory records) to adequately assess the burden of cCMV infection and/or disease and inform potential strategies to prevent or reduce cCMV-associated disabilities.

iii) Engage in multi-sector collaborations and communications, with healthcare professionals (e.g., neonatologists, pediatric critical care specialists, pediatric hospitalists, pediatric infectious disease specialists, speech language pathologists, audiologists), public health partners (e.g., infectious disease, maternal and child health, and birth defects), and systems (e.g., CDC SET-NET) to support case ascertainment and data collection for cCMV surveillance.

iv) Inform prevention and intervention through analysis and dissemination of cCMV surveillance data to general public, families and people of childbearing age, health communicators, and healthcare providers.

☐ Required ☒ Optional

q) Enhance surveillance for VPDs, respiratory diseases, and related conditions

i) If Tier 2 activities for other VPDs, respiratory diseases, and related conditions are proposed, activities should be defined in collaboration with CDC programs to improve surveillance and public health response.

☐ Required ☒ Optional

r) Enhance Legionnaires' disease (LD) Core Capacity

(Note: if applying for LD Core Capacity, workplans should include all sub-activities).

i) Develop and maintain an LD investigative team involving epidemiology, environmental health, and laboratory staff to support case surveillance, outbreak response, testing, reporting, and prevention.

ii) Develop and implement a comprehensive, multi-disciplinary LD outbreak response protocol (If applicant has previously developed an LD outbreak response protocol, applicant should describe ongoing plans to implement and review their protocol).

iii) Establish an LD Laboratory Response plan to identify pathways and resources to test clinical and environmental samples (If applicant has previously developed an LD laboratory response plan, applicant should describe ongoing plans to review and update their protocol).

iv) Attempt to interview all confirmed and suspect legionellosis cases to obtain exposure information (e.g., using a form like the Supplemental Legionnaires Disease Surveillance System (SLDSS) Core Case Report Form or the SLDSS Extended Case Report Form).

v) Collect and report case information, if feasible, according to the SLDSS Extended Case Report Form if not already implemented.

vi) Submit legionellosis case information to SLDSS, if feasible, by data extract if not already implemented.

vii) Collaborate with hospital and clinical laboratory systems to encourage testing of lower respiratory specimens for Legionella.

viii) Develop and distribute communication materials regarding programmatic activities to relevant audiences, including at least one community at increased risk for LD (e.g., operators of assisted living facilities or a group at increased risk associated with social determinants of health).

☐ Required ☒ Optional

s) Enhanced capacity for Legionnaires' disease (LD)

(*Note: if applying for LD Enhanced Capacity, all sub-activities are OPTIONAL, except where otherwise indicated).*

i) Perform enhanced legionellosis surveillance*, outbreak response, testing, and reporting* to improve capture of possible sources of exposure. Workplan could include routine use

of an extended hypothesis-generating questionnaire such as the SLDSS Expanded Case Report Form or environmental testing of possible sources for single cases.

ii) Utilize GIS software such as SATScan for geospatial detection of legionellosis clusters and outbreaks.

iii) Improve laboratory testing for surveillance and response. Workplan could include: develop or maintain training of laboratory staff for Legionella testing; implement or maintain clinical diagnostic testing for Legionella infection; implement or maintain environmental sample testing for Legionella detection.

iv) Enhance laboratory testing for response. Workplan could include: implement clinical Polymerase Chain reaction (PCR) capacity at the state laboratory; build internal capacity for Legionella whole genome sequencing and analysis; achieve accreditation by a regional, national, or international accrediting body to a recognized standard for routine Legionella test methods, such as ISO/IEC 17025; and collaborate with hospital and clinical laboratory systems to increase number of respiratory specimens cultured for Legionella.

v) Identify and assess interventions resulting from outbreak investigations. Workplan could include: identify deficiencies that contributed to outbreaks; review recommended facility actions and interventions; and confirm with facilities which interventions were implemented for prevention.

vi) Enhance communication, coordination, and partnership with communities experiencing LD disparities. Workplan could include: establishing or leveraging partnerships with community groups to better understand health inequities within the jurisdiction and to promote primary prevention to mitigate health disparities.

vii) Other optional activities as defined by the recipient

☐ Required ☒ Optional

t) LD Center of Excellence to support building public health capacity*

(*Note: if applying for LD Center of Excellence, all sub-activities are OPTIONAL, except where otherwise indicated).*

i) *Support building public health capacity in other jurisdictions that conduct surveillance, investigate, test, and promote primary prevention of LD cases and outbreaks*.

ii) Develop and deliver trainings, tools, resources, and/or courses to strengthen the knowledge base of, improve surveillance and investigations of LD cases and outbreaks. Make tools and resources publicly available via a single website (required).

iii) Conduct in-person/remote site visits and reverse site visits with other health departments/recipients. Site visit goals could include identifying health departments' needs to inform resource development, training, or other activities as proposed by applicants (required).

iv) Develop a disparity impact statement that describes how data will inform planning, implementation, and evaluation of required activities (required).

v) Support workforce development activities for future public health practitioners. Examples could include: establish stipend/scholarships for LD program participation; support students and projects through internships/field placements.

vi) Assist public health agencies to perform analyses to assess the timeliness and effectiveness of surveillance and investigation of legionellosis cases and outbreaks including assistance on the use of performance metrics and/or evaluation tools.

vii) Support public health agencies with implementation of geographic data analyses (e.g., SaTScan, social vulnerability index analyses).

viii) Identify barriers for collection of potential Legionella exposure data and develop materials or tools to address identified barriers.

ix) Identify and characterize barriers for collection and testing of lower respiratory specimens for Legionella and develop materials or tools to address identified barriers.

x) Identify and characterize issues related to changing climate and impact on LD.

xi) Develop educational materials for health departments' use (e.g., social media posts regarding hot tub risks or air conditioner myths).

xii) Engage other funded sites to support implementation of primary prevention activities and response interventions targeted towards vulnerable populations.

xiii) Other optional activities as defined by the recipient.

☐ Required ☒ Optional

* Legionnaires' disease Center of Excellence (LD CoE): The CoE will collaborate with other funded sites and share resources publicly for broader distribution. The activities are intended to enhance capacity across STLT jurisdictions through training, resource development, and distribution. For example, the CoE could support implementation of new laboratory methods, surveillance best practices. The CoE is not intended to provide technical support to jurisdictions during LD outbreak investigations.

The CoE will be established at a state or local health department that has demonstrated excellence in surveillance, investigation, and primary prevention of LD cases and outbreaks. LD CoE applicants may also propose additional activities not listed in this guidance that are compatible with program goals, build on current capacity and public health needs, and do not duplicate other efforts. However, funding cannot and will not be provided through ELC for any research-associated activities. If research activities are described for the purpose of providing program context, please clearly indicate that no ELC funds are requested to support such activities.

Area B: Prevention and Intervention

10) Improve/sustain support for disease prevention and public health intervention

a) Support disease prevention, interventions, and use of public health tools.

i) Enhance surveillance for VPDs, respiratory diseases, and related conditions to support disease prevention (e.g., vaccine history).

ii) Support technological interventions to enhance public health surveillance (e.g., integration of health information and surveillance systems).

iii) Ensure the use and implementation of standard investigative questionnaires, data collection/sharing tools, and methods.

☒ Required ☐ Optional

b) Facilitate use of surveillance data to inform public health policies.

i) Enhance equitable prevention and intervention strategies to communities and settings placed at increased risk (e.g., health equity).

☒ Required ☐ Optional

Area C: Communication, Coordination, and Partnerships

11) Enhance, sustain, and coordinate partnerships

a) Foster collaboration among diverse groups and multi-sector/level partnerships

i) Engage city, county, state, federal, and other internal and external partners to improve outbreak and case-based reporting for VPDs, respiratory diseases, and related conditions (e.g., AFM) based upon CDC and state/local jurisdiction guidance.

ii) Engage and collaborate with diverse groups of stakeholders by providing surveillance data to inform measure, monitor, analyze health impact and equity and to support policies and public health evaluations for VPDs, respiratory diseases, and related conditions (e.g., AFM).

☒ Required ☐ Optional

b) Communicate and coordinate with multi-sector/diverse public health partners

i) Ensure appropriate investigation, testing, and case-based reporting for VPDs, respiratory diseases, and related conditions (e.g., AFM).

ii) Ensure public health partners receive ongoing training and education so they are informed of the importance of collecting the key variables (e.g., for meningococcal disease surveillance).

iii) Ensure public health partners receive ongoing training and education so they are informed of the importance of collecting the key variables for case-based surveillance (e.g., varicella).

iv) For varicella, disseminate information to reporting sources (e.g., schools, physicians' offices) to raise awareness of reporting requirements (e.g., what variables to report, how to report, when and how to report cases/outbreaks).

v) For AFM, Educate and increase awareness by ensuring that public health partners (e.g., infectious disease specialists, intensive care physicians, pediatricians, neurologists, radiologists/neuroradiologists, infection preventionists, primary care providers, emergency departments, microbiology laboratories) are provided AFM-related clinical,

epidemiologic, and laboratory information (e.g., importance of early collection of 2 stool specimens at least 24 hours apart to rule out poliovirus infection).

vi) In recipient jurisdictions where AFM cases are reported to the local/state health department and specimens are submitted, ensure awareness of access to laboratory testing of appropriate specimens (e.g., stool, respiratory, serum, and cerebrospinal fluid specimens for poliovirus, non-polio enteroviruses, West Nile virus, and other known infectious etiologies) to support surveillance.

vii) In recipient jurisdictions where AFM is a reportable condition, communicate reporting requirements to clinicians (e.g., report suspect cases of AFM to local/state health department, collect specimens from cases as early in the course of illness as possible, collect 2 stool specimens at least 24 hours apart and as early in the course of illness as possible to rule out poliovirus infection).

☒ Required ☐ Optional

Additional Information for Optional (Tier 2) Activities

Points of Contact for Optional (Tier 2) Activities:

- Jamie Tappe (varicella), qyi8@cdc.gov
- Amy Rubis (pertussis), wgi9@cdc.gov
- Amy Rubis (*Haemophilus influenzae)*, wgi9@cdc.gov
- Ryan Gierke (invasive pneumococcal disease), ipe3@cdc.gov
- Chris Gregory (group A streptococcus), hgk4@cdc.gov
- Adria Mathis (measles), xda5@cdc.gov
- Jamie Tappe (mumps), qyi8@cdc.gov
- Adria Mathis (measles, mumps, rubella), xda5@cdc.gov
- Adriana Lopez (acute flaccid myelitis), ail7@cdc.gov
- Michael Wu (multisystem inflammatory syndrome in children), oke4@cdc.gov
- Kerry Souza (industry and occupation), hkv4@cdc.gov
- Alicia Budd (influenza), acp4@cdc.gov
- Mila Prill (post-COVID conditions, RSV, & respiratory virus), gik8@cdc.gov
- Kelley Raines (congenital cytomegalovirus), pvw2@cdc.gov
- Elizabeth (Liz) Hannapel (Legionnaires' disease), qlr0@cdc.gov

Notes for Optional (Tier 2) Activities:

- Legionnaires' Disease:

Legionnaires' Disease (LD) is a severe pneumonia caused by the bacteria *Legionella*. From 2000 to 2018 there has been a 900% increase in the incidence of LD in the United States. Data has shown that racial and socioeconomic disparities play a role in the increase in incidence with Black or African American persons and areas with lower incomes having higher rates of disease. As the incidence of LD has increased overall, data shows the 2018 incidence rate was more than two times higher in Black or African American persons when compared to White persons, highlighting widening racial disparities. The burden of LD is substantial, with case fatality rates of 10% (25% among healthcare-associated cases) and hospitalization cost estimates of $433 million per year. LD outbreaks comprise over half of all reported potable water outbreaks.

In the United States, LD case surveillance is currently conducted through the National Notifiable Diseases Surveillance System (NNDSS) and the Supplemental Legionnaires' Disease Surveillance System (SLDSS). SLDSS collects exposure information such as travel history and exposure to healthcare facilities. CDC's Legionella program receives SLDSS data captured through an Extended Form or a Core Form. LD outbreak surveillance is conducted through the National Outbreak Reporting System (NORS).

Transmission of Legionella occurs through inhalation of aerosolized water rather than person-to-person spread. Capture of potential exposures through public health interview is critical for identifying shared exposures and outbreaks. Once detected, LD outbreak investigations require an environmental assessment to identify potential sources of exposure. Environmental health capacity for legionella environmental assessments varies widely across recipients.

LD prevention depends on control of *Legionella* growth and spread in the built environment. Common sources of outbreaks include potable water systems and devices such as cooling towers, hot tubs, and decorative fountains. Certain buildings have characteristics (e.g., over 10 stories) or populations (e.g., healthcare facility) that make them high risk for *Legionella* growth and spread. These high-risk devices and buildings should have water management programs (WMP) to prevent *Legionella* growth and spread. CDC recommends that all buildings and devices meeting criteria defined by ASHRAE Standard 188 have a WMP to support primary prevention of LD.

Cases of LD must be identified and interviewed to collect history of exposure to potential sources of *Legionella*. Interviews and reporting must be timely to recognize clusters and outbreaks. Collection and testing of lower respiratory specimens must be prioritized to support outbreak detection and investigation. Upon recognition of a cluster or outbreak, environmental assessment must be performed to identify areas where *Legionella* can grow and spread to enable intervention. During outbreaks and as a primary prevention strategy, implementation of control measures can interrupt the amplification, aerosolization, and transmission of *Legionella*, thereby reducing disease incidence. As such, CDC's focus is on enhancing capacity at the state and local levels among epidemiologists and public health laboratorians regarding 1) enhanced case surveillance, investigation, and reporting; 2) improved environmental assessments and outbreak response; 3) enhanced collection of and laboratory testing for clinical specimens and environmental samples; and 4) primary prevention through *Legionella* control in the built environment.

Racial disparities exist for LD, with the highest incidence among Black or African American persons. As incidence has increased overall, the relative increase was more than twice as large for Black or African American persons than for any other race. Comorbidities associated with increased risk are more common among Black or African American persons, such as diabetes and end-stage renal disease. Social determinants of health associated with LD also disproportionately impact Black or African American communities, such as median household income, proximity to cooling towers, working in hazardous or service industries, or living in census tracts with high poverty or more vacant homes. Proposed workplans for optional LD activities should consider jurisdiction-specific inequities and social determinants of health to target activities among communities at increased risk.

Populations at increased risk for developing Legionnaires' Disease (LD) include people who are 50 years or older, current or former smokers, have chronic lung disease, and have weakened immune systems. Incidence is disproportionately higher for Black or African American persons than White, Native American or Alaskan Native, or Asian or Pacific Island persons. Investigations of building-associated outbreaks show the most common places for getting the disease are hotels, long-term care facilities, and hospitals. Health departments, building managers, and healthcare facilities can facilitate implementation of control measures for the primary prevention of LD in building water systems. Applicants can work with disproportionately impacted communities to target interventions.

Applicants for Enhanced Legionnaires' disease Capacity activities (Activity 8s) or Center of Excellence activities (Activity 8t) are not required to apply for Core Legionnaires' disease Capacity (Activity 8r) funds, but may do so if they wish to. Enhanced Capacity and Center of Excellence (CoE) funds will be prioritized for sites that demonstrate they can accomplish LD Core Capacity activities through existing capacity or proposed LD Core Capacity workplans.

Collaborations:

a. With CDC-Funded Programs

Collaboration with ELC, epidemiology, laboratory, health information, and immunization programs (including Immunization Program Manager) is required.

b. With Organizations External to CDC

APHL, VPD Reference Centers, CSTE, jurisdiction health departments, building managers, healthcare facilities, industry organizations, groups involved in WMPs, and other partners

Population(s) of Focus:

For NNDSS VPD Surveillance Coordination: Surveillance for VPDs, respiratory diseases, and related conditions should be coordinated across epidemiology, laboratory, immunization, and health information partners within the recipient jurisdiction. See additional guidance in the Manual for the Surveillance of Vaccine-Preventable Diseases | CDC.

For AFM: Focus should be on patients with acute onset of flaccid limb weakness and abnormalities of the spinal cord gray matter on magnetic resonance imaging (MRI) scan. Although AFM has been more commonly

reported in children, monitoring reports of cases in all ages will be important for describing the full spectrum of illness. See additional guidance on the CDC AFM website AFM Case Definitions | CDC.

For Meningococcal Disease: Monitoring individual cases of meningococcal disease in all ages is important to track progress of the vaccination program. See additional guidance in the *Manual for Surveillance of Vaccine-Preventable Diseases* Meningococcal - Vaccine Preventable Diseases Surveillance Manual | CDC.

For Respiratory Virus Surveillance: Virologic and disease surveillance should be coordinated to ensure systems and partnerships are in place so that CDC and partners can rapidly detect and monitor the occurrence and impact of respiratory viruses with pandemic potential to prevent or control transmission and minimize morbidity in the U.S. PUBL002.PS (congress.gov).

For Varicella: Monitoring individual cases of varicella in all ages is important to track progress of the vaccination program. See additional guidance in the *Manual for Surveillance of Vaccine-Preventable Diseases* Varicella - Vaccine Preventable Diseases Surveillance Manual | CDC.

Evaluation and Performance Measurement:

Required performance measures are listed below and will be used to indicate progress toward the specific cooperative agreement outcomes. Timely surveillance data will be submitted electronically to CDC through approved systems or disease-specific reports. Data for the performance measures will be provided to jurisdictions by CDC, submitted by jurisdictions during the performance monitoring process, or submitted by jurisdictions throughout the program year via required reports. See footnotes regarding sources of data for the performance measures.

Performance measures included here are representative and may not be final at the time of NOFO publication. Please see the CK-24-0002 Performance Measure Guidance document for all final measures and descriptions.

a. ACTIVE Performance Measures

For NNDSS VPD Surveillance Coordination:

- Utilization of modernized messaging (e.g., HL7) to enhance standardization, harmonization, interoperability, and use of surveillance information systems by jurisdiction and CDC[1]
- Review of Surveillance Indicator Reports at least annually (e.g., provisional, final) and documentation of regular (e.g., quarterly) utilization of surveillance data and Surveillance Indicator Reports to improve and/or make changes to current processes to improve the quality of surveillance data[2,3]

For AFM:

- Documentation that AFM education is in place in the jurisdiction and description of educational tools developed/outreach conducted[3]
- Number of AFM cases investigated, confirmed, and ruled out[3]

For Meningococcal Disease:

- N/A

For Respiratory Virus Surveillance:

- Number of specimens associated with respiratory virus surveillance and outbreaks that were received at the public health laboratory from clinics, hospitals, coroners, LHDs, or other source
- Number of specimens associated with respiratory virus surveillance and outbreaks that were tested for respiratory viruses at the public health laboratory from clinics, hospitals, coroners, LHDs, or other source
- Status of implementing HL7 messaging from health department laboratories to CDC via PHLIP for non-influenza non-SC2 respiratory virus tests (e.g., RSV and others)
- Status of setting up case ascertainment, data collection, and reporting of RSV- and COVID-associated deaths among children and adolescents <18 years of age)

For Varicella:

- N/A

b. PASSIVE Indicators

For NNDSS VPD Surveillance Coordination:

- Identification of a VPD Surveillance Coordinator[1]
- Participation in VPD Surveillance calls (e.g., Quarterly All-Jurisdiction calls, meningococcal disease-specific calls, AFM-specific calls)[1]
- Proportion of cases with complete and timely information for key surveillance indicator variables[2]

For AFM:

- N/A

For Meningococcal Disease:

- Proportion of meningococcal disease cases with isolates and enhanced surveillance data submitted to CDC[1]
- Proportion of cases with complete information for key surveillance indicator variables (e.g., serogroup, vaccination status, outcome)[2]

For Respiratory Virus Surveillance:

- Number of specimens shipped to CDC (e.g., influenza specimens shipped every two weeks to the National Influenza Reference Center, aliquots for additional or confirmatory non-influenza respiratory virus testing, meningococcal disease specimens)
- Appropriate and timely participation in respiratory virus surveillance reporting systems (i.e., NREVSS & NATRS)
- For influenza surveillance, the percentage of influenza A viruses tested by the public health laboratory that are subtyped.

- Utilization of modernized messaging (e.g., HL7) to enhance standardization, harmonization, interoperability, and use of surveillance information systems by jurisdiction and CDC[1]
- Number of clinical labs whose aggregate test results were transmitted to CDC for inclusion in NREVSS on a weekly basis, either directly or on their behalf with pass-through reporting by a health department
- ILINET provider engagement
- Identification and reporting of respiratory deaths of public health concern (e.g., RSV, COVID, and influenza among children and adolescents <18 years of age in which key clinical and other data are obtained and transmitted to CDC)

For Varicella:

- Number of varicella cluster- or outbreak-associated cases with enhanced surveillance data submitted to CDC[1]
- For sites where varicella is a reportable condition and case-based varicella surveillance is conducted, proportion of cases with complete information for key surveillance indicator variables (e.g., age, number of lesions, hospitalization status, confirmation status, laboratory testing, relation to outbreak, vaccination status)[1,2]

Program K: Vector-borne Diseases and Tick-Associated Conditions:

Building Comprehensive Programs to Identify, Diagnose, Report, Prevent, and Respond

Program Activity Contact Information:

General program inquiries and questions on this guidance: VBDELC@cdc.gov; Jeff Borchert, gqx1@cdc.gov; (970) 221-6494
Arboviral diseases: Nicole Lindsey, frd3@cdc.gov; (970) 266-3595
Bacterial vector-borne diseases, including Lyme disease, plague, tularemia: Sarah Hook, vhx8@cdc.gov, (970) 221-6411
Rickettsial diseases and Alpha-gal syndrome: Nicolette Bestul, pue8@cdc.gov; (404) 718-3827
Parasitic vector-borne diseases (not including malaria or Chagas disease): Susan Montgomery, zqu6@cdc.gov; (404) 718-4731
Dengue: Vera Soltero, eeu4@cdc.gov; (787) 706-4244

Funding Opportunity Description:

a. Overview

Vector-borne diseases and tick-associated conditions, including those transmitted to humans by mosquitoes, ticks, fleas, mites and lice, are a large and growing public health problem in the United States. Mosquito-borne viruses such as West Nile virus (WNV) are often characterized by unpredictable and episodic epidemics that vary in place and time. Tickborne diseases, including, but not limited to, Lyme disease, Spotted Fever rickettsioses, anaplasmosis, ehrlichiosis, and babesiosis, have more than doubled in number and increased in geographic range over the last few decades. Additionally, tick-associated Alpha-gal Syndrome (AGS) (https://www.cdc.gov/ticks/alpha-gal/index.html) is an emerging condition with a standardized surveillance case definition put in place in 2022. Timely surveillance and reporting, accurate diagnostics, and vector control are needed. This program supports sustainable, locally relevant vector-borne disease prevention programs to respond to the increasing threat of vector-borne diseases.

Note: Although AGS is not truly a vector-borne *disease*, for simplicity, the phrase vector-borne disease (VBD) will be used throughout this guidance and is meant to encompass both vector-borne diseases and AGS.

Additional information on the Program K: Vector-Borne Diseases can be found here: www.cdc.gov/ncezid/dvbd/vbdelc/

b. Health Equity

The Vector-Borne Diseases ELC Program recognizes that certain demographic groups may be at greater risk of contracting vector-borne diseases, experiencing adverse consequences, or facing barriers in accessing VBD-trained healthcare or laboratory services. Recipients are encouraged to engage partners and collect surveillance data needed to identify and reduce these health inequities and to ensure that all communities receive equitable protection from illness and death due to vector-borne diseases.

Program K will consider support for proposed activities that align with this guidance and focus on addressing inequities in health risks, outcomes, and access to preventive and laboratory services for groups that have been historically marginalized. Applicants should highlight these activities in their applications.

c. Healthy People

NA

d. Local Health Department and Tribal Engagement

Program K encourages recipients in state, large local, and U.S. territories to include activities that benefit local health departments and tribal nations. Applicants should describe plans for how they will interact with local jurisdictions including description of activities at the local level, methods to assess local needs, and description of funding mechanisms to support local vector control and vector-borne disease related activities.

e. Other National Public Health Priorities and Strategies

A National Public Health Framework for the Prevention and Control of Vector-Borne Diseases in Humans https://www.cdc.gov/ncezid/dvbd/framework.html

National Public Health Strategy to Prevent and Control Vector-borne Diseases in People https://www.TBD.gov (will be released December 2023)

CDC Project Description:

a. Problem Statement

Vector-borne diseases, caused by a diverse array of pathogens, are transmitted to humans by various types of vectors. These recognized threats, as well as novel and emerging conditions, have increasingly challenged the public health programs tasked with preventing, detecting, reporting, and controlling them.

b. Purpose

The purpose of this program is to support state and local health departments to implement and maintain accurate and relevant surveillance for human disease and their vectors, improve laboratory practices and capacity, and to implement and evaluate prevention strategies. This program comprises all vector-borne surveillance and control activities related to a subset of vector-associated diseases. Applicants should focus their proposed activities on the most important vectors and vector-borne diseases in their jurisdiction, referring to priority pathogens listed on the CDC's Division of Vector-borne Diseases (https://www.cdc.gov/ncezid/dvbd/index.html). Please note that at this time, our program does not support activities related to the investigation of imported, cryptic, or locally acquired malaria cases or the surveillance and control of Chagas disease.

c. Outcomes

1. Improved human diagnostic, veterinary and vector laboratory capacity to support vector-borne disease surveillance.
2. Improved completeness (e.g., race and ethnicity data) and timeliness of reporting of vector-borne disease surveillance data to monitor the epidemiology, incidence, and geographic spread of vector-borne diseases.
3. Improved ecologic surveillance to detect and monitor vector species distribution, abundance, infection, and insecticide resistance to inform vector control and public health response.
4. Increased availability of timely and accurate information on vector-borne disease risk and prevention to public health partners, healthcare providers, vector control agencies, decision makers, and the public.

5. More rapid and complete identification of vector-borne disease outbreaks to facilitate timely, equitable and effective control measures.
6. Better prepared workforce to identify, diagnose, report, prevent, and respond to vector-borne disease cases (including travel-associated cases) and outbreaks.

Funding Strategy:

Funds are intended to support building and maintaining a vector-borne disease program that focuses on the most relevant vector-borne diseases in the recipient jurisdiction. Activities for vector-borne disease programs are organized as Basic or Enhanced levels so that recipients can demonstrate capacity at various levels. Recipients should document that they have existing Basic capacity if applying for Enhanced activities.

- Basic core capacity for locally relevant vector-borne disease surveillance, laboratory testing, and response across all recipients receiving funds (Required Activities)
- Enhanced capacity for advanced vector-borne disease surveillance, laboratory testing, and response, in addition to coordination with multiple external partners (Optional Activities)

Recipients should utilize funds for any combination of personnel, travel, supplies, equipment, or contractual support needed to execute proposed activities and in line with recipient need and proposed capacity. There should be only one budget for the vector-borne-disease program (Program K).

- Estimated total availability of funds: $14,000,000
- Estimated number of awards given: 60
- Estimated average award amount: Approximately $233,000.
- Larger awards will be considered for well-conceived, well-written, and concise work plans that include enhanced activities, that are reasonable and appropriate for the recipient jurisdiction. Additionally, funding preference will be given to applications in which the budget request is clearly justified within the proposed activities and workplan. If applications are well written and include the information noted below, recipients proposing Basic activities should expect awards up to $300,000. Recipients proposing Basic plus Enhanced activities should anticipate awards between $150,000 and $800,000 depending on the activities proposed, size and population of the jurisdiction and vector-borne disease burden.

Higher ranking and funding preference will be given to applications that include the following information as appropriate for each activity or implementation plan. Efforts should be made to avoid repeating the same information throughout the application:

- Concise, well-written implementation plans. Additionally, applications will be evaluated on evidence of the incorporation and response to CDC comments on the previous year's application.
- A brief overview of recipient jurisdiction's vector-borne disease program as it relates to the proposed activities. Define any acronyms used throughout the application.
- Brief description of annual progress from prior budget period, provide updates on newly requested activities, explain any unmet milestones from past budget periods. Also, include narrative on the successes and challenges of the last budget period.
- Description of and relevance of proposed activities, including local relevance and connection to national public health priorities and strategies where appropriate.

- Description of current or planned collaborations with external partners local health departments, Vector-borne Disease Centers of Excellence and Training and Evaluation Centers.
- Clear explanation of how work plan activities relate to proposed budget line items.
- Description of the staff contributing to vector-borne disease program as proposed in this application. Include names, titles, and a brief statement of roles. Indicate if contributing staff are non-ELC funded. Provide a point of contact for each of the programmatic areas where relevant to facilitate communication:
    - Arboviral diseases
    - Lyme disease, plague, tularemia
    - Rickettsial diseases
    - Parasitic vector-borne diseases (**not** including malaria or Chagas disease)
    - Alpha-gal Syndrome

Additional Hurricane Funding Availability for Puerto Rico, Florida, South Carolina, and North Carolina

Additional funding (made available through the *Consolidated Appropriations Act of 2023, p. 1855; Division N – Disaster Relief Supplemental Appropriations Act, 2023*) is available to recipients who submitted disaster declarations in response to hurricanes Fiona and Ian (i.e., Puerto Rico, Florida, South Carolina, and North Carolina). Applicants must clearly indicate in both their applications and budgets which proposed activities will be supported with this funding versus ELC Program H: Vector-borne funding.

For the purposes of this NOFO, approved activities for laboratory and vector surveillance and control are listed below. Program H: Vector-borne will support impacted states and territories to reduce the impact of vector-borne diseases through collaborative activities in key areas:

- Supporting states and territories in their implementation of enhanced mosquito surveillance and control strategies in jurisdictions that received significant rainfall, as these jurisdictions may also be at greater risk of mosquito and vector proliferation and subsequent vector-borne diseases;
- Supporting states and territories in their implementation of mosquito surveillance and control strategies to prevent a subsequent surge in mosquito populations in the next mosquito season, including the implementation of innovative vector control strategies; and
- Providing surge support of laboratory diagnostic testing for vector-borne diseases in storm-affected jurisdictions, including supporting states and territories that may have decreased capacity for testing due to damage to state and local diagnostic testing laboratories.

Required Tasks:

Acceptance of DVBD Program K funding conveys acknowledgement and indication that the following required tasks will be completed. Completion of required tasks should not be used as milestones in activities.

1) Participate in a BP1 kick off call with DVBD.
2) Participate in routine communication with DVBD to provide budgetary and programmatic updates, including, calls (up to quarterly), quarterly updates in ELC CAMP, webinars, site visits and meetings.
3) Hire, onboard, and retain staff needed to accomplish activities.
4) Participate in the ELC Annual Meeting and CDC's bi-annual vector-borne disease meeting (Vector Week).

5) If vector surveillance and insecticide resistance activities are funded, submit data to the appropriate state or local system. Tick surveillance data should be submitted to ArboNET Tick Module if DVBD performs pathogen testing. For jurisdictions doing their own pathogen testing, vector surveillance data should be submitted to ArboNET Tick Module prior to submitting the next budget period's application.

Strategies and Activities:

0) Strategy to Address Required Tasks

a) Address Required Tasks in program guidance

The Required Tasks are required by all funding recipients. Selecting this optional activity simply allows applicants to describe an implementation plan and link budget line items to complete the Required Tasks. If applicable, jurisdictions should link travel costs for Vector Week to this activity. If completion of a Required Task is fully described in another activity section, applicants **do not** need to restate that information here.

☐ Required ☒ Optional

Area A: Surveillance, Detection, and Response

1) *Improve human surveillance, outbreak response and reporting for VBD*

Basic Capacity:

a) Identify and report nationally notifiable human vector-borne disease cases to CDC

Report using standard CSTE case definitions with complete reporting of key variables to NNDSS. Describe processes for case identification and efforts to obtain, maintain, or improve data quality and completeness.

☒ Required ☐ Optional

b) Identify and report blood donations with evidence of vector-borne pathogens

Pathogens of interest include West Nile virus, Ehrlichia and Anaplasma spp., and Babesia spp. Possible transfusion and transplant transmitted infections should be included in these efforts. Describe how such infections will be identified, confirmed, and investigated.

☒ Required ☐ Optional

c) Onboard or develop plans to onboard Message Mapping Guides (MMG)

Describe plans for onboarding the Arboviral Message Mapping Guide (MMG) and Lyme and Tickborne Rickettsial Diseases (TBRD) MMG in accordance with current NNDSS data transmission guidance. If onboarding is complete, provide descriptions of monitoring system or processes in place for troubleshooting data transmission problems. If developing plans to onboard, describe any relevant information to explain the anticipated process (staffing, timeline, anticipated challenges, etc.).

☒ Required ☐ Optional

Enhanced Capacity:

d) Identify and report non-nationally notifiable vector-borne disease cases to CDC

Non-arboviral conditions, including Borrelia miyamotoi, tickborne relapsing fever (TBRF), Alpha-gal syndrome, murine typhus (Rickettsia typhi), scrub typhus (Orientia tsutsugamushi), epidemic typhus (Rickettsia prowazekii) should be directly reported to CDC via email to the respective point of contact listed in the Program K guidance. Include description of how such infections will be identified.

☐ Required ☒ Optional

e) Investigate and report novel vector-borne disease cases

Include those with new or unusual modes of transmission or clinical manifestations and description of how such infections will be identified.

☐ Required ☒ Optional

f) Describe efforts to conduct enhanced case investigations and surveillance

Include ongoing or planned efforts for vector-borne diseases to: 1) improve estimates of disease incidence and burden; 2) describe clinical features and outcomes; 3) identify groups at increased risk for infection or disease to target prevention, better understand health inequities and/or 4) evaluate novel ways to conduct improved public health surveillance, such as through use of electronic health records or claims data. ***This activity must expand beyond activities described in responses to Activities 1a-1e (above).***

☐ Required ☒ Optional

2) Improved ecological and vector surveillance, response, and reporting.

Basic Capacity:

*a) Collect and report **passive** ecologic surveillance data already being collected*

For example, veterinary cases, sentinel animal infections, vector abundance and infection prevalence. Report vector-borne disease data to ArboNET and local vector control programs. "Passive" is defined as entomological surveillance activities already occurring in the recipient jurisdiction, but not performed or coordinated by the program (e.g., universities, other state agencies, agriculture, or veterinary agencies). For each vector relevant to the recipient jurisdiction plan (e.g., mosquito and/or tick), describe known data already available to the jurisdiction, plans to gather and analyze ecologic data, and efforts to obtain and report the data to ArboNET.

☒ Required ☐ Optional

b) Provide vector surveillance and control guidance to local agencies

Provide guidance on surveillance and control of vectors to reduce human disease where appropriate. Examples of local agencies could include mosquito abatement districts and local

health departments among others. Describe what information is provided, the process of how information is supplied, and who is responsible (whether ELC-funded staff or a collaborating partner).

☒ Required ☐ Optional

c) Host a Public Health Entomology for All (PHEFA) fellowship graduate

If you have existing entomological capacity in your jurisdiction and are interested in hosting a CDC/Entomological Society of America PHEFA graduate to expand your entomological capacity, please indicate you interest in your workplan.

☐ Required ☒ Optional

Enhanced Capacity:

*d) Conduct/coordinate **active** ecologic/vector surveillance and vector pathogen testing*

Report results to ArboNET. "Active" is defined as entomological surveillance activities performed or coordinated by your program (e.g., collaborations with universities, local health departments, local vector control agencies, or subcontracted to an outside group). For each vector relevant to the recipient jurisdiction plan (e.g., mosquito and/or tick), describe the objectives and geographic scope of the surveillance, process for collecting and reporting the data, and the partners involved. Please include details on pathogen testing strategies for vectors if performing.

☐ Required ☒ Optional

e) Perform or obtain insecticide resistance testing results for mosquitos

Use data to inform mosquito control activities. Describe the process for actively collecting these data and if the data are analyzed to inform mosquito control.

☐ Required ☒ Optional

f) Implement advanced vector surveillance activities

i. Conduct insecticide field-testing and evaluate insecticide resistance management plans.

ii. Provide regional capacity for pathogen testing in vectors.

☐ Required ☒ Optional

3) Analysis and interpretation of vector-borne disease surveillance data.

Basic Capacity:

a. Analyze and interpret human and/or non-human vector-borne disease surveillance data
Include details on types and frequencies of analyses conducted and interpretation/use of data to guide public health action. Distinguish the activities by human and non-human data, as needed.

Efforts to disseminate surveillance data should be described in Area C. Activities for interventions and outbreak response should be described in Area B.)

☒ Required ☐ Optional

Enhanced Capacity:

*b. Perform expanded analysis and interpretation of vector-borne disease surveillance data This includes **human and/or non-human** data to inform public health action. This activity must expand beyond activities described in Activity 3a (above), and may include activities such as spatial analysis, hot spot or cluster analysis, surveillance modeling or innovative methods to measure, monitor, and understand health inequities (e.g. collection of qualitative data to understand inequities in risks, behaviors, knowledge/attitudes). Describe the implementation plan in separate paragraphs for human and non-human where appropriate. (Efforts to disseminate surveillance data should be described in Area C. Activities for interventions and outbreak response should be described in Area B.)*

☐ Required ☒ Optional

4) Strengthen human laboratory testing for vector-borne diseases of relevance.

Basic Capacity:

*a) Maintain core capacity to perform **human diagnostic** testing for vector-borne diseases*

Testing should include diseases of public health importance to the jurisdiction, including but not limited to:

iii. PCR and IgM antibody testing for at least one arbovirus

iv. Where geographically relevant, PCR Rickettsia 510(k) assay

Please describe what human diagnostic testing is provided by the applicant and provide explanations for tests that are relevant but not being performed (e.g., testing is commercially available or barriers to testing).

Note: Program K does not support jurisdiction testing for pathogens when adequate commercial tests are available (e.g., Lyme Disease diagnostics) except in circumstances where these tests would not otherwise be available to individuals who have limited income, are uninsured, or lack access to laboratory services.

☒ Required ☐ Optional

b) Participate in annual proficiency testing for human vector-borne disease diagnostics

Participation could include CDC program for arbovirus diagnostics or as part of maintaining CLIA compliance for clinical vector-borne diagnostic testing.

☒ Required ☐ Optional

Enhanced Capacity:

c) Enhanced capacity for human diagnostic testing

*Maintain enhanced capacity to perform **human diagnostic testing** or confirmatory testing for an expanded number of vector-borne diseases of public health importance to the jurisdiction such as for a panel of arboviral infections, species-specific real-time assays or IFA IgG for Rickettsia, Ehrlichia, and Anaplasma species.*

☐ Required ☒ Optional

d) Provide support to other states and jurisdictions for vector-borne disease diagnostics

Testing could include the plaque reduction neutralization testing or participating in a specimen sharing program.

☐ Required ☒ Optional

5) Enhance workforce capacity for VBD surveillance and response.

Enhanced Capacity:

a) Workforce training on vector-borne diseases

Participate in training and development for the jurisdiction's vector-borne disease workforce. This could include attending skill-building training courses or events (e.g., training provided by regional Centers of Excellence) or attendance and presentation at regional/national vector-meetings and conferences (e.g., hosted by CSTE, AMCA, etc.).

☐ Required ☒ Optional

6) Hurricane Fiona and Ian Recovery (Florida, North Carolina, Puerto Rico, South Carolina only). (Additional progress reporting may be requested to document impact of this disaster recovery funding)

a) Enhanced mosquito surveillance and control

Implement enhanced mosquito surveillance, pathogen testing, and prevention and control strategies.

☐ Required ☒ Optional

b) Preparedness for mosquito and mosquito-borne disease prevention

Implement mosquito and mosquito-borne disease prevention and control strategies to prevent subsequent surges in mosquito populations in the next mosquito season, including the implementation of innovative vector control strategies.

☐ Required ☒ Optional

c) Surge support of diagnostic testing

Implement surge support of laboratory human diagnostic testing for vector-borne diseases in storm-affected jurisdictions.

☐ Required ☒ Optional

Area B: Prevention and Intervention

7) Implement vector-borne disease interventions and tools.

Basic Capacity:

a) Investigate and respond to vector-borne disease outbreaks

Describe capacity or plans to investigate and respond to vector-borne disease outbreaks, unusual clusters or trends, implement timely integrated control measures, and disseminate findings. At minimum, jurisdictions are expected to develop and maintain a written outbreak response plan, identify partners, have a communication strategy, and establish MOUs when necessary. More comprehensive integrated vector surveillance and control strategies may include emerging infections surveillance, social mobilization, policy development, and real-time evidence-based decision making for vector control. Please include description of anticipated partners, and available or planned control measures that may be implemented and by which partner.

☒ Required ☐ Optional

Enhanced Capacity:

b) Implement emergency vector control, as appropriate

☐ Required ☒ Optional

Area C: Communication, Coordination, and Partnerships

8) Disseminate VBD data to stakeholders to improve situational awareness.

Basic Capacity:

a) Distribute vector-borne disease surveillance data to diverse stakeholders

Stakeholders could include healthcare providers, public health partners, policy makers, and the public. Describe frequency and modes of delivery, which may include presentations, newsletters, emails, social media, etc. At minimum, describe availability and frequency of updating jurisdiction-specific vector-borne disease surveillance data on the health department website. Please distinguish and be specific about the types of data being distributed and frequencies of distributions (e.g., human and/or non-human surveillance or testing results, monthly or annual data, etc.).

☒ Required ☐ Optional

9) Implement health promotion and education strategies for VBDs.

Enhanced Capacity:

a) Conduct culturally sensitive outreach and educational activities

Outreach to increase awareness of local healthcare providers, public health personnel and the public regarding the risks, clinical manifestations, diagnosis and prevention of vector-borne

diseases. Please describe frequency and modes of delivery, which may include presentations, newsletters, emails, social media, radio, etc. that are tailored for the population of focus.

☐ Required ☒ Optional

*b) Develop **and evaluate** vector-borne disease communication plans and tools*

Modify messages as appropriate and implement innovative approaches to enhance reach and improve understanding for populations with higher risk of negative outcomes accessibility needs, and cultural considerations. Activities in this section should be an expansion or strategic development of Basic communications activities.

☐ Required ☒ Optional

10) Enhance coordination and collaboration with external stakeholders.

Enhanced Capacity:

a) Establish, support or manage regional or national collaborations

Describe active involvement or coordinated efforts with other state and local health departments to improve resource sharing, staffing and capacity for vector-borne disease surveillance and control measures.

☐ Required ☒ Optional

Collaborations:

a. With CDC-Funded Programs

Recipients are expected to collaborate with subject matter experts in CDC's Division of Vector-Borne Diseases (DVBD) including the Arboviral Diseases Branch, Bacterial Diseases Branch, Dengue Branch, and Rickettsial Zoonoses Branch, and with the Parasitic Disease Branch in CDC's Division of Parasitic Diseases and Malaria, as well as with DVBD and ELC programmatic staff.

b. With Organizations External to CDC

Recipients are encouraged to increase collaborations with vector-borne disease stakeholders as they advance their programs. Collaborations could include the business community, universities (including the Centers of Excellence, Training and Evaluation Centers and EIP partners), emergency management groups, hospitals, cultural groups as well as physician offices, media, non-government and non-profit organizations, and other federal, state, local government or tribal agencies.

Populations of Focus:

This guidance focuses on the entire U.S. population and the public health system within the U.S. and its territories. Funding awarded for vector-borne disease programs is intended to support the needs of jurisdictions impacted by vector-borne diseases and to ensure that the public health system is ready and capable to mitigate the impacts of endemic and new introductions or discoveries of vector-borne diseases. Applicants are encouraged to use their funding to enhance understanding of and focus efforts to reduce populations experiencing health inequities related to vector-borne diseases.

Evaluation and Performance Measurement:

a. ACTIVE Performance Measures

Measure #1 – Human Diagnostic Laboratory Capacity

1. Reported jurisdiction vector-borne disease diagnostic capability (Tables 1 and 2). Note, this includes all testing performed at the jurisdiction's laboratory, but does not include testing options sent to commercial labs.

Table 1: Jurisdiction Arboviral Diagnostic Capability (check all that apply)

Pathogen	ELISA		MIA		IFA		PRNT	PCR
	IgM	IgG	IgM	IgG	IgM	IgG		
California serogroup†								
Chikungunya								
Colorado tick fever								
Dengue								
Eastern equine encephalitis								
Japanese encephalitis								
Powassan								
St. Louis encephalitis								
Western equine encephalitis								
West Nile								
Zika								
Yellow fever								

†Such as La Crosse or Jamestown Canyon viruses

Table 2: Jurisdiction Other Vector-Borne Diseases Diagnostic Capability (check all that apply)

Pathogen	ELISA		IFA		Culture	PCR
	IgG	IgM	IgG	IgM		
Spotted fever group *Rickettsia*						
Typhus group *Rickettsia*						
Ehrlichia spp.						
Anaplasma spp.						
Yersinia pestis						
Francisella tularensis						
Relapsing fever *Borrelia* spp.						

Measure #2 – Surveillance Capacity and Completeness of Reporting

1. Is your jurisdiction planning or onboarding Message Mapping Guides (please check all that apply)

MMG	Planning	Onboarding	Production
Lyme and TBRD			
Arboviral v1.3			

2. Proportion of spotted fever rickettsiosis cases confirmed by PCR
    a. *Numerator*: Number of PCR confirmed spotted fever rickettsiosis cases
    b. *Denominator*: Total number of confirmed and probable spotted fever rickettsiosis cases

Measure #3 – Vector Surveillance and Control Capacity

1. Does your jurisdiction perform mosquito insecticide resistance (IR) testing? If yes, what agency performs the IR testing?
2. Number and proportion of vector-borne disease or vector control staff that are trained in tick identification and collection.
3. Number and proportion of vector-borne disease or vector control staff that are trained in mosquito identification and collection.
4. Description of vector control capacities and enhancements.
5. Vector control activities undertaken in response to identified arboviral disease outbreaks.

Measure #4 – Cross Cutting Coordination and Collaborations

1. Estimated number of stakeholders reached through presentations/outreach activities, including healthcare professionals (physicians, nurses, nurse practitioners, physician assistants), local jurisdictions, and public.
2. Reported breakdown of vector-borne disease activities:
    a. Estimated percent of the total Program K budget which was allocated to tick-borne disease activities in BP1.
    b. Estimated percent of the total Program K budget which was allocated to mosquito-borne disease activities in BP1.

b. PASSIVE Indicators

ArboNET Reporting

1. Completeness of arboviral surveillance data reported to CDC via ArboNET including:
    a. Number of arboviral disease cases and infections (i.e., viremic blood donors) reported to ArboNET
    b. Proportion of reported human disease cases with complete data for the following data elements: age, sex, clinical syndrome, hospitalization, and death
    c. Proportion of total jurisdiction population that live in an area with environmental surveillance data (bird, mosquito, and sentinel animal; numerator and/or denominator) reported to ArboNET
    d. Number of veterinary disease cases reported to ArboNET

e. Number and proportion of counties from which ticks were collected and reported to ArboNET.

Section III: Disease-Specific Projects

Project L: Prion Surveillance

Program Activity Contact Information:

Ryan Maddox; 404-374-2333; zzp7@cdc.gov

Funding Opportunity Description:

a. Overview

This project contributes to national surveillance of human prion diseases with goals of monitoring their incidence in the United States (U.S.) and assisting clinicians with accurate diagnoses. This family of diseases, which are progressive, transmissible, neurodegenerative disorders that are always fatal, includes variant Creutzfeldt-Jakob disease (vCJD), the human form of bovine spongiform encephalopathy (BSE, or "mad cow" disease). Other human prion diseases include sporadic Creutzfeldt-Jakob disease (sCJD, iatrogenic (iCJD), genetic CJD (gCJD), fatal familial insomnia (FFI), and Gerstmann-Sträussler-Scheinker (GSS) syndrome.

b. Health Equity

Persons exposed to the agent of chronic wasting disease (CWD), a prion disease of deer and elk, may be more likely to live in a rural area.

c. Healthy People

Not applicable

d. Local Health Department and Tribal Engagement

When appropriate and as needed, recipients should engage with local health departments and tribes to accomplish specific surveillance objectives (e.g., investigation of cases of interest).

e. Other National Public Health Priorities and Strategies

Not applicable

CDC Project Description:

a. Problem Statement

Prion diseases, or transmissible spongiform encephalopathies (TSEs), are a family of rare progressive neurodegenerative disorders that affect both humans and animals. These diseases are characterized by unusually long incubation periods, often measured in years. They are 100% fatal and are caused by unconventional transmissible agents that are highly resistant to usual inactivation methods. Human prion diseases include the classic forms of Creutzfeldt-Jakob disease (sporadic, iatrogenic, genetic), the types most commonly occurring throughout the world, including the U.S., and variant Creutzfeldt-Jakob Disease (vCJD), a type of human prion disease that emerged in the United Kingdom in the mid-1990s associated with eating meat products contaminated with the agent of bovine spongiform encephalopathy (BSE). Prion disease surveillance in the United Kingdom enabled recognition of the emergence of vCJD. Similarly, prion disease surveillance in the U.S. is monitoring for the emergence of vCJD and other potentially preventable new prion diseases (iatrogenic CJD and possible human chronic wasting disease (CWD)). In 2018, results of a study by researchers in Canada and Germany supported concerns that CWD may pose a risk to human health. The

researchers reported that CWD was transmitted to cynomolgus macaques that were fed infected brain or muscle tissue from infected elk or deer. CWD has been identified in free-ranging cervids in increasing numbers of states (31 states as of 2023) and is regularly found in new areas. Once CWD is present in an area, it is difficult or impossible to eradicate. Prion disease surveillance data is also used in the assessment of the efficacy of ongoing U.S. prevention measures. Many clinicians and public health personnel have little experience dealing with prion diseases; funding of surveillance personnel at state health departments helps these departments to work more closely with CDC in developing and disseminating knowledge about prion diseases and enhancing prion disease surveillance.

b. Purpose

Human prion disease surveillance serves to provide a better understanding of this illness and the prions that appear to cause it. The purpose of this project is to maintain and enhance surveillance for Creutzfeldt-Jakob disease (including sporadic, iatrogenic, and genetic) as well as to detect the possible emergence of new forms of human prion disease such as variant CJD (vCJD) and possibly human CWD. Human prion disease surveillance is critical for the early detection of any new prion disease as well as monitoring for the occurrence of previously described rare classic forms of prion disease attributable to medical procedures. A sensitive human prion disease surveillance system can also help determine whether efforts and expenditures made to reduce and minimize exposures are adequate. For prion diseases, particularly for recognition of new human prion diseases, brain autopsies constitute the "gold standard" for confirmation of diagnoses. Hence, CDC currently pays the National Prion Disease Pathology Surveillance Center (NPDPSC) to provide U.S. clinicians and public health surveillance personnel access to, free-of-charge, state-of-the-art prion disease diagnostic autopsy services. NPDPSC also performs the Real-time Quaking-Induced Conversion (RT-QuIC) test, typically using a cerebral spinal fluid specimen, which, when positive, is highly indicative of the presence of prion disease.

c. Outcomes

- Outcome 1: Follow-up investigations of all suspected CJD or clinically diagnosed cases reported to the state department of health, especially for high priority cases: cases in persons less than 55 years of age; cases in hunters of cervids or consumers of venison from free ranging deer; reported case clusters of concern to the public; suspected iatrogenic cases.
- Outcome 2: Effective coordination and exchange of information and data between state health departments, NPDPSC, the CJD Foundation, and CDC.
- Outcome 3: Development of an effective collaborative network between pathologists, neurologists, funeral and mortuary directors, and other appropriate professionals within the state dealing with persons diagnosed with human prion disease and distribute educational materials about CJD surveillance and the role of state health departments, CDC, and NPDPSC.
- Outcome 4: Effective coordination and exchange of information and data between the state departments of health and wildlife/natural resources.
- Outcome 5: Complete reporting of all suspected CJD cases to CDC through a bi-annual line list of cases, including those with a positive or indeterminate RT-QuIC result.

Funding Strategy:

Funds should be used for personnel, supplies, travel, and other requisite support to enhance prion disease surveillance within the recipient's jurisdiction.

- Estimated total availability of funds: $400,000–$500,000
- Approximate number of awards given: 6
- Approximate average per award: $70,000

***Please note:**

1. For State Health Departments (SHDs), when entering budget requests, recipients must use the 'Public Health Allocation' to indicate the portion of financial support going towards 'Local/Regional Health Department (LHD) support versus staying at the SHD level. This allocation data helps ELC answer inquiries regarding the financial support to LHDs which is crucial given the important role LHDs have in addressing infectious diseases.
2. For Local Health Departments (LHDs), when entering budget requests, please ensure the 'Public Health Allocation' is set to 100% 'Local/Regional Health Department (LHD) support.
3. For Territorial Health Departments, if you have local/regional jurisdictions, please follow the instructions for State Health Departments in #1.

Required Tasks:

1. Promptly report cases of interest to CDC. Examples of higher priority cases of suspected prion disease include suspected cases in persons <55 years of age, cases in hunters of cervids or consumers of venison from free ranging deer, suspected cases of variant CJD or possible human CWD, suspected iatrogenic cases, and suspected case clusters.

2. Submit bi-annual (July and January) line list report of all persons with a suspected or confirmed diagnosis of CJD, indicating which reports your project area accepts as a case (i.e., definitive, probable, possible, neurologist diagnosed). For each case submitted, the following information should be included: a) Year of death (exact date when possible), b) State of residence, c) Sex, d) Age, e) Date of birth, f) CJD Status, g) Was the case diagnosed by a neurologist?, h) Is the case still under investigation? If yes, please explain, i) Was CJD noted on the death certificate?, j) Was an Autopsy performed?, k) Was a Biopsy performed?, l) RT-QuIC result, m) Were specimens sent to NPDPSC?, n) Were specimens sent to another laboratory?, o) Were clinical data for cases < 45 years of age sent to CDC?, p) Was the CJD Surveillance Report Form completed for cases < 55 years of age?). For RT-QuIC positive/indeterminate persons lacking neuropathologic confirmation, report the following: date of death (if applicable), discharge/death certificate diagnoses, and, if still alive, current status (i.e., diagnosis, location (e.g., transferred to another institution (name if available), lost to follow-up)).

3. Participate in calls with CDC/other funded sites.

4. Work collaboratively with the National Prion Disease Pathology Surveillance Center at Case Western Reserve University by maintaining regular contact including at least twice-yearly phone or email contact.

Strategies and Activities:

Area A: Surveillance, Detection, and Response

1) Enhance investigation, response, and reporting

a) *Actively investigate all cases of suspected prion disease in state residents*

i) Track the number of suspected cases of prion diseases (i.e., meeting the case definition (possible, probable, or definite) or physician-diagnosed) for which autopsy or biopsy was conducted.

ii) Submit line list of persons reported with suspected prion disease to CDC at least twice a year.

iii) Refer out-of-state cases to the health department of patient's residence.

iv) Use surveillance data to inform prion disease-related strategies and recommendations within the state.

☒ Required ☐ Optional

b) *Investigate all high priority suspected prion cases within 2 weeks of report.*

i) Examples of higher priority cases of suspected prion disease include suspected cases in persons <55 years of age, cases in hunters of cervids or consumers of venison from free ranging deer, suspected cases of variant CJD or possible human CWD, suspected iatrogenic cases, and suspected case clusters.

ii) Submit to CDC the pertinent portions of the medical record for the highest priority cases of suspected prion disease in persons less than 45 years of age, or whenever variant CJD or possible human CWD is suspected, or whenever an unusual mode of transmission is suspected. (Medical records for persons 45 – 55 years of age are not required to be submitted unless an exogenous source of infection is suspected.) Pertinent sections of the medical record include: the admission summary, discharge summary, EEG reports, MRI reports, neurology consultation notes, psychiatry consultation notes, pathology reports from a biopsy, and pathology reports from autopsy.

iii) Attempt to ascertain whether the case hunted (deer, elk, or moose) or consumed venison. If so, attempt to determine when and where the hunting occurred or from where the venison was harvested.

☒ Required ☐ Optional

c) *Cross check data sources to ensure all cases are identified in project area.*

i) Specifically, access State Vital Statistics' death certificate data looking for specific codes or terms appearing anywhere on the death certificate.

ii) Specific codes/terms to search for are: ICD-9 046.1 for deaths before 1999; ICD-10 A81.0 for deaths from 1999 to the present, 'jakob', 'jacob ', 'creutz', 'crutz', 'critzfield', 'cjd', 'spongiform', 'spongioform', 'spongeform', 'sponaiform', 'tse', 'prion, 'gss', 'gerstman', 'gertsman', 'straussler', 'strausler','scheinker', 'ffi', 'familial insomnia', 'familial fatal insomnia', 'sfi', 'sporadic fatal insomnia'

☒ Required ☐ Optional

Area C: Communication, Coordination, and Partnerships

2) Advance policies to improve public health capabilities

a) Utilize surveillance to better inform health professionals and the public.

☒ Required ☐ Optional

b) Obtain scientific data to support evidence-based and cost-effective policies.

☒ Required ☐ Optional

3) Coordinate and engage with partners

a) Work collaboratively with the state wildlife/natural resources department.

i) Ascertain the degree of CWD surveillance within the state, conduct chronic wasting disease related education and consider other activities aimed at persons who hunt within the state and those who consume venison provided by hunters.

ii) In areas where chronic wasting disease is endemic, inform/educate hunters about this disease in cervids and how to protect themselves from possible exposure to the disease agent.

☒ Required ☐ Optional

b) Identify facilities that can perform brain autopsy for suspected prion cases.

☒ Required ☐ Optional

c) Develop relationships with the CJD Foundation or comparable patient groups.

i) Enhance collaborative work to educate and provide assistance to family members of persons affected by prion diseases.

☒ Required ☐ Optional

d) Conduct outreach with hospitals/facilities caring for prion disease patients.

i) Educate caregivers, including family members and medical personnel, about prion disease-related infection control issues and about the importance of prion disease surveillance and confirming clinically suspected cases.

☒ Required ☐ Optional

e) Work collaboratively with appropriate professionals in the state.

i) Work with pathologists, neurologists, funeral and mortuary directors, and other appropriate professionals to ensure these professionals are aware of the state's prion disease surveillance system as well as the prion disease-related resources available to support them, including at CDC, the National Prion Disease Pathology Surveillance Center, the state health department and the CJD Foundation.

☒ Required ☐ Optional

f) Disseminate data and information on human prion disease within the state.

i) Disseminate data via reports, workshops, grand rounds, etc.

☒ Required ☐ Optional

g) Provide education to infection control practitioners/other relevant staff.

i) Explain the importance of appropriate infection control regarding human prion diseases.

☒ Required ☐ Optional

Collaborations:

a. With CDC-Funded Programs

Recipients funded through ELC for enhanced prion surveillance will actively collaborate with CDC, other funded sites, and the CDC (NCEZID/DHCPP/PPHO)-funded National Prion Disease Pathology Surveillance Center (NPDPSC) located at Case Western Reserve University.

Recipients should provide referrals to the CJD Foundation to educate and assist family members of persons affected by prion diseases. CDC (NCEZID/DHCPP/PPHO) partially funds this Foundation.

b. With Organizations External to CDC

Recipients will collaborate with health care facilities within the state that are able to perform brain autopsy on persons suspected of, or clinically diagnosed with, a prion disease.

When applicable, health departments funded for enhanced prion surveillance through ELC are asked to work collaboratively with state wildlife/natural resources to conduct chronic wasting disease related education and other activities aimed at persons who hunt within the state and those who consume venison provided by hunters.

Populations of Focus:

Clinicians who see suspected and diagnosed cases of human prion disease, infection control personnel in hospitals, others in the community who work with patients suspected of having or diagnosed with a human prion disease and their families. When applicable, hunters and consumers of venison.

Evaluation and Performance Measurement:

Performance measures included here are representative and may not be final at the time of NOFO publication. Please see the CK-24-0002 Performance Measure Guidance document for all final measures and descriptions.

a. ACTIVE Performance Measures

1) Number of cases of suspected prion disease received via surveillance (by reporting source) and the number of investigations conducted.

2) Number of suspected and clinically diagnosed cases of prion disease for which a brain biopsy or brain autopsy was conducted. (If possible human CWD is suspected, tissues other than brain may be requested.)

3) Number of suspected or confirmed cases of CJD in a person less than 55 years of age, suspected cases of variant CJD or possible human CWD, suspected iatrogenic cases, and suspected case clusters reported to CDC within two weeks of the report to the state department of health; for those less than 45 years of age and for

each of the other above investigations: the number of persons for whom the pertinent portions of the medical record were submitted to CDC.

4) Number of suspected cases of CJD identified through at least annual review of death certificate data or other data sources; the number of newly identified cases found by this review; the number of cases identified through surveillance that did not indicate CJD on the death certificate; and If possible, for those cases, where CJD was not indicated on the death certificate, what was listed as the cause and underlying cause of death.

5) For awardees where CWD has been identified: Number of meetings with wildlife/natural resources department to conduct CWD-related education and other activities aimed at persons who hunt within the state and those who consume venison provided by these hunters.

b. PASSIVE Indicators

Not applicable

Project M: Mycotics: Detecting and Preventing Fungal Infections

Program Activity Contact Information:

Ashleigh Passafume, uau6@cdc.gov, 404-639-5260
Lynette Benjamin, bil0@cdc.gov, 404-639-5475
Tom Chiller, tnc3@cdc.gov, 404-639-4753

Funding Opportunity Description:

a. Overview

The Mycotics activities are intended to help prevent disability and death as a result of fungal infections by improving state and local health departments' capacity to:

- Conduct surveillance for nationally notifiable fungal diseases through existing reporting systems, such as CDC's National Notifiable Diseases Surveillance System (NNDSS)
- Conduct enhanced surveillance (e.g., patient interviews, medical chart reviews) for some priority fungal diseases through a new national fungal disease surveillance program, FungiSurv. Pathogens may differ from jurisdiction to jurisdiction based on location, disease burden, etc. Examples of priority fungal diseases could include:
  - **Endemics**: Key endemic mycoses like coccidioidomycosis (Valley fever), histoplasmosis, and blastomycosis
  - **Antimicrobial-resistant fungi***: Some examples include the emerging pathogen *Candida auris* and azole-resistant *Aspergillus fumigatus*
  - **Mold**: Surveillance for invasive mold infections like invasive aspergillosis and mucormycosis
  - **Other emerging fungal diseases**: including Zoonotic infections such as cat-associated sporotrichosis
- Enhance laboratory capacity for fungal diseases
- Improve fungal disease outbreak tracking and response
- Engage with clinicians and the public to improve awareness of fungal diseases, which are frequently neglected, to save lives by early detection

*Provided that activities are not covered by a different section of ELC

b. Health Equity

Activities described in Overview could be used to identify and monitor trends in health disparities related to fungal infections, ultimately to inform efforts to mitigate disparities. Partners are encouraged to engage in educational and outreach opportunities to educate underserved communities about fungal health disparities, specifically culturally and linguistically materials about prevention, signs, and symptoms.

c. Healthy People

- EH-22 – Environmental health objective. Increase the number of States, Territories, Tribes, and the District of Columbia that monitor diseases or conditions that can be caused by exposure to environmental hazards
- HAI-1 – Healthcare-associated infection objective. Reduce central line-associated bloodstream infections (CLABSIs)

d. Local Health Department and Tribal Engagement

When appropriate and as needed, recipients should engage with local health departments and tribes to accomplish specific surveillance objectives (e.g., investigation of cases of interest).

e. Other National Public Health Priorities and Strategies

N/A

CDC Project Description:

a. Problem Statement

Pathogenic fungi are found throughout the environment and cause a broad spectrum of illness, including community-acquired respiratory diseases, healthcare-associated infections, and opportunistic infections in persons with immunocompromising conditions. Fungal diseases cause substantial morbidity and mortality but are often overlooked and misdiagnosed. Improved surveillance can guide efforts to prevent exposures, detect concerning trends, and improve early diagnosis. Several fungal diseases of particular concern are described below:

- Endemic mycoses, including coccidioidomycosis (Valley fever), histoplasmosis, and blastomycosis, are common causes of respiratory infections in certain U.S. regions. These infections, usually acquired from soil and other environmental exposures, are frequently misdiagnosed as acute viral respiratory infections or community-acquired pneumonia. Because many patients with these infections are misdiagnosed as bacterial pneumonia, they receive multiple courses of antibacterial drugs that are ineffective against fungal infections. Delayed antifungal treatment and inappropriate antibacterial therapy may lead to worse outcomes for patients. Each endemic mycosis can cause severe and invasive disease, and has caused large outbreaks, including among non-immunocompromised hosts.
- Antifungal resistance among *Candida* spp. is a growing problem worldwide, especially for certain species and with limited antifungal drugs available for treatment. In particular, *Candida auris* is an emerging drug-resistant yeast that spreads easily in healthcare facilities and can cause severe, invasive infections associated with high mortality. Preventing the spread of *C. auris* requires intensive public health response and adherence to appropriate infection control measures.
- *Aspergillus fumigatus* can cause severe invasive infections in person with weakened immune systems. Azole drugs are the first line treatment for invasive aspergillosis, and the emergence of azole-resistant *A. fumigatus* in the United States poses a concerning public health threat. Infections with azole-resistant *A. fumigatus* are an important cause of illness in Europe, but the burden is poorly understood in the United States. The development of azole-resistant *A. fumigatus* has been linked to the agricultural and other environmental use of azole fungicides. Other invasive mold infections, such as mucormycosis, also have high mortality. Such infections can be acquired in the community or in healthcare settings.
- Ringworm (a.k.a., tinea, dermatophytosis) is a common (estimated global prevalence ~25%), highly contagious, superficial infection of the skin, hair, or nails caused by dermatophyte molds. It spreads easily by skin-to-skin contact with infected animals or persons, secondary spread from other affected body sites, and fomites. Most skin infections are localized and resolve with topical antifungal treatment, and oral antifungal therapy is generally reserved for cases that do not improve with topical treatment or those with extensive disease or infection of the hair follicles. However, antimicrobial-resistant ringworm is an emerging public health concern in the United States. The epidemiology is poorly understood, and surveillance is lacking.

b. Purpose

The purpose of this project is to strengthen state, local, and tribal health department epidemiologic and laboratory capacity to detect and prevent fungal diseases. Specifically, this project aims to:

- Strengthen epidemiologic data on fungal diseases by ensuring reporting of nationally notifiable or reportable fungal diseases through existing reporting systems. For nationally notifiable fungal diseases, this would ideally include completion of pathogen-specific message mapping guide, but at a minimum would include reportable data elements for NNDSS as outlined in the Generic v2 message mapping guide.
- Strengthen epidemiologic data on endemic mycoses, *C. auris,* and invasive mold infections (including those involving strains triazole-resistant *A. fumigatus*) by implementing enhanced surveillance to guide prevention efforts (including targeted outreach) and to improve early diagnosis and treatment. Participation would involve piloting enhanced surveillance efforts, possibly including in-depth chart review, patient interviews, and retrospective microbiology look-backs depending on the priority pathogen.
- Enhance laboratory fungal testing and identification capacity.
- Strengthen environmental sampling for fungal pathogens to inform public health measures.

c. Outcomes

1. Improved tracking and epidemiologic data on known and emerging fungal diseases, including coccidioidomycosis, histoplasmosis, blastomycosis, *C. auris*, and invasive mold infections. Comprehensive data on fungal diseases will enable analyses to understand the impacts of climate change and health inequities, as well as the geographic spread, temporal trends, environmental and healthcare exposures, patient and occupational risk groups, clinical outcomes, and potential exposure sources. These analyses will guide prevention measures aimed at reducing morbidity and mortality from fungal infections.
2. Improved tracking, lab detection and epidemiologic data on fungal disease outbreaks.
3. Increased healthcare provider and public awareness of fungal infections and their diagnosis and treatment (e.g., via local outreach, reports, and participation in Fungal Disease Awareness Week activities).
4. Improved laboratory detection of pathogenic fungi.

Funding Strategy:

- Funds should be utilized for personnel, travel, supplies, equipment, or contractual support for proposed activities.
    - Estimated total availability of funds: $2,000,000
    - Estimated number of awards given: 40
    - Estimated average per award: $5,000–$100,000

  We estimate ~15 awards up to $10,000; ~10 awards between $10,000 and $25,000; ~10 awards between $25,000 and $50,000; and ~5 awards above $50,000.

***Please note:**

1. For State Health Departments (SHDs), when entering budget requests, recipients must use the 'Public Health Allocation' to indicate the portion of financial support going toward 'Local/Regional Health Department (LHD)' support versus staying at the SHD level. This allocation data helps ELC answer inquiries regarding the financial support to LHDs which is crucial given the important role LHDs have in addressing infectious diseases.
2. For Local Health Departments (LHDs), when entering budget requests, please ensure the 'Public Health Allocation' is set to 100% 'Local/Regional Health Department (LHD)' support.
3. For Territorial Health Departments, if you have local/regional jurisdictions, please follow the instructions for State Health Departments in #1.

Required Tasks:

1. Acceptance of funding conveys acknowledgement and indication that the following requirements will be met. Provide a revised workplan following the Notice of Award.
2. Work with Mycotic Diseases Branch staff to ensure completeness and timeliness of nationally notifiable disease data for fungal diseases.
3. Participate in twice yearly Mycotics Webinars. Volunteering to present on these webinars is encouraged.
4. Participate in relevant fungal topic-based public health calls (i.e., endemic mycoses, *C. auris*, and invasive mold infections) to share current practices and challenges encountered.
5. For those participating in enhanced surveillance efforts (i.e., FungiSurv), submitting case report forms and data quality checks in agreed-upon format and cadence.

Administrative

1. Identify at least one designated point of contact(s).
2. Participate in three touch base calls throughout the budget period---kickoff, mid-line, and end-line and ad-hoc calls as they relate to the administrative pieces of the project.
3. Complete, sign, and return project governing documents, such as: Memorandum of Understanding (MOU) and Terms of Reference (TOR) document, Rules of Behavior (RoB) and Non-Disclosure Agreement (NDA) documents, as needed.

Surveillance, Outbreak Detection, Response, and Control

1. Collaborate with Area/Regional/Reference/CDC laboratories for troubleshooting issues and other issues affecting network function.
2. Submit samples/isolates to Regional/Area labs or CDC for testing with appropriate documentation.
3. Regularly coordinate and share information and apply data-sharing tools among epidemiology, laboratory, and environmental health.

https://www.cdc.gov/nors/downloads/guidance.pdf

Strategies and Activities:

0) Strategy to Address Required Tasks

a) Address Required Tasks in project guidance.

☐ Required ☒ Optional

Area A: Surveillance, Detection, and Response

1) Improve surveillance and reporting

a) Use CSTE case definitions to conduct surveillance for fungal diseases and report nationally notifiable fungal diseases (i.e., Valley fever, Candida auris) to NNDSS for jurisdictions in which they are reportable.

☒ Required ☐ Optional

b) Conduct enhanced surveillance through FungiSurv to better characterize patient characteristics, diagnostics used, clinical illnesses, and possible exposures.

i) Endemics: Complete case report form via patient interviews and limited medical chart review for endemic mycoses under surveillance (e.g., coccidioidomycosis, histoplasmosis, blastomycosis) on a subset of reported cases.

ii) Antimicrobial-resistant fungi: For jurisdictions with ongoing transmission of *C. auris*, complete case report form for *C. auris* cases based on medical chart reviews.

iii) Mold: Develop surveillance for invasive mold infections (e.g., invasive aspergillosis, mucormycosis), including completion of case report forms based on medical chart reviews.

iv) Other fungal infections, such as antimicrobial-resistant dermatophytes, chromo, sporo, etc.

☐ Required ☒ Optional

c) Report to NORS all reportable outbreaks as defined in NORS user guidance, including data for environmental health, contributing factors, interventions, and preventative measures., including data for environmental health, contributing factors, interventions, and preventative measures.

☐ Required ☒ Optional

d) Collaborate with CDC on data cleaning and closeout activities.

☐ Required ☒ Optional

2) Enhance investigation and outbreak response

a) Respond to and/ or participate in fungal outbreak investigations. Report findings to CDC. For endemic mycoses outbreaks, report via the National Outbreak Reporting System (NORS).

i) Key tasks include: collecting and sharing case data with CDC (e.g., case counts, detailed exposure history, demographics such as race and ethnicity, patient treatment and outcomes) participating in multistate analytic epidemiologic investigations and conducting analytic investigations of localized illness sub-clusters.

ii) Implement appropriate control measures based on cluster and outbreak investigations.

☐ Required ☒ Optional

b) Collaborate with CDC and other relevant jurisdictions to provide epidemiology and laboratory technical support for multi-jurisdictional investigations, outbreaks, and emergency preparedness activities during investigation of national and international outbreaks and other public health activities.

i) Federal governmental entities,
ii) Healthcare facilities
iii) Other entities as deemed necessary

☐ Required ☒ Optional

c) Contain or prevent the spread of antifungal-resistant fungal pathogens where not otherwise covered through other ELC activities, *i.e.*, Program M.

☐ Required ☒ Optional

3) Enhance laboratory testing for surveillance and reporting

a) Establish or enhance fungal testing capacity. Priorities include developing capacity to perform (1) MALDI-ToF to identify pathogenic molds and dimorphic fungi and (2) testing for endemic mycoses.

☐ Required ☒ Optional

b) Conduct environmental sampling for fungal pathogens to inform public health measures.

☐ Required ☒ Optional

4) Enhance workforce capacity

a) Recipients are encouraged to apply under this activity to send laboratory personnel to participate in MDB training opportunities to improve laboratory detection of fungal infections.

i) Attend the CDC Mycotic Diseases Branch - Mold Identification Course.

ii) Travel to CDC for specific 1:1 training for fungal identification procedures such as DNA sequencing, MALDI-TOF, or serology.

☐ Required ☒ Optional

Area C: Communication, Coordination, and Partnerships

5) Implement public health interventions and tools

a) Disseminate health promotion materials for healthcare providers to promote prompt diagnosis and testing and for the public to increase health literacy about fungal disease prevention (*e.g.*, participate in national Fungal Disease Awareness Week activities, share fungal disease educational materials). Level of participation will vary based on resources available.

☐ Required ☒ Optional

6) Enhance communication, promote coordination, and develop partnerships

a) Develop and maintain strategic partnerships with diverse partners (including public health, industry, community, institutional, and other prevention partners) to support surveillance, and investigations

☐ Required ☒ Optional

b) *Collaboratively identify and implement evidence-based interventions to reduce illnesses in high-risk settings (e.g., correctional institutions, long-term care facilities, and daycares) or populations*
☐ Required ☒ Optional

c) *Disseminate public health information include presenting or disseminating surveillance and/or outbreak summaries to relevant stakeholders (this includes public webpages, newsletters, conferences, publications) at least once per year*
☐ Required ☒ Optional

Collaborations:

a. With CDC-Funded Programs

Applicants should describe participation in the Antibiotic Resistance Lab Network (ARLN) http://www.cdc.gov/drugresistance/solutions-initiative/ar-lab-network.html for *Candida* and *Aspergillus fumigatus (e.g.,* involvement in coordinating isolate transfer to a regional laboratory, recruitment of isolates from clinical laboratories, or participation as a regional laboratory).

Please note that Mycotics funding for *C. auris* is dedicated to enhanced surveillance data collection, as response efforts and laboratory testing are covered under broader funding for multidrug-resistant organisms provided elsewhere. Specific response efforts covered by the ARLN in ELC Program I include *C. auris* colonization testing, *Candida* ID isolate testing, and *C. auris* whole-genome sequencing (FungiNet).

b. With Organizations External to CDC

- Partnerships with clinical laboratories and healthcare organizations can improve public health surveillance and early diagnosis.
- Applicants may wish to collaborate with other state health departments, academic institutions, and other non-governmental organizations (*e.g.*, community partners) in developing and disseminating fungal disease awareness materials.

Population(s) of Focus:

Fungal diseases can affect a wide range of people. Endemic mycoses can cause disease in nearly anyone exposed and pose an even higher risk for outdoor workers in endemic areas. Immunocompromised persons or those with prolonged or frequent healthcare encounters are at greater risk than the general population for nearly all systemic fungal infections, particularly those caused by *Candida* and *Aspergillus*.

Evaluation and Performance Measurement:

Performance measures included here are representative and may not be final at the time of NOFO publication. Please see the CK-24-0002 Performance Measure Guidance document for all final measures and descriptions.

a. ACTIVE Performance Measures

Measure M.1: Annual Percentage Increase in Reported Cases and Incidence Rate Surveillance for Targeted Fungal Diseases

Measure M.2: Number of fungal disease clusters and outbreaks detected, and number and % tracked and reported through NORS or by any other means.

Measure M.3: Number and types of educational interactions (presentations, dissemination of printed materials, poster presentation, workshops, Grand Rounds, etc.)

Measure M.4: Number of Accurate Fungal Pathogen Identifications Out of Total Identifications

b. PASSIVE Indicators

Measure M.1: Percentage Completion of Minimum Reportable Data Elements for Fungal Disease Outbreaks in Electronic Reporting Platforms

Measure M.2: Fungal Infection Awareness Campaign Reach and Engagement

Measure M.3: For jurisdictions that opt-in for FungiSurv: Number of fungal disease cases reported, and number and % of medical chart reviews and patient interviews completed.

Measure M.4: For jurisdictions that received laboratory related Mycotics funding: Description of implementation of fungal laboratory capacity (could include SOP, protocols, environmental sampling results, etc.).

Project N: Binational Border Infectious Disease Surveillance (BIDS)

Program Activity Contact Information:

DGMH Coordinator: Gwendolyn O'Neal, gbr8@cdc.gov, 404-639-7871; Technical POC: Alba Phippard, ign7@cdc.gov, 619-206-0461

Funding Opportunity Description:

a. Overview

The Binational Border Infectious Disease Surveillance (BIDS) Program was established to foster local, state, and federal collaboration to improve surveillance and control strategies for infectious diseases of binational importance and to advance health equity among mobile populations in the United States-Mexico border region. Mobile populations of interest include: US-Mexico border–crossing populations and their networks; residents of the border region at risk for diseases of binational concern, migrant farmworkers, and migrants transiting through Central America and Mexico to the U.S.-Mexico border region.

b. Health Equity

As part of the CDC's commitment to addressing racism as a serious threat to the public's health, BIDS activities aim to improve health equity. BIDS activities should focus on U.S.-Mexico border-crossing populations and their networks, migrants (crossing the land-border through Mexico to the U.S.), and residents of the U.S.-Mexico border region at risk for diseases of binational concern; strategies may include a focus on foreign-born Latino populations, Spanish speakers with limited English proficiency, or other binational groups that have been economically and/or socially marginalized. These efforts also align with the HHS Equity Action Plan and the HHS Office of Minority Health Strategic Framework.

c. Healthy People

The BIDS Program supports the Healthy People 2030 overarching goals to: 1) attain healthy, thriving lives and well-being free of preventable disease, disability, injury, and premature death, 2) eliminate health disparities, achieve health equity, and attain health literacy to improve the health and well-being of all, and 3) engage leadership, key constituents, and the public across multiple sectors to take action and design policies that improve the health and well-being of all.

BIDS furthers the Healthy People 2030 specific goals:

- Reduce sexually transmitted infections and their complications and improve access to quality STI care.
- Improve health by preventing, detecting, and responding to public health events worldwide.
- Reduce rates of infectious diseases and improve health for people with chronic infections.
- Make sure public health agencies at all levels have the necessary infrastructure for key public health services.
- Reduce foodborne illness.
- Reduce sexually transmitted infections (STI) and their complications and improve access to quality STI care.

d. Local Health Department and Tribal Engagement

Close collaboration with local and tribal border region health departments is highly encouraged to address border region mobile populations.

e. Other National Public Health Priorities and Strategies

BIDS binational surveillance activities also support the National Action Plan for Combating Antibiotic Resistant Bacteria 2020-2025 by improving international collaboration to detect, monitor and reduce antibiotic resistance in the border region.

CDC Project Description:

a. Problem Statement

Numerous binational infectious disease outbreaks, including vector-borne, vaccine-preventable, foodborne, waterborne, mycotic, and mycobacterial diseases have been documented over the last two decades. The U.S.- Mexico border region has unique and dynamic epidemiologic features partly due to the bidirectional population flow across the international land boundary, with approximately 180 million northward crossings each year. Mobile populations and their networks may be at increased risk of infectious diseases with the potential to introduce these diseases into destination communities, and gaps in public health response and access can occur when disease events and outbreaks are binational in nature.

Optimal investigation and control of binational disease cases and outbreaks require enhanced surveillance, quantification of disease burden, epidemiological and laboratory resources and expertise, and collaboration between U.S. and Mexico public health (PH) agencies at all levels to eliminate health disparities and achieve health equity for border and binational communities.

b. Purpose

The purpose of this funding is to improve prevention, detection, reporting, and control of infectious diseases of binational concern in the U.S.-Mexico border region, while supporting and advancing health equity and national security priorities.

Infectious diseases of binational concern are those affecting humans that can be introduced or amplified in the other country by virtue of the movement of people, products, or animals between countries, generally requiring binational coordination to identify, monitor, and control.

c. Outcomes

- Improved binational case surveillance and data sharing through training, resulting in:
  - Improved completeness, accuracy, and representativeness of binational data
- Increased use and improved timeliness of binational data and distribution to public health partners, communities, and other types of partners
- Binational variable and specific binational reporting criteria are used to describe trends and binationality for reportable infectious diseases in border and non-border regions
- Use of data to inform public health response and control U.S.-Mexico border-crossing populations and their networks
- Improved understanding of the epidemiology and incidence of binational infectious disease cases
- Development and implementation of strong public health interventions and tools using a health equity lens

- Engaged and sustained strategic binational and multi-sectorial partnerships to improve awareness, coordination, and exchange of public health information in the border region

Funding Strategy:

Funding to print paper communication and outreach materials will not be approved without clear justification that includes the specific project, purpose, demonstrated need, a description of whether the materials have been tested or validated, and confirmation that there is no other resource or more effective method to disseminate information to the population of focus.

U.S. states that share a border with Mexico are eligible to apply for BIDS funding. Funding may be used for personnel, travel, supplies, equipment, or contractual support for proposed activities. Awards will preferentially support integration of Binational Reporting Criteria (as specified by the Council of State and Territorial Epidemiologists' position statement, 13-SI-02) and related variables into jurisdictions' investigations and electronic disease surveillance systems, operationalization of the Operational Protocol for U.S.-Mexico Binational Communication and Coordination on Disease Notifications and Outbreaks(cdc.gov), and implementation of recommendations made for BIDS by the 2018 US-Mexico Border Disease Prioritization Work Group. These recommendations are available in the Workshop Summary: Infectious Disease Prioritization for Multijurisdictional Engagement at the United States Southern Border Region (cdc.gov). For projects related to a specific infectious disease or technical area, program planning and funding decisions may be administered by the most appropriate state program or office to manage and implement activities, in consultation with the state ELC principal investigator, ELC, and CDC BIDS. Funding recipients will be required to attend a BIDS recipient meeting to be held within the US-Mexico border region. BIDS funds requested for demonstration projects should be considered as seed funding to identify gaps, best practices and engage partners that can sustain project activities after the pilot or demonstration phase.

- Estimated total availability of funds for Project N: **Binational Border Infectious Disease Surveillance (BIDS) Program**: $1,200,000
- Estimated number of awards: 1–4
- Estimated average per award: $100,000–$700,000

***Please note:**

1. For State Health Departments (SHDs), when entering budget requests, recipients must use the 'Public Health Allocation' to indicate the portion of financial support going toward 'Local/Regional Health Department (LHD)' support versus staying at the SHD level. This allocation data helps ELC answer inquiries regarding the financial support to LHDs which is crucial given the important role LHDs have in addressing infectious diseases.
2. For Local Health Departments (LHDs), when entering budget requests, please ensure the 'Public Health Allocation' is set to 100% 'Local/Regional Health Department (LHD)' support.
3. For Territorial Health Departments, if you have local/regional jurisdictions, please follow the instructions for State Health Departments in #1.

Required Tasks:

Acceptance of funding conveys acknowledgement and indication that the following requirements will be met. Related strategy/activity noted in parentheses after Required Task.

1. Attend a yearly BIDS recipient meeting held within the U.S.-Mexico border region.
2. Participate in conference calls with CDC project consultants and twice-yearly BIDS all-state calls.
3. In coordination with CDC's BIDS program staff, provide at least annual program updates to the U.S. Department of Health and Human Services' Office of Global Affairs, US-Mexico Border Health Commission, and the Binational Technical Working Group.
4. Disseminate relevant public health information on ongoing or previous BIDS demonstration projects, assessments, tailored interventions for binational cases or mobile populations through abstracts, reports and publications.
5. Facilitate feedback and collaboration on the US-Mexico Border infectious Disease Dashboard (advising on inclusion of additional state, county level data and other indicators).
6. Collaborate or facilitate participation with CDC on a border-wide tuberculosis (TB) gap analysis to provide technical feedback from subject matter experts at the local, regional, state level as needed.
7. Reinforce local health department notifications of persons who were infectious during travel through the land ports of entry to CDC quarantine stations in accordance with 2020 CSTE Guidance for Health Departments Notification to CDC Quarantine Stations.
8. Recipients should develop an implementation plan in the first quarter, and a report of key findings by the end of the project period, for submission to CDC BIDS program for each optional activity proposed (2a, 2b, 3a, 3b, 4b and 4c).
    i. For activities 1d and 1e, recipients should develop *implementation plans with quarterly milestones and description of how outcomes or findings will be monitored or reported within the first quarter.*

Strategies and Activities:

1. For Strategy 1, activities (a), (b), and (c) are required, along with at least one of the two optional activities, (d) or (e).
2. For Strategy 4: activity (a) is required.

0) Strategy to Address Required Tasks

(a) *Address Required Tasks in program/project guidance.*

☐ Required ☒ Optional

Area A: Surveillance, Detection, and Response

1) Improve surveillance, reporting, investigation, preparedness, and response

a) Evaluate the integration and use of the Binational Reporting Criteria variable.

i) Collaborate with CDC BIDS program to evaluate the integration and use of the Binational Reporting Criteria variable (BRC variable, AKA Binational Variable) in border states.

ii) A binational case is defined as a case in which one or more of the binational reporting criteria have been met. These criteria should be used to identify the nature of the binational nexus of the cases. The Binational Reporting Criteria, as defined in NNDSS, are:

- Potentially exposed while in Mexico or Canada

- Potentially exposed by a resident of Mexico or Canada
- Resident of Mexico or Canada
- Has case contacts in or from Mexico or Canada
- Exposure to suspected product from Mexico or Canada
- Other situations that may require binational notification or coordination of response

☒ Required ☐ Optional

b) Train state and local staff on the use of the BRC and related variables

i) Develop plan(s) for providing periodic, on-demand, and asynchronous training to expand reach and reduce staff training burden. May include recordings or other content and plans for regularly reaching case investigators and epidemiologists at state, regional and local forums.

ii) Develop/integrate specific instructions for the BRC and related variables into disease case investigation guide. Related variables include Country of Exposure, Country of Usual Residence, and Country of Birth.

☒ Required ☐ Optional

c) Assess the actionability of binational cases*.

i) Develop a process to assess and document the actionability* of binational cases, facilitate the timely** notification of actionable cases and outbreaks to Mexico, and assess and document the outcomes of reporting the binational cases and outbreaks. The binational case report outcomes (mutually exclusive) categories are: 1) known public health follow-up in Mexico, 2) binational collaboration on investigation or cluster/outbreak and 3) unknown public health follow-up in Mexico. Recipients should describe methods for determining actionability of notifications.

ii) *Case reports may be considered actionable if they are **timely** and contain **sufficient information** to pursue public health action for cases and contacts

iii) **The recipient may define timely notification, as a report made within the time period for public health intervention. Recipients may use more specific definitions of timeliness, e.g., timeliness **by disease** according to incubation period, days elapsed after exposure or post exposure prophylaxis, vaccination for contacts, etc.

iv) Incorporate guidance on elements of timeliness and actionability into binational protocols for binational case notification.

☒ Required ☐ Optional

(Either activity 1d or 1e is required)

d) Address infectious disease surveillance gaps among mobile/border populations

i) Implement or enhance human infectious disease surveillance that addresses documented or identified surveillance gaps among mobile populations or in border region areas affected by cross-border population mobility.

ii) Recipients are required to develop a plan to with quarterly milestones and description of how outcomes or findings will be monitored or reported within the first quarter.

iii) The state may prioritize surveillance activities for diseases (tuberculosis, dengue, chikungunya, Zika, vibriosis, listeriosis, non-typhoidal salmonellosis and brucellosis, Spotted Fever Group rickettsioses, murine typhus) as recommended by the Infectious Disease Prioritization for Multijurisdictional Engagement at the U.S. Southern Border Region, as appropriate. If no specific surveillance gaps have been identified, recipients may conduct formative work to identify potential gaps, see section 1 (e) below.

iv) Enhanced surveillance activities include activities beyond those routinely conducted, e.g., conducting laboratory testing on a greater number or broader scope of patients, laboratory testing not usually performed (e.g., genotyping), or collecting additional exposure information during a case interview, not typically collected. Some examples include:

(a) Surveillance for antibiotic resistance in TB, enteric pathogens, or sexually transmitted infections among mobile populations.
(b) Influenza-like illness (ILI)/severe acute respiratory infections (SARI) surveillance with laboratory testing among mobile populations or in regions with documented gaps or limited coverage. Surveillance methods should be consistent with BIDS border-wide protocol.

☐ Required ☒ Optional

e) Conduct formative work to inform surveillance opportunities

i) Identify gaps in disease surveillance among specific border populations. Examples of such populations include day laborers in border region occupations, farmworkers, and transiting migrants. Surveillance gaps could for example relate to cases classified as non-countable due to residency or other criteria.

ii) Recipients are required to develop a plan for formative work with quarterly milestones and description of how outcomes or findings will be monitored or reported within the first quarter.

☐ Required ☒ Optional

2) Support collection and reporting of actionable border data to advance health equity.

a) Enhance data collection for binational/mobile populations.

i) This may include collecting data for binational/mobile populations on mobility, access to care, or other data elements impacting health equity. Some options are:

ii) Conduct representative surveys of border-region mobile populations. Recipients are encouraged to publish reports/manuscripts on the findings to document data gaps, promote promising strategies and advocate for sustainable resources to address inequities

and gaps. Recipients are encouraged to use standardized and validated survey questions and to collaborate with BIDS and other CDC programs (e.g., CDC National Center for Health Statistics [NCHS] Collaborative Center for Questionnaire Design and Evaluation Research) to evaluate key questions before conducting assessments.

iii) Collaborate with CDC, Health Resources and Services Administration, migrant health centers, and other agencies or organizations as needed to develop and pilot test strategies for infectious disease surveillance and tracking of vaccination coverage for migrant and seasonal farmworkers through data sharing with public health agencies. Budget request may include staff time to coordinate with clinics and manage data.

iv) Assess and document burden of notifiable infectious diseases and adoption of preventive measures (e.g., vaccinations) among migrants, (including asylum seekers, parolees, and irregular migrants). These can include developing possible solutions for regularly aggregating data collected by organizations or agencies serving these populations for analysis and situational awareness, drafting protocols, developing reports documenting disease burden, and potentially suggesting new surveillance system/methods. Examples of such activities may include identifying or reviewing migrant movement and notification processes to establish or strengthen mechanisms for public health notifications and sharing of aggregate health screening and other relevant data. Collaborative partners may include Department of Homeland Security (DHS) agencies as well as other organizations running migrant shelters.

☐ Required ☒ Optional

b) Conduct demonstration projects related to disease control or data collection

i) Plan and develop demonstration projects to gain evidence on promising practices or methods for disease control or data collection. Recipients can focus on the US Southern Border Region prioritized infectious diseases or other diseases affecting border populations. These should be considered pilot projects to test and expand the evidence base for methods or interventions. Recipient are encouraged to engage relevant and interested partners that can sustain the activities after the pilot phase. For example,
   (a) Explore promising practices for conducting binational contact investigations (CI) (e.g., collaborate with Mexico to enhance binational TB CI, or collaborate with travel and binational partners to identify and establish mechanisms for collecting and sharing contact information for land travelers on international buses).

☐ Required ☒ Optional

3) Implement public health interventions and tools

a) Implement interventions to address health inequities through disease control.

i) Interventions should address gaps in disease control to reduce health disparities among populations of focus. Proposal may include pilot testing. Examples include:

(a) Improve educational approaches for people who leave DHS custody before completing treatment for or after exposure to a communicable disease.
(b) Validate existing educational/outreach resources/messages used for populations of focus, testing for accuracy, cultural appropriateness, and comprehensibility.

☐ Required ☒ Optional

b) Train border region public health and clinical staff on surveillance and response. For example:

i) Coordinate and facilitate trainings for health care providers on the clinical and laboratory diagnosis and treatment of Spotted Fever Group Rickettsioses in areas of need.

☐ Required ☒ Optional

Area C: Communication, Coordination, and Partnerships

4) Sustain or develop strategic partnerships

a) Update and test binational coordination and reporting protocols with Mexico.

i) Regularly review current binational protocols, update (or develop) as needed, and test or conduct exercise at least twice during the 5-year ELC cycle. These activities should be done in conjunction with U.S. and Mexican state and local partners in the U.S.-Mexico border region, consistent with International Health Regulations (IHR), U.S.-Mexico Guidelines, and the Operational Protocol for Binational Communication and Coordination.

ii) For new or updated protocols, funding recipient will be required to develop either a brief summary of progress or impact in coordinating public health information exchange.

iii) For protocol exercises, the recipient should develop an after-action report with lessons learned, recommendations, and next steps related to the protocol.

☒ Required ☐ Optional

b) Identify and engage employers of binational essential workers

i) For example: recipients can establish, sustain, and expand strategic partnerships with employers of, or community-based organizations that work with binational essential workers to improve awareness, coordination, and exchange of public health information in the border region.

☐ Required ☒ Optional

c) Identify and engage binational health insurance providers to reinforce case reporting

i) For example: recipients can establish, sustain, and expand strategic partnerships with binational health insurance providers to improve awareness, coordination, and exchange of public health information in the border region.

☐ Required ☒ Optional

Collaborations:

a. With CDC-Funded Programs

Sites should collaborate with NNDSS Program, Emerging Infections Program, ILI-Net, BioSense, PulseNet, National Syndromic Surveillance Program, CDC/NCHS Collaborative Center for Question Design and Evaluation, appropriate Tribal Epidemiology Centers and other states participating in the BIDS program, as applicable, and provide descriptions of these collaborations in the application. Sites will collaborate closely with the CDC BIDS program and the CDC Quarantine Stations in El Paso and San Diego. CDC BIDS program staff will provide technical oversight and assistance; liaise with other CDC subject matter experts; and review products resulting from activities.

b. With Organizations External to CDC

Collaboration with infectious disease offices of local/regional/state health departments is required and must be described in the proposal, along with how proposed activities fit into the state's broader disease surveillance plans. Collaborations with universities and non-governmental institutions are encouraged, with associated letters of support. Programs are encouraged to work with the US Section of the US-Mexico Border Health Commission (BHC) through interaction with their state-specific BHC appointees and should describe planned interactions in the proposal.

Populations of Focus:

Projects should focus on U.S.-Mexico border-crossing populations and their networks, migrants (crossing the land-border from Mexico to the U.S.), and residents of the U.S.-Mexico border region at risk for infectious diseases of binational concern; strategies may include a focus on foreign-born Latino populations, Spanish speakers with limited English proficiency, or other binational groups that have been economically and/or socially marginalized. Applicants should clearly identify which population(s) will be prioritized by each proposed project. Examples of these priority groups are:

(a) Frequent crossers of the U.S.-Mexico land border

(b) Migrant farmworkers, such as workers with H2A visas

(c) Transnational persons with infectious diseases of binational concern, including border crossers and travelers at land, air, and seaports of entry

(d) Hispanic or Latino persons with limited English proficiency, particularly Spanish or indigenous language speakers

(e) Migrants transiting through Central America and Mexico to the U.S.-Mexico border region

Evaluation and Performance Measurement:

Performance measures included here are representative and may not be final at the time of NOFO publication. Please see the CK-24-0002 Performance Measure Guidance document for all final measures and descriptions.

a. ACTIVE Performance Measures

N.1. Binational Reporting Criteria Trainings (BRC Trainings) on the collection of the binational variable in surveillance systems

N.2. Binational Case Reporting

N.3. Binational Partnerships

b. PASSIVE Indicators

N/A

Project O: Global Migration, Border Interventions, and Migrant Health

Program Activity Contact Information:

Gwendolyn O'Neal, gbr8@cdc.gov, (404) 636-7871; Adamma Ibe qag9@cdc.gov, Sheila Roy svz7@cdc.gov – Refugee/Immigrant Health; Argie Figueroa, iic7@cdc.gov – Ports of Entry; Ashley Brown, prf3@cdc.gov – Travelers Health

Funding Opportunity Description:

a. Overview

The mission of the Division of Global Migration and Quarantine (DGMQ) is to reduce morbidity and mortality among globally mobile populations and to prevent the introduction, transmission, and spread of communicable diseases through regulation, science, research, preparedness, and response.

b. Health Equity

Newcomers are likely to experience limited access to health care services after arriving in the U.S. Recipients can assist by including components that specifically address health inequity in their respective projects or activities.

c. Healthy People

Topic Area: Global Health--Improve public health and strengthen U.S. national security through global disease detection, response, prevention, and control strategies.

d. Local Health Department and Tribal Engagement

Recipients will partner with local health departments and tribes to address the needs of newcomer populations through funding or project collaboration.

e. Other National Public Health Priorities and Strategies

N/A

CDC Project Description:

a. Problem Statement

Every day, close to one million travelers arrive in the United States by air, sea, or land. Some arrive from areas endemic for infectious diseases and have limited healthcare access. Communicable diseases can spread quickly during travel, due to seating proximity on conveyances and prolonged contact in transit, which may result in cases or outbreaks in communities. Additionally, about 30,000-125,000 refugees, 36,000 asylees, and 400,000 immigrants settle in the United States every year. Refugees, asylees, and migrants (also known as newcomers) experience unique disadvantages because of limited access to health care in their country of origin and in countries providing temporary asylum. They may have complex healthcare issues, such as low baseline vaccination rates and high rates of infectious diseases. After arrival, newcomer populations continue to experience health inequities and disparities due to a number of reasons including socioeconomic, cultural and linguistic barriers. Social determinants of health are the root causes of health inequities, which are often beyond the control of the individual and can result in adverse health outcomes.

b. Purpose

The purpose of this funding is to mitigate the public health risks of travel-associated importation of pathogens into the U.S. by improving public health surveillance, case management, and response to communicable diseases of public health concern among globally mobile populations.

c. Outcomes

Newcomer Health

Newcomers: Includes refugees, asylees, special immigrant visa holders, and other migrant populations at increased risk of infectious disease.

- Improved understanding of infectious disease health disparities and their causes (e.g., social determinants of health) in newcomer populations
- Improved understanding of best and promising practices in achieving health equity in newcomer populations
- New culturally and linguistically responsive and relevant resources or tools—including audiovisual resources—to address infectious disease health disparities in newcomer populations
- Strengthened partnerships to improve community outreach—which could include working with community health workers and/or patient navigators—and identify and resolve barriers to accessing health care among newcomer populations (e.g., working with state's Centers for Medicare & Medicaid Services)
- Improved access to programs that help achieve health equity in newcomer populations
- Improved coordination and exchange of data (e.g., linking between various databases to allow for long-term follow up of newcomers and linkage of overseas vaccination information for refugees from the DGMQ's Electronic Disease Notification (EDN) system into state immunization registries)

Health at Ports of Entry

- Improved surveillance of diseases of public health concern associated with or identified by travel
- Improved timeliness of travel-associated case notifications of diseases of public health concern to CDC Quarantine Stations
- Improved completeness of travel-associated case notifications of diseases of public health concern to CDC Quarantine Stations
- Improved efforts in responding to travel-associated cases of diseases of public health concern (e.g., conducting contact investigations and reporting outcomes)

Traveler's Health

- Improved surveillance of diseases of public health concern associated with or identified by travel or border crossings
- Improved completeness of travel-associated case reports
- Improved timeliness of travel-associated case reports
- More efficient efforts in:
    - Detecting cases and outbreaks of diseases of public health concern
    - Responding to cases and outbreaks of diseases of public health concern (e.g., providing recommendations to healthcare providers)

- Investigating cases and outbreaks of diseases of public health concern (e.g., determining risk factors)
- Implementing disease control measures

General

- Reduced infectious disease health disparities among globally mobile populations
- Minimized transmission of infectious diseases in globally mobile populations

Funding Strategy:

Funding should be used for personnel, travel, supplies, equipment, or contractual support for proposed activities.

- Approximate total availability of funds: $150,000
- Approximate number of awards given: 2
- Approximate average per award: $50,000–100,000

***Please note:**

1. For State Health Departments (SHDs), when entering budget requests, recipients must use the 'Public Health Allocation' to indicate the portion of financial support going toward 'Local/Regional Health Department (LHD)' support versus staying at the SHD level. This allocation data helps ELC answer inquiries regarding the financial support to LHDs which is crucial given the important role LHDs have in addressing infectious diseases.
2. For Local Health Departments (LHDs), when entering budget requests, please ensure the 'Public Health Allocation' is set to 100% 'Local/Regional Health Department (LHD)' support.
3. For Territorial Health Departments, if you have local/regional jurisdictions, please follow the instructions for State Health Departments in #1.

Required Tasks:

Acceptance of funding conveys acknowledgement and indication that the following requirements will be met.

1. Participate in quarterly calls with CDC and provide verbal communication of progress on activities.
2. Complete a final report at the end of the budget period that provides details on summaries of progress on activities, achievement of performance measures and any other evaluation data.

Strategies and Activities:

0) Strategy to Address Required Tasks

a) Address Required Tasks in project guidance.

☐ Required ☒ Optional

Area A: Surveillance, Detection, and Response

Strategies and activities are all optional, and applicants should address at least one of the strategies and activities listed below.

1) Enhance investigation response and reporting

a) Develop investigation materials to efficiently detect cases among newcomers.

☐ Required ☒ Optional

2) Improve surveillance to drive public health action

a) Improve surveillance of diseases of public health concern among globally mobile populations

☐ Required ☒ Optional

3) Implement and evaluate routine evidence-based public health interventions

a) Implement interventions addressing the health needs of globally mobile populations at conveyances, at border crossings, or in communities.

☐ Required ☒ Optional

b) Evaluate the effectiveness of interventions addressing the health needs of globally mobile populations.

☐ Required ☒ Optional

4) Maintain and enhance integrated surveillance information

a) Facilitate coordination/exchange of surveillance, epidemiological, and/or clinical data for globally mobile populations.

☐ Required ☒ Optional

Area C: Communication, Coordination, and Partnerships

5) Coordinate and collaborate

a) Enhance staff training and education on surveillance and port of entry International Health Regulations core capacities (http://www.emro.who.int/international-health-regulations/about/ihr-core-capacities.html).

☐ Required ☒ Optional

6) Communicate

a) Develop culturally relevant resources to address health disparities in newcomers.

☐ Required ☒ Optional

Collaborations

a. With CDC-Funded Programs

Collaboration with other CDC-funded programs is optional. However, if applicants propose to collaborate with other CDC-funded programs to conduct activities, then they should provide evidence of prior collaborations with these groups and should describe: 1) the work of the collaborating CDC-funded programs in their jurisdiction or community, 2) the programs' success in achieving cooperative agreement outcomes; and 3) the way the applicant will work with the program. Prior evidence may be provided as a MOU, MOA, or letters of support.

b. With Organizations External to CDC

Collaboration with organizations external to CDC is optional. However, if applicants propose to collaborate with organizations external to CDC, then they must provide evidence of prior collaborations with such groups and should describe the organization's success in achieving cooperative agreement outcomes and indicate how the applicant will interact with the organization in specific terms. Prior achievements and evidence may be provided as an MOU, MOA, or letters of support.

Populations of Focus:

Projects should prioritize globally mobile populations such as refugees, immigrants, travelers, expatriates, migrants, asylees, Special Immigrant Visa Holders, Afghan evacuees, those adjusting to LPR (legal permanent residency) status in the United States (status adjusters), or communities with significant migrants or refugees. Applicants should clearly identify which population(s) will be prioritized by the proposed project.

Evaluation and Performance Measurement:

Performance measures and evaluation activities used to track progress will be specific for each approved and funded project. This is necessary as the number and scope of projects may vary in the area of emphasis, strategy, and activity. As projects are approved and funded, CDC will work with recipients to develop the specific performance measures that best meet the purpose and objective of that project, if needed. The performance measures will be closely tied to the pertinent strategies, activities, and outcomes. There may be both qualitative and quantitative data collected for evaluation purposes. Performance measures, other evaluation data and summaries of progress will be provided in the final report at the completion of the budget period. Any interim evaluation data and summaries of progress will be collected via quarterly calls through verbal communication, as recipients are not required to provide a written summary of data during these times. A discussion guide for collection of interim evaluation data and progress may be provided to the recipient beforehand to guide discussions during these calls. Recipients may be given an optional opportunity to share or present their work at Division-wide seminars or on peer-to-peer networking calls (i.e., networking calls where recipients will be given an opportunity to present their work to one another). Overall, reports will be submitted a minimum of once per budget period (i.e., final progress report), not including the ELC application.

Performance measures included here are representative and may not be final at the time of NOFO publication. Please see the CK-24-0002 Performance Measure Guidance document for all final measures and descriptions.

a. ACTIVE Performance Measures

N/A

b. PASSIVE Indicators

N/A

Project P*:* Parasitic Diseases Surveillance

Program Activity Contact Information:

Vitaliano Cama; phone: 404-718-4131; email: vec5@cdc.gov (SME focus)

Theresa Benedict; phone: 404-718-4124; email: tgd5@cdc.gov (business focus)

Funding Opportunity Description:

a. Overview

This project aims to strengthen the capacity for state/local public health departments to detect and respond to parasitic disease infections in the United States (U.S.) The goals of Project P, Parasitic Disease Surveillance, are to:

- advance the detection of parasitic diseases towards improved public health responses for their treatment and containment,
- improve quality standards for testing and surveillance,
- establish protocols to improve data exchange systems.

Funding to support these goals will be offered through two tiers:

Tier I: improvements in diagnostic testing for parasitic diseases

Tier II: Genotyping of parasites of public health importance

b. Health Equity

The U.S. has limited capacity for the diagnosis of parasitic diseases and this responsibility has been assumed by state and federal reference laboratories. Some of the most frequent diagnostic requests received at CDC include Chagas disease, leishmaniasis, strongyloidiasis, and neurocysticercosis, all of which are classified by the World Health Organization as neglected tropical diseases (NTDs). In the U.S., NTDs are diagnosed primarily in groups that have been socially and/or economically marginalized. Improving the timely diagnosis of parasitic diseases and NTDs could lead to improved health outcomes and contribute to advancing health equity in the nation.

c. Healthy People

The Healthy People initiative is designed to guide national health promotion and disease prevention efforts for improving health in our nation. The U.S. Department of Health and Human Services identifies science-based objectives with targets to monitor progress and motivate and focus action.

Project N relates to Healthy People 2030 measure # PHI-R07: Explore quality improvement as a way to increase efficiency and effectiveness in health departments.

d. Local Health Department and Tribal Engagement

Specific engagements with local lor tribal health departments are not planned buy may occur as part of the activities to strengthen laboratory and epidemiology capacity of this project.

e. Other National Public Health Priorities and Strategies

Not applicable

CDC Project Description:

a. Problem Statement

Laboratory capacity for diagnosing parasitic diseases in the U.S. has gradually decreased over time, and many diagnostic requests are referred to State or national reference laboratories.

However, parasitic infections like babesiosis, free-living amoeba meningitis, Chagas disease, eosinophilic meningitis due to *Angiostrongylus cantonensis*, neurocysticercosis, or toxoplasmosis that can have life-threatening presentations and require prompt and accurate diagnosis.

There are other parasitic diseases that were historically endemic, like those caused by soil transmitted helminths, or diseases like cyclosporiasis, malaria or leishmaniasis, for which the current burden of disease is poorly defined.

Public health laboratories (PHLs) play an important role in the diagnosis of parasitic diseases. Prompt diagnosis allows for timely responses that are beneficial for patients and public health. Additionally, new molecular methods will help to understand the transmission and burden of parasitic diseases, especially for outbreak investigations and associated surveillance. Therefore, there is a need to maintain and advance parasitic diseases diagnostics at PHLs.

b. Purpose

This project aims to increase the parasitic diagnostic capacity in public health laboratories, to provide timely results and help identify and track diseases that may represent a burden in their jurisdictions, and to expand the ability of states to participate in national surveillance activities for parasitic diseases.

c. Outcomes

Tier I – Improvements in diagnostic testing for parasitic diseases

1. Expanded diagnostic capacity for parasitic diseases initially focusing on visceral leishmaniasis (via rapid diagnostic tests) and trichinosis (via indirect antibody enzyme immunoassays)
2. Expanded submission of digital images for remote diagnosis (telediagnosis) of parasitic diseases
3. Improved specimen submission processes for requesting reference diagnostic services.

Tier II – Genotyping of parasites of public health importance

4. Increased genotyping of outbreak-associated parasitic infections, initially focusing of *C. cayetanensis* and malaria.

Funding Strategy:

Funds may be used for personnel, supplies and capacity building, which may include travel or software. Applicants may request funds for activities in either Tier I, or Tier II, or both Tiers. The activities in Project P were tiered to reflect different levels of performance.

Total availability of funds for *Project P:* Parasitic Disease Surveillance:

Tier 1 – Improvements in diagnostic testing for parasitic diseases

- Approximate number of awards: 7
- Approximate average per award: $ 12,000

Tier 2 – Genotyping of parasites of public health importance

- Approximate number of awards: 4
- Approximate average per award: $ 80,000

***Please note:**

1. For State Health Departments (SHDs), when entering budget requests, recipients must use the 'Public Health Allocation' to indicate the portion of financial support going toward 'Local/Regional Health Department (LHD)' support versus staying at the SHD level. This allocation data helps ELC answer inquiries regarding the financial support to LHDs which is crucial given the important role LHDs have in addressing infectious diseases.
2. For Local Health Departments (LHDs), when entering budget requests, please ensure the 'Public Health Allocation' is set to 100% 'Local/Regional Health Department (LHD)' support.
3. For Territorial Health Departments, if you have local/regional jurisdictions, please follow the instructions for State Health Departments in #1.

Required Tasks:

N/A

Strategies and Activities:

0) Strategy to Address Required Tasks

a) Address Required Tasks in project guidance.

☐ Required ☒ Optional

Area A: Surveillance, Detection, and Response

Tier I: Improvements in diagnostic testing for parasitic diseases.

1) Strategy: Expand the number of assays for parasitic disease diagnosis offered at PHLs (Tier I)

a) Implement and sustain the sero-diagnosis of visceral leishmaniasis and trichinosis using FDA-cleared in-vitro diagnostic assays.

☒ Required ☐ Optional

2) Strategy: Expand the use of telediagnosis for morphology parasite identification (Tier 1)

a) Sustain or increase the number of quality digital images submitted for the remote diagnosis of parasites (telediagnosis) of specimens that require parasite identification by microscopy.

☐ Required ☒ Optional

3) Strategy: Increase the number of specimens successfully accessioned at CDC (Tier I)

a) Improve the specimen submission processes when requesting reference diagnostic services from CDC.

☐ Required ☒ Optional

Tier II: Genotyping of parasites of public health importance

4) Strategy: Increase PHL capacity to genotype parasitic agents associated with outbreaks, initially focused on *Cyclospora cayetanensis* and malaria (Tier II)

c) Establish the capacity to generate next-generation-sequencing (NGS) data to genotype C. cayetanensis and malaria.

☒ Required ☐ Optional

d) Submit NGS genotyping sequences to CDC.

☒ Required ☐ Optional

5) Address parasitic disease diagnostic needs that are unique for specific PHLs

e) Specific activities that can be linked to budget line items to the public health laboratory workplan which are important for those items that do not directly link to another Activity.

☐ Required ☒ Optional

Area C: Communication, Coordination, and Partnerships

Tier I:

6) Expand parasitic disease testing capacity by supporting other PHL (Tier I)

a) Conduct outreach with PHLs in the appropriate PulseNet area for sero-diagnosis of trichinosis and visceral leishmaniasis.

☒ Required ☐ Optional

b) Provide sero-diagnostic support for trichinosis and visceral leishmaniasis in the appropriate PulseNet area.

☒ Required ☐ Optional

Tier II:

7) Increase PHL capacity to genotype parasitic agents associated with outbreaks, initially focused on Cyclospora cayetanensis and malaria (Tier II)

a) Conduct outreach with PHLs in the appropriate PulseNet area for next-generation-sequencing (NGS) of C. cayetanensis and malaria.

☒ Required ☐ Optional

b) Provide NGS sequencing support to PHLs in the appropriate PulseNet area.

☒ Required ☐ Optional

Collaborations:

a. With CDC-Funded Programs

N/A

b. With Organizations External to CDC

N/A

Population(s) of Focus:

No specific populations of focus.

Evaluation and Performance Measurement:

Performance measures included here are representative and may not be final at the time of NOFO publication. Please see the CK-24-0002 Performance Measure Guidance document for all final measures and descriptions.

a. ACTIVE Performance Measures

Tier I – Improvements in diagnostic testing for parasitic diseases

1. Dates when new diagnostic assays for parasitic diseases were published in the test directory of the Public Health Laboratory

2. Number of public health laboratories that have been supported for the newly implemented assays for parasitic diseases.

3. Number of requests submitted to CDC for a) Parasites: Telediagnosis (CDC-10563) AND b) number of physical specimens for Parasites: Morphologic identification (CDC-10234).

Tier II: Genotyping of parasites of public health importance

4. Number of NGS sequences AND number of physical specimens submitted to CDC for *Cyclospora* genotyping

b. PASSIVE Indicators

N/A

Project Q: Combating Antimicrobial Resistant Gonorrhea and Other STIs (CARGOS)

Program Activity Contact Information:

Emily Learner, Lead, Epidemiology Research Team, kvd7@cdc.gov, 404-718-7339

Funding Opportunity Description:

a. Overview

The goal of Combating Antimicrobial Resistant Gonorrhea and Other STIs (CARGOS) is to strengthen and coordinate surveillance and preparedness and response (P&R) activities for antimicrobial resistance (AR) in sexually transmitted infections (STIs) in the United States. Surveillance and P&R structures for AR in *Neisseria gonorrhoeae* (GC) have been in place for many years within the U.S. Centers for Disease Control and Prevention's (CDC) Division of STD Prevention (DSTDP) through the Gonococcal Isolate Surveillance Project (GISP) and the Strengthening the United States Response to Resistant Gonorrhea (SURRG) programs. CARGOS is a comprehensive strategy designed to streamline and improve the coordination of AR surveillance and P&R activities within DSTDP, state and local jurisdictions, and participating laboratories. Given the continued threat of AR in STIs in the United States, CARGOS aims to strengthen the existing infrastructure and P&R activities focused on GC and expand capacity to include other STIs with emerging AR that may not have spread widely but could become common without decisive action.

b. Health Equity

Many risks for antimicrobial-resistant infections are tied to social determinants of health, which are conditions in the places where people live, learn, work, and play that affect a wide range of health outcomes and quality of life. Antimicrobial-resistant infections impact men who have sex with men (MSM), minority racial/ethnic groups, and other communities who are disproportionately affected by STIs due to a range of social and economic factors. Applicants should use data, including those collected on social determinants of health, to identify communities within their jurisdictions that are disproportionately affected by STIs and related disparities. In collaboration with partners and appropriate sectors of the community, applicants should use social determinants of health in the development, implementation, and evaluation of activities for CARGOS that are tailored for the intended communities.

c. Healthy People

This project supports Healthy People 2030 objectives to:

- Reduce rates of GC in male adolescents and young men. (STI-02)
- Increase the number of national surveys that collect data on lesbian, gay, and bisexual populations. (LGBT-01)
- Increase the number of national surveys that collect data on transgender populations. (LGBT-02)
- Increase the proportion of public health laboratories (PHLs) that provide services to support emerging public health issues. (PHI-D04)
- Increase the proportion of state PHLs that use emerging technology to provide enhanced services. (PHI-D05)
- Enhance the use and capabilities of informatics in public health. (PHI-R06)

d. Local Health Department and Tribal Engagement

This project aims to develop and enhance capacity to detect, monitor, and respond to AR in STIs in the United States. It further seeks to make gains in surveillance and P&R made to monitor and respond to AR in GC, improve the coordination and efficiency of current programs/projects, and strengthen capacity to respond to other STIs with emerging AR. Recipients are expected to engage with local health departments (HDs) and tribes through funding and/or collaboration, as necessary, to meet these objectives.

e. Other National Public Health Priorities and Strategies

This project supports a variety of goals from multiple national public health strategies including:

- The 2020–2025 National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB):
  - Objectives 1.2, 1.3, 1.4; and 3.2: Slow the emergence of resistant bacteria and prevent the spread of resistant infections.
  - Objectives 1.1 and 3.1: Advance development and use of rapid and innovative diagnostic tests for identification and characterization of resistant bacteria.

- STI National Strategic Plan for the United States 2021–2025:
  - Goal 1.4: Increase the capacity of public health, health care delivery systems, and the health workforce to prevent STIs.
  - Goal 2.2: Work to effectively identify, diagnose, and provide holistic care and treatment for people with STIs by increasing the capacity of public health, health care delivery systems, and the health workforce.
  - Goal 3.3: Support the development and uptake of innovative STI diagnostic technologies, therapeutic agents, and other interventions for the identification and treatment of STIs, including new and emerging disease threats.

- CDC's Division of STD Prevention Strategic Plan 2022–2026:
  - Goal 1.3: Reduce AR in GC infections domestically and internationally.
  - Goal 3.2.3: Support the development of rapid diagnostic tests to identify and characterize antimicrobial resistance, STI, and other emerging threats.
  - Goal 5.1.2: Develop processes for integration of molecular assay data and genomics data with epidemiologic data for monitoring of STIs and strains of concern and for application to a targeted public health response.

CDC Project Description:

a. Problem Statement

Nearly 3 million infections with AR occur in the U.S. each year, with a disproportionate number of these infections negatively impacting people who are at higher risk for health disparities and inequities. Surveillance is a critical process for monitoring and defending against AR. CARB has made the strengthening of surveillance a fundamental component of its action plan. However, the purpose of surveillance is ongoing monitoring; therefore, information is typically not available quickly enough to allow for rapid local response to identified strains of concern.

Monitoring for and responding to the development of AR in STIs in the U.S. has been solely focused on GC for nearly the past four decades. However, AR is increasing in many bacteria worldwide, including other STIs, such as *Mycoplasma genitalium* (MG). GC is currently designated as one of five "Urgent Threat" level pathogens in the U.S. and is a priority of both CARB and the CDC's Antibiotic Resistance Solutions Initiative. In addition, MG has been added to the "Watch List" of pathogens in the U.S. given its rapidly increasing AR and ability to cause significant morbidity.

Combined with the need for strategies that provide both regular monitoring and the capacity to quickly combat emerging threats, there is also a need to streamline DSTDP's approach towards monitoring and responding to AR in STIs. Developing local and state public health capacity for timely detection of and rapid response to emerging threats of AR in STIs is urgently needed to mitigate their spread.

b. Purpose

Core activities funded as part of CARGOS will focus on GC and will include monitoring trends in antimicrobial susceptibilities of *N. gonorrhoeae* strains in the U.S. as well as strengthening state and local capacity in participating jurisdictions to support rapid detection of and response to threats of AR in GC. These core activities will be performed among males with symptomatic gonococcal urethritis and males and females with pharyngeal GC presenting to STI clinics in participating recipient jurisdictions.

Optional activities will include using the core infrastructure to monitor GC antimicrobial susceptibility testing (AST) trends and strengthen local rapid detection and response capacity among other anatomic sites of infection (e.g., males with rectal GC in participating STI clinics) and in populations where resistance is likely to emerge (e.g. sex workers, frequent travelers, people with high exposure risk), as well as other STIs with the potential for AR (e.g., urethral *N. meningitidis* infections, MG), and surveillance for molecular markers of AR in GC.

c. Outcomes

1. Improved epidemiologic capacity to identify, investigate, respond to, and interrupt transmission of AR in GC.
2. Improved laboratory capacity to conduct gradient strip AST.
3. Increased collaboration between state and local jurisdictions, regional Antimicrobial Resistance Laboratory Network (ARLN) laboratories, and CDC/DSTDP.
4. Improved quality and availability of epidemiologic, clinical, and laboratory data on AR in GC and other STIs to inform protective and appropriate public health actions.

Funding Strategy:

Funding should be used for personnel (e.g., Project Coordinator/Epidemiologist, Data Manager, Microbiologist, Case Investigator), travel and related topical training, specimen collection supplies, laboratory equipment and supplies, local specimen transport, information technology enhancements, or contract work with local jurisdictions for proposed activities. Funds can be used for up to 1 SAS license. Personnel requests should match the anticipated FTE needed to complete proposed activities. Awardees must provide justification for using a percentage of current staff for proposed activities, hiring new full-time staff, or using contractual mechanisms. Any FTE requests for IT/programming staff needed to support

strategic system modifications should be considered time-limited and included in the Contractual section of the budget.

Participation on cooperative agreement-related phone calls and communications by all project team and key personnel at the state and/or local level is a requisite of funding. Funding is dependent upon continued appropriations for related efforts and should not duplicate other funding mechanisms (e.g., the ELC Strengthening HAI/AR Program [SHARP]). Final award amounts may be less than requested. Funding availability in subsequent fiscal years is subject to the availability of appropriated funds.

Funding will not be approved for costs such as staff cell phones, data plans, office furniture, and supplies for initial diagnostic identification (e.g., diagnostic nucleic acid amplification tests, Nucleic Acid Amplification Tests (NAATs)) and routine STI care. Costs for shipping isolates to the assigned ARLN regional laboratory and DSTDP are covered through other funding sources and will not be funded through this budget request.

Successful applications should include the following information specific to their recipient jurisdiction:

- Discussion of overall GC burden and population at risk.
- Discussion of ability to enroll specific populations and collect the specimens needed.
- Demonstrated success with past CDC funding, if applicable.
- Description of existing STI surveillance, laboratory, and response capabilities.
- Description and relevance of proposed workplan to program activities.
- Description of current or planned collaborations with external partners and local HDs, as applicable.
- Clear explanation of how workplan activities relate to proposed budget line items.

- **Estimated total availability of funds: $13,000,000**
    - Estimated number of awards: 20
    - Estimated average per award: $650,000
    - Estimated range for average award: $400,000–$770,000

1. The anticipated level of specific project management capacity needed to execute the required activities includes the:
2. Ability to enroll men for the collection of urethral specimens and men and women for the collection of pharyngeal specimens, culture isolation of *N. gonorrhoeae*, storage of duplicate isolates for the project year, and shipment of viable and non-contaminated isolates.
3. Ability to collect and electronically transmit requested demographic, clinical, and laboratory data elements.
4. Organizational leadership and support of the project.
5. Human resource and financial management to support the project.

In addition to capacities #2-4 described above for the required activities, the anticipated level of specific project management capacity needed to execute the optional activities, as applicable, includes the:

1. Ability to enroll men for the collection of rectal specimens, culture isolation of *N. gonorrhoeae*, storage of duplicate isolates for the project year, and shipment of viable and non-contaminated isolates.
2. Ability to collect urogenital and/or extragenital specimens for culture from men and/or women from high-risk populations of interest.
3. Ability to collect urethral specimens from men for safe culture isolation and NAAT testing of *N. meningitidis*, storage, and shipment of isolates to CDC.
4. Ability to collect, store, and ship urogenital and/or extragenital specimens from men and/or women for AR testing in STIs with emerging AR (e.g., *M. genitalium*).
5. Ability to perform molecular testing for concerning markers associated with AR from remnant NAAT specimens positive for *N. gonorrhoeae.*

***Please note:**

1. For State Health Departments (SHDs), when entering budget requests, recipients must use the 'Public Health Allocation' to indicate the portion of financial support going toward 'Local/Regional Health Department (LHD)' support versus staying at the SHD level. This allocation data helps ELC answer inquiries regarding the financial support to LHDs which is crucial given the important role LHDs have in addressing infectious diseases.
2. For Local Health Departments (LHDs), when entering budget requests, please ensure the 'Public Health Allocation' is set to 100% 'Local/Regional Health Department (LHD)' support.
3. For Territorial Health Departments, if you have local/regional jurisdictions, please follow the instructions for State Health Departments in #1.

Required Tasks:

Acceptance of funding conveys acknowledgement and indication that the requirements listed throughout this NOFO will be met. In addition to all required activities listed throughout this project guidance, recipients are required to have core team staff:

1. Attend and participate in CDC-facilitated cross-recipient planning calls and/or calls with regional laboratories, as well as regular individual recipient check-in calls with CDC.
2. Attend and participate in a CARGOS-specific recipient meeting (anticipated to be in-person).

Strategies and Activities:

0) Strategy to Address Required Tasks

a) Address Required Tasks in project guidance.

☐ Required ☒ Optional

Area A: Surveillance, Detection, and Response

For the purposes of this guidance, STI clinics are defined as any clinical facility providing timely, comprehensive, confidential, and culturally sensitive STI care as the facility's primary function. Clinics need not be 'stand-alone' and may be integrated into broader practice settings. However, the selected facility must have a specifically identifiable STI clinic and have the ability to identify and extract records from their electronic medical records (EMR) system(s) for patients specifically seeking STI clinical services separately from any broader patient population.

1) Strengthen local epidemiologic capacity to detect, monitor, and respond to AR in STIs

a) Improve surveillance and reporting of male urethral GC in STI clinics.

i) Identify at least one STI clinic and a local PHL in a jurisdiction that will execute the program activities.

(a) The STI clinic(s) should diagnose ≥200 cases of GC per year.

(b) STI clinic(s) leadership should be committed to modifying existing protocols and clinic flows and provide ongoing leadership to facilitate robust collection of specimens for GC culture and AST and required data from EMRs.

ii) Collect urethral *N. gonorrhoeae* isolates from the first 25 men with symptomatic gonococcal urethritis seen in participating STI clinic(s) each month.

iii) Ship isolates associated with cultures positive for *N. gonorrhoeae* monthly to the assigned ARLN regional laboratory for AST by agar dilution and possible whole genome sequencing (WGS).

iv) Review AST results received from the ARLN regional laboratory, describe the epidemiology of resistant *N. gonorrhoeae* in submitting jurisdictions, and use results to help inform local public health response.

v) Collect line-listed laboratory, clinical, and demographic data elements associated with each *N. gonorrhoeae* isolate and electronically submit to CDC following project protocols.

☒ Required ☐ Optional

b) Improve surveillance and reporting of pharyngeal GC in STI clinics.

i) Collect pharyngeal *N. gonorrhoeae* isolates from the first 25 patients (men or women) seen in participating STI clinic(s) each month. Patients meeting any of the following criteria should be prioritized for the collection of pharyngeal swabs: 1) known pharyngeal exposure; 2) reported sexual contact; 3) reporting symptoms; 4) returning for treatment.

ii) Inoculate specimens for culture onto selective media at the STI clinic(s). Subculture gonococcal isolates from the selective primary medium to a non-inhibitory medium in the local PHL, as described in project protocols.

iii) Ship isolates associated with positive gonorrhea cultures monthly to the assigned ARLN laboratory for AST by agar dilution and possible WGS.

iv) Review AST results received from the ARLN laboratory, describe the epidemiology of resistant *N. gonorrhoeae* in submitting jurisdictions, and use results to help inform local public health response.

v) Collect line-listed laboratory, clinical, and demographic data elements associated with each isolate and electronically submit to CDC following project protocols.

☒ Required ☐ Optional

c) Enhance workforce capacity to detect, monitor, and respond to AR in STIs.

i) Identify and train appropriate staffing including but not limited to:

(a) Epidemiologist Coordinator responsible for coordinating all program activities.

(b) Data Manager with capacity to manage, clean, extract, and submit high-quality data to CDC in specified formats.

(c) Laboratorian(s) capable of handling specimens and performing *N. gonorrhoeae* culture, AST by Etest™, and molecular assay validation activities.

(d) Disease Intervention Specialists (DIS) trained for conducting AR in STI investigations.

☒ Required ☐ Optional

d) Conduct rapid & robust investigations when concerning isolates are identified.

i) Rapidly initiate (within 48 hours of AST results) robust field investigations (enhanced case investigation interview, treatment confirmation, ascertainment of symptom resolution, contact tracing, and partner services) of all patients infected with GC with elevated minimum inhibitory concentrations (MICs) to ceftriaxone or cefixime as identified by E-test™ (see Strategy 3, Activity 1).

ii) Any new case of GC identified as a result of the investigation into the index "alert" case (regardless of susceptibility) should be classified as a new index case and DIS must attempt to perform partner services from these newly identified cases.

iii) Encourage all patients infected with a gonococcal strain identified as having elevated MICs to ceftriaxone or cefixime to return to the health care facility for a test of cure using NAAT and culture ≥7 days after initial treatment.

☒ Required ☐ Optional

e) Improve surveillance & reporting of GC from populations where AR is likely.

i) Collect genital, pharyngeal, and/or rectal specimens from patients of all genders at high-risk for AR in GC for culture.

ii) High-risk populations may include but are not limited to sex workers, frequent travelers, and individuals with high exposure risk.

iii) Locations may include categorical STI clinics and/or community-based, non-STI healthcare centers that serve high GC morbidity areas.

iv) Applicants should provide justification for the population(s) and location(s) selected.

v) Inoculate specimens for culture onto selective media at the healthcare center. Subculture gonococcal isolates from the selective primary medium to a non-inhibitory medium in the local PHL, as described in project protocols.

vi) Ship isolates associated with positive *N. gonorrhoeae* cultures monthly to the assigned ARLN laboratory for AST by agar dilution and possible WGS.

vii) Review AST results received from the ARLN laboratory, describe the epidemiology of resistant *N. gonorrhoeae* in submitting jurisdictions, and use results to help inform local public health response.

viii) Collect line-listed laboratory, clinical, and demographic data elements associated with each isolate and electronically submit to CDC following project protocols.

☐ Required ☒ Optional

f) Improve surveillance and reporting of male rectal GC in STI clinics.

i) Collect rectal *N. gonorrhoeae* isolates from the first 25 men seen in participating STI clinic(s) each month. Patients meeting any of the following criteria should be prioritized for collection of rectal swabs: 1) known rectal exposure; 2) reported sexual contact; 3) reporting symptoms; 4) returning for treatment.

ii) Inoculate specimens for culture onto selective media at the STI clinic(s). Subculture gonococcal isolates from the selective primary medium to a non-inhibitory medium in the local PHL, as described in project protocols.

iii) Ship isolates associated with positive *N. gonorrhoeae* cultures monthly to the assigned ARLN laboratory for AST by agar dilution and possible WGS.

iv) Review AST results received from the ARLN laboratory, describe the epidemiology of resistant *N. gonorrhoeae* in submitting jurisdictions, and use results to help inform local public health response.

v) Collect line-listed laboratory, clinical, and demographic data elements associated with each isolate and electronically submit to CDC following project protocols.

☐ Required ☒ Optional

g) Sustain monitoring of Neisseria meningitidis male urethral isolates.

i) Identify and maintain records of all male urethral isolates that are suggestive of *N. meningitidis*. Isolates are suggestive of *N. meningitidis* when they have "discordant results" demonstrated by bacterial growth on culture consistent with *N. gonorrhoeae* (positive culture) and have a negative gonorrhea NAAT result. In the case of urethral specimens, the isolate should demonstrate Gram-negative intracellular diplococci by microscopy but have a negative gonorrhea NAAT result.

ii) Safely ship presumed *N. meningitidis* isolates monthly to CDC for storage and additional analyses.

iii) Collect line-listed demographic and clinical data elements associated with each isolate and electronically submit to CDC following project protocols.

☐ Required ☒ Optional

h) Enhance surveillance and reporting of STIs with emerging AR.

i) Perform a needs assessment for your jurisdiction to monitor and report other STIs with emerging AR that may not have spread widely but could become common without decisive action (e.g., MG).

ii) If the need has already been identified, applicants may propose an activity of local interest to expand the surveillance of AR to STIs other than GC.

☐ Required ☒ Optional

2) Improve coordination of AR in STI preparedness and outbreak response activities

a) Establish/refine statewide AR in STI response infrastructure and protocols.

i) Infrastructure, protocols, and approaches should be developed for community healthcare providers to report suspected treatment failures and for public health to facilitate access to culture-based testing/AST and respond to such cases.

(a) This effort should at a minimum include: identifying a state or local point of contact for providers to report cases of suspected GC treatment failure; a protocol for what case information will be requested from the provider; protocols for how providers/patients can access culture-based GC testing and AST from PHLs or other entities; and a protocol for how the state/local HD will respond if treatment failure likely due to AR in GC is identified (e.g., clinical management, partner services, etc.).

ii) Establish and make available to local healthcare providers a list of laboratories within the jurisdiction that conduct GC culture and AST. The list should include information about each laboratories' specimen submission procedures.

☒ Required ☐ Optional

b) Develop/maintain a state and/or local jurisdiction outbreak response plan.

i) An outbreak response plan should include at a minimum: case and outbreak definitions; outbreak response team composition, structure, and thresholds for activation; clinical management of cases and their sexual partners; considerations for enhanced surveillance, laboratory activities, partner services and field investigations, and communication plans.

ii) The plan should also address what response activities should be initiated if a molecular marker of cephalosporin resistance is detected via molecular testing. CDC-developed STI outbreak response planning resources can be found here: https://www.cdc.gov/std/program/outbreakresources/default.htm.

☒ Required ☐ Optional

c) *Conduct ≥1 preparedness exercise to practice the outbreak response plan.*

i) A tabletop exercise is recommended. If tabletop exercises have been previously conducted, findings should be reviewed and exercises to improve or address key findings should be conducted. Resources for tabletop exercises may be found here: https://www.cdc.gov/std/program/outbreakresources/default.htm

ii) At least once per year, review the public health importance and local epidemiology of AR in GC and the outbreak response plan with local partners and key participants.

☒ Required ☐ Optional

3) Enhance local laboratory testing for surveillance, reporting, and response

a) Establish or enhance gradient strip AST capacity.

Note: ELC SHARP funding for GC Etest™ should NOT be used for CARGOS activities.

i) Applicants with existing capacity to perform gradient strip testing (Etest™) must perform AST for ceftriaxone and cefixime on GC cultures obtained during all surveillance activities funded in Strategy 1.

ii) Applicants without current capacity to perform gradient strip AST must develop and implement a plan to build Etest™ capacity in year one of the 5-year project period.

iii) Obtain/maintain CLIA (or local equivalent) certification for conducting GC Etest™ and align local laboratory protocols and standard operating procedures (SOPs) with project SOPs to process specimens efficiently and consistently for GC culture and AST.

iv) Enroll and participate in the semi-annual GC Etest™ Proficiency Test program provided by the Wisconsin State Laboratory of Hygiene.

v) Rapidly communicate all Etest™ results to ordering clinicians within 5 days.

vi) Notify appropriate local and CDC contacts/partners if GC isolates with elevated MICs or resistance are identified.

☒ Required ☐ Optional

b) Pilot the implementation of molecular PCR assays.

i) Pilot molecular assays to detect markers of cephalosporin non-susceptibility (e.g., targeting mutations in the *penA* gene) using a CDC-provided real-time PCR SOP.

(a) At least one run should be conducted using 20 GC-positive remnant specimens from molecular testing from either the state or local PHL, AND

(b) At least one run should be conducted using 20 GC-positive remnant specimens from NAA testing from a high GC-volume clinic or non-PHL (e.g., submitted to a commercial or university laboratory).

☐ Required ☒ Optional

4) Enhance coordination between epi-lab-health information technology

a) Improve data management and quality.

i) Regularly assess surveillance data and implement processes to improve data completeness, quality, and timeliness.

(a) Provide training and routine data monitoring, feedback reports (e.g., culture criteria adherence, culture positivity), and technical support to participating health centers to implement project protocols and improve protocol adherence.

ii) Facilitate coordination/exchange of data with CDC.

(a) Collect, process, and clean data for submission to CDC and the regional ARLN laboratory.

(b) Required patient and specimen level line-listed data must be formatted using specifications provided by CDC (e.g., defined variable names, response options, data structure, specimen ID formatting, etc.) and meet CDC-defined quality standards.

iii) Analyze data for ongoing process and outcome evaluations and quality improvement activities, as well as enhanced epidemiological characterization of AR in STIs.

☒ Required ☐ Optional

b) Improve data and information flow.

i) Develop and implement strategies to improve data and information flow between local and state agencies responsible for managing responses to isolates of concern.

ii) Support linkage of laboratory (e.g., specimens, isolates, results) data with epidemiological and clinical data.

(a) Modify and/or enhance data systems to facilitate and improve rapid detection and response activities. Activities include but are not limited to collection and extraction of required data elements from Laboratory Information Management Systems, EMRs, and other surveillance information systems and rapid communication of AST results to surveillance and field epidemiology staff.

☒ Required ☐ Optional

Collaborations:

a. With CDC-Funded Programs

Recipients are required to work with their assigned ARLN regional laboratory. The ARLN regional laboratories serve as reference labs and will perform additional AST and advanced molecular characterization of locally tested specimens. Recipients are also expected to work with state and local STI prevention programs funded through the CDC Strengthening STD Prevention and Control for Health Departments (STD PCHD) cooperative agreement.

b. With Organizations External to CDC

Recipients are also expected to work with clinical providers in the participating clinic(s)/facilities in their jurisdiction where funded activities are occurring.

Populations of Focus:

The required activities for this program prioritize men with symptomatic gonococcal urethritis and males and females with pharyngeal GC presenting to STI clinics. Optional activities prioritize men with rectal GC presenting to STI clinics, high-risk populations where GC resistance may be likely, men with urethral infections caused by *N. meningitidis*, and men and women with other STIs with the potential for AR.

Evaluation and Performance Measurement:

Performance measures included here are representative and may not be final at the time of NOFO publication. Please see the CK-24-0002 Performance Measure Guidance document for all final measures and descriptions.

a. ACTIVE Performance Measures

1. Number of specimens collected for *Neisseria gonorrhoeae* culture, by specimen source (urethral, pharyngeal, rectal, and/or endocervical) and gender.
2. Number of cultures positive for *Neisseria* gonorrhoeae, by specimen source (urethral, pharyngeal, rectal, and/or endocervical) and gender.
3. If gradient strip AST already implemented locally and will be performed in the first year:
   a. Number of isolates tested by gradient strip AST for the required surveillance activities by specimen source and gender.
   b. Number of cases meeting “alert” criteria.
   c. Number of cases meeting “alert” criteria that were followed up with field/case investigations.

b. PASSIVE Indicators

Recipients must submit high-quality line-listed data containing all required data elements to DSTDP on an ongoing basis according to CDC project protocols. Cumulative annual data submissions will also be submitted to DSTDP. DSTDP will review and provide feedback on all submissions. Data that lack sufficient data quality or completeness will be considered unsatisfactory and DSTDP will require participants to continue to clean data and resubmit until data quality standards are met.

Project R: Rabies Surveillance and Laboratory Capacity

Program Activity Contact Information:

Xiaoyue Ma, hjv4@cdc.gov, 404-639-0282; T'hani Bradford, trw2@cdc.gov, 770-488-2937

Funding Opportunity Description:

a. Overview

Proficient diagnosis of rabies suspect animals by state laboratories is the cornerstone of rabies prevention in the United States. Each year public health laboratories test approximately 100,000 animals based on a suspicion of rabies. Accurate laboratory rule-out of rabies in animals involved in potential human exposures prevents over $650 million in unnecessary post-exposure prophylaxis (PEP) costs. To ensure national laboratory network provides timely and accurate diagnostic support, adapts to new diagnostic technologies, and remains proficient, continuing education and infrastructure support is required. Improved communication between laboratories conducting rabies diagnosis and those supporting clinical decisions of exposed individuals is critical for improving adherence to national recommendations for PEP. In addition, more timely transfer of standards-based laboratory information for national notification improves the ability to respond to regional and national changes in the epidemiology of rabies. This is particularly critical in relation to the national oral rabies vaccination programs conducted by USDA and monitoring of the incursion of foreign rabies viruses into the United States.

b. Health Equity

N/A

c. Healthy People

N/A

d. Local Health Department and Tribal Engagement

Applicants are encouraged to work with local health department and tribes to collect and submit animal samples for rabies testing.

e. Other National Public Health Priorities and Strategies

N/A

CDC Project Description:

a. Problem Statement

Approximately 90,000 to 100,000 animals are tested for rabies each year. Most of these animals are submitted following a potential human or domestic animal exposure. Rabies is nearly universally fatal if appropriate post-exposure treatment is not initiated in a timely manner. However, PEP is costly and prone to supply limitations; therefore, initiation needs to be based upon an assessment of risk by public health professionals and, ideally, laboratory diagnostic results. As such, each animal rabies diagnosis has a direct impact on the clinical management of an exposed human or the quarantine status of domestic pets or livestock.

Well-trained diagnostic laboratory staff, as well as functional equipment, within public health, veterinary, and agricultural laboratories are necessary to ensure that samples are processed and tested appropriately. Furthermore, recent acceptance by international bodies (i.e., OIE) of new standard diagnostic assays such as the direct rabid immunohistochemistry test (dRIT) and real time RT-PCR assays will require new training and development of proficiency standards within diagnostic laboratories.

An estimated 60,000 persons receive rabies PEP each year due to potential rabies exposures. Another 180,000 persons each year have a potential rabies exposure that is ruled out by diagnostic testing of the suspect animal and hundreds of thousands more by public health observation of suspect animals. Managing a person who has a suspect rabies exposure involves information sharing between public health, healthcare provider, laboratory, animal control, and veterinary providers to provide timely and appropriate care. Delays or inability to share information while managing a suspect exposure case can result in unnecessary administration of rabies biologics or, more worrisome, failure to provide timely treatment. Electronic management systems can help increase access and accountability of all persons involved in managing rabies exposures but are not widely available across state health departments.

Introduction of foreign rabies viruses or translocation of native rabies viruses into new animal populations can have devastating effects for human and animal health and results in hundreds of thousands of dollars to respond to these events. Accurate and timely diagnostic testing, characterization of viruses from high-interest animals, and immediate reporting and notification are critical to ensuring quick mitigation of importation and translocation events. Current threats monitored by the national program include: (i) importation of animals with the canine rabies virus variant; (ii) detection of vampire bats or vampire bat rabies virus variants; and (iii) raccoon variant rabies cases found to the West of the USDA management zone.

b. Purpose

Funding will support state health partners to improve laboratory diagnostic capacity through necessary equipment upgrades, procurement of critical supplies and reagents for diagnosis and typing, participation in national proficiency testing, and training of laboratory diagnosticians on current and new methodologies. Funding will support public health partners in developing electronic laboratory reporting mechanisms or improving existing systems for the electronic management of suspect rabies exposures. Funding will improve state and national capacity to quickly detect and respond to imported and translocated rabid animals.

c. Outcomes

- Appropriate equipment is available and maintained within the laboratory to ensure reliable lab diagnostics
- Appropriate laboratory supplies and reagents are available in the laboratory to ensure timely and reliable diagnostics as well as secondary rabies virus variant typing
- A well-trained and proficient laboratory workforce is available to ensure compliance with national protocols and standards
- Improved timeliness of the exchange of state laboratory and animal observation data within reporting jurisdictions for the management of potential rabies exposure cases
- Improved data accuracy and timeliness for reporting and national notification of laboratory diagnosis of rabies in animals
- Improved completeness of data reported to CDC for the national notification of animal rabies cases

- Improved frequency of virus characterization and species identification for high-interest animals, particularly among bats along the US-Mexico border, all dogs, and any animals with a history of foreign travel/origins
- Improved training materials are available to health departments and the public to support rabies surveillance and PEP recommendations

Funding Strategy:

Funds will be used to cover lab equipment, supplies, reagents, training and to support implementation of data transmission systems such as Electronic Laboratory Reporting.

Total availability of funds for Project R: Rabies Surveillance and Laboratory Capacity*:* $200,000

- Approximate number of awards: 20
- Approximate average per award: $10,000

***Please note:**

1. For State Health Departments (SHDs), when entering budget requests, recipients must use the 'Public Health Allocation' to indicate the portion of financial support going toward 'Local/Regional Health Department (LHD)' support versus staying at the SHD level. This allocation data helps ELC answer inquiries regarding the financial support to LHDs which is crucial given the important role LHDs have in addressing infectious diseases.
2. For Local Health Departments (LHDs), when entering budget requests, please ensure the 'Public Health Allocation' is set to 100% 'Local/Regional Health Department (LHD)' support.
3. For Territorial Health Departments, if you have local/regional jurisdictions, please follow the instructions for State Health Departments in #1.

Required Tasks:

Acceptance of funding conveys acknowledgement and indication that the following requirements will be met. Related strategy/activity noted in parentheses after Required Task.

1) Submitting case-based (line listed) rabies surveillance data to CDC National Rabies Surveillance System (NRSS) on a monthly basis, in accordance with CSTE guidance.
2) Maintain equipment for rabies diagnosis.
3) Procure supplies for rabies diagnosis.

Strategies and Activities:

0) Strategy to Address Required Tasks

a) Submitting case-based (line listed) rabies surveillance data to CDC National Rabies Surveillance System (NRSS) on a monthly basis, in accordance with CSTE guidance.

☐ Required ☒ Optional

b) Maintain equipment for rabies diagnosis

☐ Required ☒ Optional

c) Procure supplies for rabies diagnosis.

☐ Required ☒ Optional

Area A: Surveillance, Detection, and Response

1) Enhance laboratory testing for surveillance and reporting.

a) Ensure timely sample collection and transfer to laboratories for diagnosis

☐ Required ☒ Optional

2) Enhance coordination between epi-lab-HIT.

a) Develop or improve electronic data sharing systems. This will facilitate real-time flow of testing results between local and state agencies responsible for managing suspect rabies exposure cases.

☐ Required ☒ Optional

b) Develop or improve educational materials or online training modules. This will improve rabies surveillance operations and management of human rabies exposures.

☐ Required ☒ Optional

3) Advance Electronic Information Exchange Implementation

a) Develop or improve electronic laboratory reporting system.

☐ Required ☒ Optional

b) Improve real-time laboratory data sharing. This will facilitate coordination of rabies response activities between local, state, and federal agencies.

☐ Required ☒ Optional

Area C: Communication, Coordination, and Partnerships

4) Enhance coordination between partners.

a) Improve communication between CDC rabies program and state partners. This will facilitate coordination of rabies response activities between local, state, and federal agencies.

☐ Required ☒ Optional

Collaborations:

a. With CDC-Funded Programs

CDC's National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)/Division of High-Consequence Pathogens and Pathology (DHCPP)/Poxvirus and Rabies Branch

b. With Organizations External to CDC

Wisconsin State Laboratory of Hygiene (Proficiency Testing)

Association of Public Health Laboratories (APHL)

The National Association of State Public Health Veterinarians (NASPHV)

Populations of Focus:

Human rabies exposures are generally higher among children and in rural populations, declines in the quality of rabies diagnosis or case management would affect these populations disproportionately.

Evaluation and Performance Measurement:

Performance measures included here are representative and may not be final at the time of NOFO publication. Please see the CK-24-0002 Performance Measure Guidance document for all final measures and descriptions.

a. ACTIVE Performance Measures

Measure R.1 Number of competent diagnosticians in laboratory conducting rabies tests
(This measure applies to recipients funded for laboratory activities.)

b. PASSIVE Indicators

N/A

Project S: Surveillance for Emerging Threats to Pregnant People and Infants Network (SET-NET)

Project Activity Contact Information:

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Funding Opportunity Description:

a. Overview

The program goals of the Surveillance for Emerging Threats to Pregnant People and Infants Network (SET-NET) are to: 1) Support surveillance systems to address emerging, reemerging, or persistent infectious threats to pregnant people, infants, and young children resulting from prenatal exposure to infectious threats and to identify and monitor adverse outcomes of infections in pregnant people, their pregnancies, and their infants or children; 2) Work collaboratively with state, local, and territorial health departments to implement longitudinal follow-up of infants born to people with evidence of infection during pregnancy to detect adverse pregnancy, infant, and child outcomes through early childhood; 3) Work with clinical experts and clinical professional organizations to develop recommendations for enhanced follow-up, targeted screening, evaluation, and treatment for pregnant people, infants, and children and to improve surveillance timeliness and quality; 4) Develop and disseminate clinical guidance and health communications materials and tools to promote the health and well-being of pregnant people, infants, and children to providers, policymakers, and the public; and 5) Promote and advance health equity through enhancing surveillance activities to monitor and assess health inequities and prioritizing prevention and treatment opportunities to address health inequities and ensure equitable access.

This project is divided into three tiers which correspond to expected levels of performance and funding support.

Tier 1 strategies and activities focus on developing methods to conduct population-based surveillance to be used locally or at the state-level to inform policy and clinical guidance efforts. Tier 1 activities include developing case ascertainment methods through data linkages, data analysis and dissemination, and implementation of findings at the local or state level. Tier 1 activities would not include transmission of line level data to CDC nor medical record abstraction; however, reports of aggregated data and on surveillance methodologies could be sent to CDC.

Tier 2 strategies and activities build upon Tier 1 and consist of conducting representative population-based surveillance in which the line level data are submitted to CDC and aggregated to inform multi-jurisdictional policy and clinical guidance efforts. Tier 2 activities include a focus on complete case ascertainment, transmission of data to CDC, medical record abstraction, data analysis and dissemination, and implementation of findings at the local or state level.

Tier 3 strategies and activities build upon Tiers 1 and 2 and include providing technical surveillance support to other funded recipients. In collaboration with CDC, this may include providing technical assistance on case ascertainment methods and consulting on jurisdiction specific data resources with the goal of improving surveillance capacity of Tier 1 recipients to conduct complete, timely and representative data collection.

Best practice strategies for pregnant people-infant linked longitudinal surveillance will be shared and implemented across jurisdictions. With this tiered approach, this jurisdictional surveillance model will be able to support high quality surveillance methodologies for pregnant people-infant linked longitudinal surveillance through sharing of best practices broadly, and if during a national or local emergency, Tier 1 recipients could launch surveillance, thereby expanding the network and enhancing data collection efforts during a public health response.

b. Health Equity

The project will address health equity through: 1) developing and enhancing efforts to collect data regarding social determinants of health to achieve goals of the program, 2) assessing and improving completeness of data around health equity and ensuring representativeness with respect to populations that have suffered historical injustices and inequities, and 3) improving partnerships, including with individuals or groups with lived experiences, to help disseminate and implement findings to inform programs working to improve equity and promote better health.

c. Healthy People

This funding addresses the Healthy People 2030 overarching goal to "Eliminate health disparities, achieve health equity, and attain health literacy to improve the health and well-being of all" and addresses the goal of improving the health and well-being of pregnant people, infants, children, and families, including the following specific objectives:

MICH-01: Reduce the rate of fetal deaths at 20 or more weeks of gestation
MICH-02: Reduce the rate of infant deaths
MICH-03: Reduce the rate of death in children and adolescents aged 1 to 19 years
MICH-04: Reduce maternal deaths
MICH-05: Reduce severe maternal complications identified during delivery hospitalization
MICH-07: Reduce preterm births
MICH-08: Increase the proportion of pregnant women who receive early and adequate prenatal care
MICH-10: Increase the proportion of pregnant women who receive early and adequate prenatal and pediatric care
MICH-16: Increase the proportion of infants who are breastfed at 1 year

d. Local Health Department and Tribal Engagement

Proposed areas of surveillance should be population-based and representative of the applicant's state, local, or territorial locations. This may include local health departments and tribal engagement to ensure surveillance efforts are representative. Applicants should ensure that data and findings will be shared back for cross communication between the groups.

e. Other National Public Health Priorities and Strategies

N/A

CDC Project Description:

a. Problem Statement

CDC developed an innovative jurisdictional surveillance program to monitor the impact of infectious disease threats on pregnant people and their infants called SET-NET. Under SET-NET, jurisdictions were able to detect threats faster and equip healthcare providers, policymakers, and the public with the information to protect the health of these populations. With help from a multitude of clinical and public health partners, this surveillance approach was built to achieve a jurisdictional surveillance network to monitor infections and outcomes and to expand and pivot to future emerging, reemerging, and persistent infectious threats (referred to as infectious threats) on pregnant people and their infants. The approach has been used to monitor COVID-19, congenital cytomegalovirus, hepatitis C, mpox, and syphilis infection during pregnancy and helped form the basis for clinical decision making and public health recommendations to protect pregnant people and their infants.

The enhanced surveillance used to monitor the impact of infectious threats to pregnant people and their infants includes the collection of information about prenatal diagnostic testing, prevention and treatment regimens, birth outcomes, and clinical outcomes among pregnant people and their infants through early childhood. This surveillance model leverages the public health reporting authority of jurisdictions or CDC. The project goal is to continue to rapidly disseminate findings on the effects of infectious threats to pregnant people and their infants, to inform and update CDC clinical recommendations and public health guidance and messages, build surveillance capacity for prevention, and to improve the health of pregnant people and their infants. This information collection is authorized by Section 301 of the Public Health Service Act [42 U.S.C. 241].

b. Purpose

The purpose of this project is to provide recipients financial and technical support for collaborative participation in surveillance data systems for infectious threats during pregnancy on the pregnant person and their pregnancy, infants, and children, through SET-NET. The major areas of focus of SET-NET are: 1) to expand and sustain surveillance efforts by monitoring for infectious threats, including associated prevention and treatment strategies, and their effects on the pregnancy and development and well-being of infants and children, and 2) to implement, sustain, innovate, and expand longitudinal follow-up of pregnancy dyads with exposure to infections to detect adverse pregnancy, infant, and childhood outcomes of these infectious threats.

Infections during pregnancy with known or unknown impacts on the pregnant individual and those that pose a known or unknown risk of congenital infection, adverse pregnancy outcomes, or adverse developmental or other outcomes in the infant or child would be considered under this NOFO. CDC will utilize a prioritization framework to strategically determine when and where to deploy the SET-NET jurisdictional surveillance model, including what exposures would be prioritized for addition or removal for surveillance. Jurisdictions may propose additional threats, but rationale and justification must be provided in the workplan that applies the prioritization framework for inclusion of the threat. The prioritization framework includes whether the infection is relevant and urgent to include for surveillance among pregnant people and infants and whether it is feasible to collect and analyze data on the exposure and outcomes through this jurisdictional surveillance model. The initial phase of the prioritization framework will be shared with applicants during the Project specific webinar which will be scheduled in February 2024.

CDC encourages all state, local, and territorial health departments to participate to expand and sustain the capability to monitor pregnant people and their infants and children with infectious threats, to address local

and national needs for these populations. Tier 1 recipients will focus on developing methods to conduct population-based surveillance to be used locally or at the state level. Tier 2 recipients will be expected to complete all Tier 1 activities and also conduct representative population-based surveillance in which line level data are submitted to CDC and aggregated to inform multi-jurisdictional policy and clinical guidance efforts. Tier 3 recipients will be expected to complete all Tier 1 and 2 activities and provide technical support to other recipients in collaboration with CDC. All recipients would be expected to participate in surveillance efforts, including data analysis and dissemination, and ensuring findings are implemented at the local or state level. These data may also be used to plan for services for pregnant people, infants, children, and families.

c. Outcomes

Tier 1 applicants will only be expected to meet Tier 1 outcomes, Tier 2 applicants will be expected to meet Tier 1 and Tier 2 outcomes, and Tier 3 applicants will be expected to meet all Tier 1, 2, and 3 outcomes.

Tier 1:

1. Improve epidemiological capacity to monitor pregnant people[OBJ], and their infants and children exposed to the selected infections during pregnancy, including for people who are at increased risk, and where applicable, those who meet the required case definition(s) defined by program. As a surveillance activity, no additional laboratory tests, follow-up visits, or preventive or medical treatment are part of these efforts or required for reporting the data requested.

2. Establish collaborations with clinical networks and healthcare systems within the jurisdictions for the overall goal to strengthen data collection efforts and translation of data to action.

3. Use of public health data and dissemination to inform local, state, and national policies and translation of public health data into clinical and public health recommendations, particularly for screening, prevention, treatment or interventions for pregnant people and their infants.

4. Establish a network for surveillance for infectious threats during pregnancy and infants that could be rapidly deployed for future public health emergencies, including those of national or local interest. This includes rapid detection of pregnant people and infants with the infection of interest.

Tier 2:

5. Ensure completeness, timeliness, and representativeness of data reported to surveillance systems for infectious threats for pregnant people and their infants to state, local, and territorial health departments and CDC in alignment with established timelines. This includes more complete information on pregnancy status for case identification through routine case interviews, medical chart review, electronic laboratory reporting, electronic case reporting, or linkages with other existing data sources.

6. Improve monitoring of infants and children to assess long-term health outcomes, with follow-up data reported up through early childhood (as applicable based on the surveillance protocol for the

exposure), utilizing strategies that promote completeness of data collection, reducing lost to follow-up, and ensuring equitable representation of vulnerable populations.

7. Implement new efforts or synergize with existing efforts to modernize health information and enterprise infrastructure. This includes processes to streamline laboratory data collection and transmission, data linkage procedures, and medical record abstraction to improve timeliness and completeness of data.

Tier 3:

8. Sustain or expand a network for surveillance for infectious threats during pregnancy and infants that could be rapidly deployed for future public health emergencies, including those of national or local interest. This includes conducting evaluations of the system and participating in efforts to disseminate models or best practices for pregnant people infant linked surveillance.

9. Support a network of jurisdictional partners to enhance the capabilities of the surveillance network. This includes providing technical assistance to recipients funded as Tier 1 or 2 and supporting efforts to streamline surveillance methods, in collaboration with CDC.

Funding Strategy:

Funds should be utilized for personnel, travel, supplies and equipment, information technology support, or contractual support for proposed activities. This funding is dependent upon continued appropriations for related efforts and should not duplicate other funding mechanisms. Applicants who have not participated in previous funding cycles of SET-NET under the *ELC Cooperative Agreement* CK19-1904, or do not have established surveillance methods for conducting population-based pregnant people and infant linked surveillance are encouraged to apply to Tier 1. Applicants that have participated in SET-NET and have demonstrated evidence of submitting representative population-based pregnant people and infant linked surveillance data are encouraged to apply to Tier 2. Applicants who meet the criteria for applying for Tier 2 and have the capacity and motivation to provide technical support to other funded jurisdictions, in collaboration with CDC, are encouraged to apply to Tier 3.

All applicants must provide a project management plan which outlines staffing, including staff to be hired or staff in place, to effectively conduct the strategies and activities of this program, and there should be justification for using a percentage of current staff for this activity, hiring new full-time staff, or using contractual mechanisms. An in-kind program director or ELC governance team member should be actively involved throughout the course of this project and is requested to attend at least 2 calls per budget period.

Tier 1 applicants should include a jurisdictional-level coordinator in their project management plan. The jurisdictional-level coordinator should be able to complete tasks required for Tier 1 activities and have the necessary skills to discuss epidemiological and surveillance topics.

Tier 2 and 3 applicants should include a jurisdictional-level coordinator (at least 75%), an epidemiologist (at least 20%), a medical record abstractor (100%), and at least 20% data management support in their project management plan.

Optional staff for all Tiers can include health communication staff to support data dissemination efforts.

The jurisdictional-level coordinator is expected to manage the project and staffing plan, coordinate and conduct surveillance activities, including the performance or oversight of linkages of existing data sources, data abstraction, data management, quality assurance, and timely reporting to CDC, and is expected to collaborate regularly with the CDC designated points of contact.

Funding will not be approved for costs such as laboratory testing supplies and equipment, incentives, or honoraria.

Funding decisions will be based on:

1. Quality of application including information in work plan on how applicant will accomplish required tasks and strategies and activities, a project management plan that outlines appropriate staffing to accomplish activities and demonstrated capacity to conduct population-based longitudinal surveillance.
2. Estimates of number of cases or overall burden of infectious threats during pregnancy in the jurisdiction.
3. Number of births per year in the proposed area of surveillance.
4. Evidence of strong collaborations, including letters of support or data use agreements, between infectious disease and maternal and child health or birth defects programs at the health department, and with external clinical or public health partners.

Applicants must provide strong justification for their requests to support the surveillance systems for infectious threats for pregnant people and their infants and the use of these funds. Applicants that have a high cost of living or that may otherwise experience difficulties hiring may request additional funds above the base amount for this activity.

- Approximate total availability of funds for Project: $8,000,000
    - Approximate number of Tier 1 awards: 11
    - Approximate average per Tier 1 award: $100,000-$250,000
    - Approximate number of Tier 2 awards: 15
    - Approximate average per Tier 2 award: $300,000-$400,000
    - Approximate number of Tier 3 awards: 4
    - Approximate average per Tier 3 award: $600,000

***Please note:**

1. For State Health Departments (SHDs), when entering budget requests, recipients must use the 'Public Health Allocation' to indicate the portion of financial support going toward 'Local/Regional Health Department (LHD)' support versus staying at the SHD level. This allocation data helps ELC answer inquiries regarding the financial support to LHDs which is crucial given the important role LHDs have in addressing infectious diseases.
2. For Local Health Departments (LHDs), when entering budget requests, please ensure the 'Public Health Allocation' is set to 100% 'Local/Regional Health Department (LHD)' support.

3. For Territorial Health Departments, if you have local/regional jurisdictions, please follow the instructions for State Health Departments in #1.

Required Tasks:

Acceptance of funding conveys acknowledgement and indication that the following requirements will be met. Related strategy/activity noted in parentheses after Required Task. Surveillance protocol and the requested variables in the format of a data dictionary, with an accompanying data abstraction guide and other surveillance resources, will be developed and distributed to ELC awardees and will also be available upon request.

Tier 1 applicants will only be expected to meet Tier 1 required tasks, Tier 2 applicants will be expected to meet Tier 1 and Tier 2 required tasks, and Tier 3 applicants will be expected to meet all Tier 1, 2, and 3 required tasks.

Tier 1:

1. Participate in all regularly scheduled calls as specified by CDC during the project period, including jurisdiction-only calls and group calls with all awardees.
2. Submit project management structure documentation sufficient to meet outcomes of the project and that clearly define roles of both funded and in-kind staff.
    a. This should be submitted in ELC CAMP under Project's Work Plan within the first six months of period of performance.
3. Submit documentation to CDC on case ascertainment processes and data linkages, including expected cases per year and available data sources.
    a. Documentation should also detail any gaps in case ascertainment of populations that are likely to experience health inequities and strategies to address these gaps. This documentation will be updated quarterly to align with the data submission time points (Tier 1 is not expected to submit line level data per case but is expected to submit documentation on case ascertainment processes).

Tier 2:

4. Report on data use agreements or letters of support indicating access to data required to conduct surveillance, including case surveillance, electronic laboratory reporting, vital statistics, and other relevant data sources.
    a. All applicants should confirm that they have access to, at a minimum, case surveillance, electronic laboratory reporting and vital records (i.e., birth and fetal death records) and provide an established data use agreements or letters of support indicating access to these data. Letters of support could come from leadership of the department in which the exposure of interest is housed within the jurisdiction's department of health (e.g., STD division) and maternal and child health leadership within the jurisdiction.
5. Submit data to CDC during the designated data submission time points on a quarterly basis.

a. Submit all variables requested according to surveillance protocol for the infectious threat, with the caveat that redaction of variables that cannot be submitted due to jurisdictional laws, limitations, or regulations is allowable.

Tier 3:

6. Present on best practices and SET-NET methods at two jurisdictional group calls or other dissemination opportunities per budget period.

Strategies and Activities:

Tier 1 applicants will only be expected to meet Tier 1 strategies and activities, Tier 2 applicants will be expected to meet Tier 1 and Tier 2 strategies and activities, and Tier 3 applicants will be expected to meet all Tier 1, 2, and 3 strategies and activities.

0) Strategy to Address Required Tasks

a) Address Required Tasks in project guidance.

☐ Required ☒Optional

Area A: Surveillance, Detection, and Response

1) Tier 1: Develop methods for surveillance of infections during pregnancy

a) Develop case ascertainment plan and inclusion criteria

i) Work with CDC to develop a comprehensive case ascertainment plan and inclusion criteria for the exposure of interest in collaboration with other jurisdictions working on the exposure of interest if applicable and case ascertainment plan. Identify data sources to be used as well as any anticipated gaps in the case ascertainment methodology. Recipient should also have the ability to send aggregated data to CDC if requested.

☒ Required ☐ Optional

b) Obtain data use agreements and develop linkages with existing data sources

i) Obtain at least one data use agreement that can be used to improve case ascertainment or completeness of key variables (e.g., vital statistics, infectious disease registries, birth defects registries). Specify methods, including algorithm for linkages and linking variables, that would be used to perform linkages across data sources with a focus on complete and timely ascertainment.

☐ Required ☒ Optional

2) Tier 2: Improve completeness of surveillance of infections during pregnancy

a) Conduct complete and timely case ascertainment for reporting

i) Identify and report all eligible cases that meet required inclusion criteria for submission to CDC SET-NET for infectious threat. Describe how cases would be ascertained to ensure completeness, timeliness, and representativeness and what the expected number of cases per year for the area of surveillance. Specify any known gaps or limitations in

identification of all cases. CDC requests that case ascertainment for first year of included cases is complete within first 6 months of period of performance.

☒ Required ☐ Optional

b) Conduct longitudinal follow up with medical record abstraction

i) Collect follow-up clinical data through linkage to data sources and medical records abstraction at designated time points for pregnant people, infants or children meeting the inclusion criteria and report to CDC SET-NET. Specify sources of data and methods for requesting medical records and strategies to increase completeness of infant follow-up data.

☒ Required ☐ Optional

c) Specify data elements that will enhance assessment of health equity

i) Specify any data elements and standards that are priority for data collection, such as location, race, ethnicity, industry, education, occupation, income, language, nativity, disability, housing status, sexual orientation, and gender identity, that will enhance the monitoring and assessment of health inequities

☒ Required ☐ Optional

3) Tier 2: Implement data modernization efforts with linked pregnancy-child data

a) Develop and modernize core surveillance capacity

i) Work with cross-cutting health information systems team within health department to develop and modernize core surveillance capacity within health departments to monitor and protect pregnant people, infants, and children. Specify methods for ensuring modernization efforts are targeted at pregnant people and infant populations. For example, improving and utilizing electronic laboratory records or electronic case reporting to ascertain pregnancy status in routine surveillance for the exposure of interest, or ensuring pregnancy related variables align with data standards or standard vocabulary.

☒ Required ☐ Optional

b) Specify processes for linking pregnancy-infant health information

i) Specify process for linking pregnancy-infant health information to assess the impact of prenatal infection. This should include information on electronic laboratory reporting processes. This may include implementing electronic mechanisms for data extraction or exchange of public health information from existing data sources.

☒ Required ☐ Optional

4) Tier 3: Pilot surveillance for other infections during pregnancy

a) Collaborate on processes for expanding existing surveillance to new threats

i) Collaborate to develop case ascertainment and inclusion criteria, identify data sources and variables, and other surveillance strategies to ensure completeness of reporting.

☐ Required ☒ Optional

b) Conduct analyses to evaluate the pilot surveillance project

i) Analyses could include monitoring trends and high-risk groups to evaluate effectiveness of pilot surveillance project.

☐ Required ☒ Optional

Area C: Coordination and Partnerships

5) Tier 1: Engage in partnerships for surveillance for infections during pregnancy

a) Identify and connect with local, state, and national partners

i) Connections raise awareness and increase provider support and collaboration and ensure data collected can inform public health action. Examples include, but are not limited to, professional societies, healthcare systems, health plans, schools/universities, and community interest groups. Specify the partners, connection frequency and format, and outputs of collaborations.

☒ Required ☐ Optional

b) Perform outreach, information sharing, and education to key partners.

i) This could be accomplished through webinars, presentations at partner meetings or workgroups, modifying and disseminating existing outreach materials.

☐ Required ☒ Optional

6) Tier 2: Develop and disseminate public health information

a) Analyze and prepare summaries of data for distribution

i) Analyze data, prepare summaries of data (e.g., reports, maps, manuscripts, presentations), and distribute to medical providers, public health partners, policy makers, and the public at the local, state, or national level. Specify the outputs and how the information could be used to inform local efforts. Public health information includes evidence-based prevention and treatment options, that will help protect pregnant people, infants, and children from infectious threats.

☒ Required ☐ Optional

b) Identify and connect with local, state, and national partners

i) Connections raise awareness and increase provider support and collaboration and ensure data collected can inform public health action. Examples include, but are not limited to, professional societies, healthcare systems, health plans, schools/universities, and community interest groups. Specify the partners, connection frequency and format, and outputs of collaborations.

☐ Required ☒ Optional

c) Identify and promote materials and policies informed by jurisdictional data

i) Quantify the use of data for action by tracking the local, state, and national tools, protocols, publications, and policies that resulted from or were informed by jurisdictional data.

☐ Required ☒ Optional

7) Tier 3: Partner with other recipients to provide technical assistance

a) Share information and best practices routinely to support advancement of project

i) This includes assisting other jurisdictional partners in determining best practices, presenting at CDC-led working groups or other venues, and reviewing CDC program materials, in collaboration with CDC.

☒ Required ☐ Optional

b) Participate collaboratively in the development of best practices

i) This includes development of best practices for preparing and responding to emerging threats and for dissemination of information for the protection of pregnant people and their infants.

☒ Required ☐ Optional

8) Tier 3: Develop and implement new and advanced methods

a) Specify new processes for timely data collection and enhanced data quality

i) This includes the creation and implementation of innovative strategies for pregnant people-infant linked surveillance and public health data dissemination.

☒ Required ☐ Optional

Collaborations:

a. With CDC-Funded Programs

Collaboration is strongly encouraged with birth defects surveillance efforts in health departments, including awardees supported by the National Center on Birth Defects and Developmental Disabilities (NCBDDD) and other CDC programs, including those focused on maternal mortality and nationally notifiable infectious diseases. Collaboration is encouraged with grantees of CDC-RFA-DD-23-0003 Pregnant People-Infant Linked Longitudinal Surveillance.

b. With Organizations External to CDC

Awardees are encouraged to collaborate with national and local professional organizations, such as American Academy of Pediatrics, American College of Obstetricians and Gynecologists, American Board of Obstetrics and Gynecology, Infectious Diseases Society for America, Society for Maternal-Fetal Medicine, American Nurses Association, American College of Nurse-Midwives, and other professional groups as appropriate to

increase provider support and collaboration with the surveillance systems. Collaboration with healthcare systems, health plans, schools/universities, and community interest groups to support surveillance efforts for infectious threats during pregnancy is also encouraged. An established network for dissemination of key findings, emerging evidence, and novel prevention and management strategies is encouraged to ensure this network is available for dissemination of information in a future public health emergency.

Populations of Focus:

Pregnant people, infants, and children

Evaluation and Performance Measurement:

The NCBDDD Programmatic Team at CDC will support recipients by ensuring that the strategies and activities are implemented as expected and that performance outcomes are achieved in a timely manner. The program will monitor activities according to the Work Plan through routine jurisdictional calls, emails, and progress summaries. The program will provide technical assistance to awardees to overcome any barriers and to improve the effectiveness of the program. Periodic evaluation of the program may be requested on a voluntary basis to inform further expansion of the surveillance network. This would be designed and conducted through close collaboration between CDC and the recipient.

Tier 1 applicants will only be expected to meet Tier 1 performance measures, Tier 2 applicants will be expected to meet Tier 1 and Tier 2 performance measures, and Tier 3 applicants will be expected to meet all Tier 1, 2, and 3 performance measures.

Performance measures included here are representative and may not be final at the time of NOFO publication. Please see the CK-24-0002 Performance Measure Guidance document for all final measures and descriptions.

a. ACTIVE Performance Measures

1) Tier 3: Number of jurisdictional support sessions completed. This can include but is not limited to phone calls, office hours, or materials reviewed.

b. PASSIVE Indicators

Passive indicators will be measured by the CDC project team from jurisdictional data submissions and required data linkage documentation.

1) Tier 1: Number of data sources used for linkage for case ascertainment and data collection for completeness of sociodemographic data variables (e.g., race and ethnicity, location/residence).
2) Tier 2: Percentage of cases submitted to CDC among expected cases for surveillance area by cohort year.
3) Tier 2: Number and percentage of infants with completed medical record abstraction or indication of lost to follow-up among all live births for surveillance area by cohort year submitted to CDC.

Project T: Human Papillomavirus Surveillance Among Men

Program Activity Contact Information:

Carla DeSisto, Epidemiologist, wup5@cdc.gov, 404-498-2846

Funding Opportunity Description:

a. Overview

Men who have sex with men (MSM) are at high risk for developing human papillomavirus (HPV) infection and associated diseases, including anal cancer, and might benefit from vaccination against HPV. Studies and monitoring data from the United States and other countries have demonstrated the impact of HPV vaccination on outcomes in women (e.g., declines in genital warts and cervical precancers), and data from some countries have shown an indirect impact on heterosexual males from female vaccination programs. However, there are limited data on HPV vaccination impact among MSM. Clinical trials of quadrivalent HPV vaccine in MSM showed high efficacy, but the trials were limited to MSM with 5 or fewer lifetime sexual partners, causing concern about generalizability. Ongoing surveillance of HPV prevalence among MSM is needed to assess HPV vaccine impact in this population.

b. Health Equity

This project can assist in advancing health equity because MSM are at high risk for developing HPV infection and associated diseases, including anal cancer, and might benefit from vaccination against HPV. Recipients are encouraged to use this funding to increase the completeness of demographic data (e.g., gender identity, race, and ethnicity), assess other social determinants of health within the population (e.g., health insurance status), and identify sub-populations within their jurisdiction that are disproportionately affected by HPV.

c. Healthy People

This project supports Healthy People 2030 objectives to: reduce infections of HPV types prevented by the vaccine in young adults (IID-07), increase the proportion of adolescents who get recommended doses of the HPV vaccine (IID-08), and increase the proportion of people with vaccination records in an information system (IID-D02).

d. Local Health Department and Tribal Engagement

Recipients should engage with local health departments and/or tribes as appropriate for collection of residual specimens from anal swabs from MSM (e.g., local health departments providing routine sexually transmitted disease [STD] screening).

e. Other National Public Health Priorities and Strategies

Since 2011, the Advisory Committee on Immunization Practices (ACIP) has routinely recommended HPV vaccination for all U.S. males at age 11 or 12 years, with catch-up vaccination through age 26 years. For adults ages 27-45 years, shared clinical decision-making is recommended because some persons who are not adequately vaccinated might benefit.

CDC Project Description:

a. Problem Statement

Infection with HPV in men can cause genital warts, and anal, penile, and oropharyngeal cancers. MSM are at particularly high risk for persistent HPV infection and related diseases. Most of these diseases could be prevented by pre-exposure vaccination against the relevant HPV types. Surveillance activities for this vaccine-preventable infection among MSM are critical to gain information to monitor ongoing vaccination programs.

b. Purpose

Ongoing assessment of HPV prevalence among MSM will identify HPV vaccine impact, including anticipated reduced prevalence of vaccine-preventable HPV among MSM. Recipients will collect residual specimens from anal swabs from sexually active MSM (n=500 annually) and coordinate batch shipment of specimens to the CDC HPV laboratory for HPV testing.

c. Outcomes

1. Improved surveillance of HPV infections among MSM

Funding Strategy:

Funding is open to applicants who have identified at least one STD care clinic or community organization providing anal STD testing to MSM in their recipient jurisdiction. The recipient must demonstrate ongoing data management and epidemiologic capacity to review local data to inform public health action and prepare data for transmission to CDC.

Funds should be used for personnel, supplies, equipment (e.g., specimen collection and shipping supplies), or contractual support for the proposed activities.

Estimated total availability of funds for T*: Human Papillomavirus Surveillance Among Men*: $375,000

- Approximate number of awards: 3
- Approximate average per award: $125,000

Applicants must have the statutory authority to conduct state- or project-area-wide communicable disease or infectious disease surveillance and the organizational structure and capacity to execute the program approach and strategies and meet the project period outcomes, including the organizational capacity to support and/or operate STD care clinics and/or organizations serving at least 500 MSM annually.

***Please note:**

1. For State Health Departments (SHDs), when entering budget requests, recipients must use the 'Public Health Allocation' to indicate the portion of financial support going toward 'Local/Regional Health Department (LHD)' support versus staying at the SHD level. This allocation data helps ELC answer inquiries regarding the financial support to LHDs which is crucial given the important role LHDs have in addressing infectious diseases.
2. For Local Health Departments (LHDs), when entering budget requests, please ensure the 'Public Health Allocation' is set to 100% 'Local/Regional Health Department (LHD)' support.
3. For Territorial Health Departments, if you have local/regional jurisdictions, please follow the instructions for State Health Departments in #1.

Required Tasks:

Acceptance of funding conveys acknowledgement and indication that the following requirements will be met. Related strategy/activity noted in parentheses after Required Task.

1) Provide the names of the participating health center(s) (i.e., health centers submitting anal swab specimens for HPV testing) to the CDC HPV Team by the end of quarter 1, and immediately following any change to participating health center(s). Health center(s) should be STD clinics or community organizations providing anal STD testing to MSM. (Improve surveillance and reporting of anal HPV prevalence among MSM)
2) Obtain any necessary approvals for data collection and shipping of specimens. (Improve surveillance and reporting of anal HPV prevalence among MSM)
3) Provide narrative information to the CDC HPV Team on sources of data for documented HPV vaccination, including specific age ranges included and excluded. (Improve surveillance and reporting of anal HPV prevalence among MSM)
4) Participate in conference calls (approximately 1 hour/quarter), providing site-specific updates on numbers of specimens and data collected/shipped/submitted to CDC to date. (Improve surveillance and reporting of anal HPV prevalence among MSM)
5) Follow standard methodology for specimen collection (i.e., residual/remnant specimens collected for gonorrhea/chlamydia testing with Aptima NAAT). (Improve surveillance and reporting of anal HPV prevalence among MSM)
6) Submit relevant epidemiologic data for specimens collected at least quarterly to CDC HPV Team, following standardized procedures. (Improve surveillance and reporting of anal HPV prevalence among MSM)
7) Ship specimens at least quarterly to CDC HPV laboratory team, following standardized procedures for storage and shipping of specimens. (Improve surveillance and reporting of anal HPV prevalence among MSM)

Strategies and Activities:

0) Strategy to Address Required Tasks

a) Address Required Tasks in project guidance.

☐ Required ☒ Optional

Area A: Surveillance, Detection, and Response

1) Surveillance and reporting of anal HPV prevalence among MSM

a) Identify participating health center(s)

Note: STD clinics or community organizations providing anal STD testing to MSM with sufficient numbers of visits from target population

☒ Required ☐ Optional

b) Obtain anal specimens from sexually active adult MSM (n=500 annually)

Note: Specimens should be from MSM ages 18-45. Ideally, the population will include 200-250 people ages 18-26 years, 150 people ages 27-35 years, and 100-150 people ages 36-45 years. Anal specimen collection should be residual/remnant specimens collected for gonorrhea/chlamydia testing with Aptima NAAT, and collection methodology should be

consistent over time. Anal specimen processing, including storage and shipping, should follow CDC HPV laboratory recommendations.

☒ Required ☐ Optional

c) For each specimen collected, obtain relevant epidemiologic information

Note: Information includes, but is not limited to: age, sex, gender identity, race, ethnicity, health insurance, sexual orientation and/or sex of sex partners, number of lifetime sex partners, HPV vaccination status (e.g., number of doses, age at first dose), and HIV status. Recipient should also track any individual participation in previous project year(s), if possible. Line-listed de-identified demographic and clinical data elements associated with each specimen will be collected by the recipient and electronically submitted to CDC following standardized protocols.

☒ Required ☐ Optional

d) Coordinate submission of specimens and epidemiologic data to CDC

Note: Follow protocol from CDC HPV Laboratory to ship anal specimens. Use provided data dictionary to prepare epidemiologic data for transmission to CDC HPV Team.

☒ Required ☐ Optional

Area B: Prevention and Intervention

2) Improve understanding of other pathogens of interest in MSM

a) Obtain approval for specimens to be tested for other pathogens of interest.

Note: If there is a pathogen of interest to public health in MSM (e.g., mpox), obtain necessary approvals for residual specimens sent to CDC for HPV testing to also be tested for that pathogen.

☐ Required ☒ Optional

3) Improve understanding of anal cancer screening among MSM

a) Obtain information about whether individuals ever had anal cancer screening.

Note: For each specimen collected from MSM in relevant groups (e.g., age groups of interest, people living with HIV).

☐ Required ☒ Optional

Area C: Communication, Coordination, and Partnerships

4) Improve cross-site communication, coordination, and partnership

a) Collaborate with CDC and other recipients to assess changes in HPV prevalence.

☐ Required ☒ Optional

b) Coordinate with CDC if conducting other activities using similar methodology

Note: If recipient is conducting additional activities within the same population using similar methodology (e.g., remnant specimens), contact CDC to discuss how other activities could impact this project.

☐ Required ☒ Optional

Collaborations:

a. With CDC-Funded Programs

Close collaboration is expected with subject matter experts and staff from the CDC HPV Team (Division of Viral Diseases, National Center for Immunization and Respiratory Diseases) and the CDC HPV Laboratory (Division of High-Consequence Pathogens and Pathology, National Center for Emerging and Zoonotic Infectious Diseases).

b. With Organizations External to CDC

Recipients are expected to work with clinical providers in the participating health center(s) in their recipient jurisdiction.

Population(s) of Focus:

Adult (i.e., ages 18-45 years) men (i.e., assigned male at birth, regardless of present gender identity or expression) who have sex with men (i.e., identify as gay or bisexual, or have ever had any type of sexual contact with a male partner) with remnant anal specimens originally collected for clinical purposes (i.e., routine anal chlamydia/gonorrhea screening), who have not participated during the current project year. Ideally, the population would include 200-250 people ages 18-26 years, 150 people ages 27-35 years, and 100-150 people ages 36-45 years.

Evaluation and Performance Measurement:

Performance measures included here are representative and may not be final at the time of NOFO publication. Please see the CK-24-0002 Performance Measure Guidance document for all final measures and descriptions.

a. ACTIVE Performance Measures

N/A

b. PASSIVE Indicators

1. Number of residual specimens from anal swabs obtained and submitted to the CDC HPV laboratory
2. Number of specimens with associated line-list of epidemiologic data submitted to the CDC HPV Team

Project U: HIV Centers for Cluster and Outbreak Response Enhancement (HIV C-CORE)

Project Activity Contact Information:

Karen Schlanger, (404) 718-5660, khs4@cdc.gov

Funding Opportunity Description:

a. Overview

The HIV C-CORE project of the Detection and Response Branch of CDC's Division of HIV Prevention (DHP) aims to advance HIV cluster detection and response (CDR), address the needs of and improve health outcomes for people in clusters of rapid HIV transmission, prevent onward transmission, address service gaps that are contributing to rapid transmission, and reduce HIV health inequities. The project provides an opportunity for recipients to enhance CDR internal health department and community engagement efforts, pilot HIV CDR innovations, evaluate ongoing and new CDR activities, and support the translation of effective practices to different jurisdictions.

The project is split into two tiers: Tier 1 is required, and Tier 2 is optional. Tier 1 includes activities to advance CDR capacity and community engagement and to adapt and translate CDR promising practices. Tier 2 includes important activities to evaluate response outcomes and to pilot and evaluate CDR innovations. Health departments with more established and experienced CDR programs are strongly encouraged to apply to both tiers (as further defined under Funding Strategy).

b. Health Equity

Stigma, discrimination*, racism, poverty, and other social and structural factors pose barriers to delivery of HIV prevention and care services, resulting in rapid HIV transmission. CDR enables health departments to identify networks experiencing rapid HIV transmission, identify gaps in HIV prevention and care services and access, and direct resources to curate tailored treatment and prevention interventions where standard population interventions have failed. By addressing the needs of populations disproportionately affected by HIV, CDR helps to reduce health inequities. Applicants are encouraged to propose using resources to address disparities in access to services identified through CDR activities.

*Stigma and discrimination that impact people's access to HIV prevention and care services are often based on HIV status, gender, sexual orientation, gender identity, race/ethnicity, drug use, and sex work.

c. Healthy People

This project supports Healthy People 2030 objectives to: Reduce the number of new HIV infections (HIV-01), Increase knowledge of HIV status (HIV-02), Reduce the number of new HIV diagnoses (HIV-03); Increase linkage to HIV medical care (HIV-04), and Increase HIV viral suppression (HIV-05).

d. Local Health Department and Tribal Engagement

Recipient's HIV programs will be expected to collaborate with local health departments and tribal entities as needed to facilitate implementation of the proposed Work Plan and to address needs identified through their CDR activities.

e. Other National Public Health Priorities and Strategies

This project also aligns with objectives and strategies of the *National HIV/AIDS Strategy* (National HIV/AIDS Strategy (2022-2025) | HIV.gov) and the federal *Ending the HIV Epidemic in the U.S. (EHE) Plan* (Ending the HIV Epidemic in the U.S. (EHE) | CDC). The fourth pillar and strategy of the EHE Plan is to "respond quickly to potential HIV outbreaks to get vital prevention and treatment services to people who need them". Respond Pillar strategies include: using data to identify communities experiencing rapid HIV transmission and gathering additional information to understand the needs of affected communities; implementing local approaches to mobilize resources for HIV treatment, prevention, and other related services in the most affected communities; and collaborating to understand local needs and provide tailored services (Key EHE Strategies | HIV.gov).

CDC Project Description:

a. Problem Statement

Effective and efficient real-time CDR is key to ending the HIV epidemic in the United States. Public health surveillance strategies, including analysis of HIV molecular data (i.e., molecular cluster detection) and HIV diagnosis data (i.e., time-space cluster detection) can help us quickly identify communities affected by rapid HIV transmission. Rapid transmission occurs when affected communities are not being reached by existing services due to factors such as stigma, discrimination, racism, poverty, and other social and structural factors. HIV CDR enables health departments to identify, investigate, and respond to clusters of rapid transmission, and helps health departments, community-based organizations, and other partners address inequities by ensuring prevention and care systems are serving, and resources are reaching, the people who need them the most. CDC has funded all health department HIV programs to conduct CDR activities since 2018 (PS18-1802 | Announcements | Funding | HIV/AIDS | CDC). While there are many examples of CDR success (CDR Science Brief), new innovations, enhanced community engagement, and more robust CDR evaluation data are needed to identify the most effective, efficient, and community-responsive CDR strategies in different settings. Further, new tools and experience translating CDR best practices to additional jurisdictions are needed to expand the reach of effective CDR approaches and meet the goals of the *Ending the HIV Epidemic in the U.S. (EHE) Plan*.

b. Purpose

To build health department capacity to develop, evaluate, and translate innovative and effective strategies to enhance HIV CDR implementation and identify CDR best practices.

c. Outcomes

1. More effective and diverse public health workforce better prepared to identify, investigate, and respond to clusters and outbreaks of rapid HIV transmission.
2. Enhanced engagement and coordination of CDR efforts within individual health department HIV programs and with other health department HIV programs (e.g., local health departments) to review cluster data, identify additional investigation needs, and effectively respond to identified prevention and care needs.
3. Enhanced community engagement in CDR planning and response activities.
4. More timely access to data and improved integration and use of data to inform HIV CDR efforts.

5. Development and implementation of innovative and effective CDR investigation, outreach, and response strategies at individual, network, and system levels that aim to improve health outcomes and reduce HIV transmission and health inequities.
6. Increased pool of effective deployable interventions that can be used to respond to clusters of rapid HIV transmission at the individual, network, and system levels in varied response contexts.
7. Enhanced evidence of outcomes and impact of CDR activities, including on reducing inequities in HIV outcomes.
8. Enhanced experience of how to effectively translate and implement CDR best practices across jurisdictions with varied local contexts.

Funding Strategy:

All applicants must apply for Tier 1 activities. Applying for Tier 2 activities is optional.

Tier 1 applicants should have an established CDR program, experience responding to one or more HIV clusters, and be committed to expanding their CDR program and enhancing CDR science and translation. Applicants who meet the following criteria should consider applying: 1) performed molecular and time-space cluster detection activities at least 10 of the past 12 months, 2) received HIV sequence data for ≥ 45% of all HIV diagnoses reported during 2020-2022, 3) submitted to CDC at least 1 cluster report form for a cluster of medium or high concern since March 2020, 4) are invested in expanding their CDR program and CDR science and translation, adopting CDR best practices, building CDR science though evaluation of CDR activities, designing and piloting new CDR approaches and methods, and enhancing their CDR community engagement activities, and 5) have HIV program and agency leadership support and commitment to implement the proposed scope of work. Sequence data completeness for diagnoses during 2020-2022 should be determined through analysis of December 2023 data using the CDC-supplied Standard Evaluation Report SAS program.

All applicants meeting criteria for Tier 1 are eligible to apply for Tier 2. However, priority for funding for Tier 2 will be given to applicants who have well-established CDR programs, as evidenced by convening a CDR leadership and coordination group, cluster committee, or similar group at least 10 of the past 12 months (that at minimum includes representatives from surveillance and prevention); and having a response to one or more identified clusters since 2020 that included extensive or ongoing collaboration with community partners to modify systems or otherwise address gaps in services thought to be facilitating rapid transmission. We strongly encourage all health departments with well-established CDR programs (as defined above) to apply for Tier 2.

Tier 1: (Strategies 1, 4, and 5 required; strategy 3 optional)

Estimated total availability of funds for *Project U: HIV Centers for Cluster and Outbreak Response Enhancement (HIV C-CORE) Tier 1*: $5,100,000

- Approximate number of awards: 6
- Approximate average per award: $850,000

Tier 2: (Strategies 2–3 required)

Estimated total availability of funds for *Project U: HIV C-CORE Tier 2*: $1,800,000

- Approximate number of awards: 3
- Approximate average per award: $600,000

Funds should be used for personnel, equipment, supplies, training, travel, and contractual support (e.g., local health jurisdictions, academic partnership, community engagement, data dashboard development) to implement the proposed Work Plan.

All budget justifications should be detailed enough to guide funding decisions:

- All personnel requests must include a clearly defined project-related role and scope of work, and percent FTE should match the anticipated FTE needed to complete activities proposed in the Work Plan.
- Budget details for proposed contract work (including work contracted to a local health department or academic partner) must be clearly justified and describe how funds will be spent, for what activities in the Work Plan, and include a breakdown by category (salary, travel, supplies, or deliverables, etc.).
- All budget line items must indicate which activities will be supported by the requested funding (and additional details can be provided in the line-item budget justification section). With regards to project staffing: All applicants must have a designated C-CORE Project Lead(s) and Project Coordinator who will serve as CDC points of contact for the project. C-CORE project lead should have authority over both HIV surveillance and prevention programs, or co-project leads should be identified from surveillance and prevention programs. This senior staff person(s) can either be in-kind or have the portion of their salary that corresponds to their effort on the project come from this budget. The C-CORE Project Coordinator should be at least .75 FTE on the project and have sufficient skills, experience, and authority to coordinate this multifaceted project. Skills and experience might include a strong understanding of a range of HIV prevention and care interventions, ability to critically review and interpret data for action, experience leading and managing projects, and experience engaging community and health department partners. Other staffing/roles should be requested as needed to complete the proposed Work Plan. Any FTE requests for IT/programming staff needed to support strategic system modifications should be considered time-limited and may not be supported in subsequent budget periods. The location of requested staffing should be determined based on proposed Work Plan and partnerships and can be based at the funded recipient health department or at partnering organizations/institutions (e.g., partnering local HD or academic partner). Applicants should consider the many evaluation-related requirements as they develop their staffing structure and may want to consider academic partnerships for this and potentially other aspects of the Work Plan.

Requests should include funding to support attendance and travel of 1) the Project Lead, Project Coordinator, and up to three additional staff to attend the annual HIV C-CORE recipient meeting (in Atlanta), 2) funding for up to five team members to travel to paired jurisdiction for consultation (Strategy 3, Activity b), and 3) funding for up to three additional team members to travel to the annual CDR Implementation Learning Collaborative (ILC) Summit (Note: The organization funded to coordinate the ILC (through a separate mechanism) will cover the summit travel costs for the first three CDR staff from the C-CORE recipient jurisdiction separately). Funds can be requested for conference related travel (registration, airfare, per diem) for up to one relevant topical conference per person who is funded at ≥0.5 FTE on this project.

Funding requests should not duplicate CDR or other activities required under the Division of HIV Prevention's flagship cooperative agreement (PS24-0047) or other CDC-funded awards to the recipient.

Recipients may not use funds for research, and recipients are responsible for ensuring that their subrecipient partners do not use ELC funds for research purposes.

Recipients may not use funds to purchase HIV pre-exposure prophylaxis (PrEP), HIV antiretroviral therapy (ART), or sterile needles or syringes for drug injection.

Recipients should be aware that future funding decisions will be based on measurable progress toward desired outcomes, as reported through quarterly Work Plan Milestone reporting, regular updates to CDC, summary presentations or reports of successes, challenges and evaluation data, renewal application Work Plan, and availability of funds.

Distribution of funds will vary across awardees and will be dependent on proposed activities (including the number and scope of optional activities proposed) and budget, the quality and composition of the application, capacity for and feasibility of completing proposed activities, the availability of funds, and agency priorities. Geographic diversity, number of clusters previously reported to CDC, and HIV morbidity will be considered during application review, as will attention to funding jurisdictions with different types of CDR infrastructure successes and challenges. Applicants should include relevant CDR background and existing capacity, as appropriate, in their implementation plans at the activity level to facilitate assessments of applications.

Funds may be used to maximize resources for addressing key priorities in the recipient jurisdiction related to health disparities and health equity.*****

Please note:

1. For State Health Departments (SHDs), when entering budget requests, recipients must use the 'Public Health Allocation' to indicate the portion of financial support going toward 'Local/Regional Health Department (LHD)' support versus staying at the SHD level. This allocation data helps ELC answer inquiries regarding the financial support to LHDs which is crucial given the important role LHDs have in addressing infectious diseases.
2. For Local Health Departments (LHDs), when entering budget requests, please ensure the 'Public Health Allocation' is set to 100% 'Local/Regional Health Department (LHD)' support.
3. For Territorial Health Departments, if you have local/regional jurisdictions, please follow the instructions for State Health Departments in #1.

Required Tasks:

Acceptance of funding conveys acknowledgement and indication that the following requirements will be met.

1) Identify/hire and train staff to complete Work Plan and fill key project roles; submit project staffing list to CDC.
2) Attend and present at in-person HIV C-CORE annual recipients' meeting (anticipated to be a two-day meeting in Atlanta, GA in September or October of 2024). Project Lead, Project Coordinator, and up to three additional project team members should attend the recipients' meeting.
3) Participate in CDC C-CORE site visit.
4) Participate in monthly individual recipient check-in calls with CDC and cross-recipient C-CORE conference calls, webinars, and working group calls.

5) Participate in the CDC-funded CDR Implementation Learning Collaborative (ILC), including having at least 3 and up to 6 staff from the jurisdiction attend the annual CDR Implementation Learning Collaborative Summit in Atlanta.
6) Submit a success story related to HIV CDR to CDC and work with CDC or a CDC-funded partner organization to further develop that story for dissemination by CDC or CDC-funded partner.
7) Submit an abstract about recipient jurisdiction's CDR activities to a national conference.
8) Be available to consult and collaborate with CDC on assessing feasibility of potential changes to CDR activities.
9) Revise Work Plan following Notice of Award (including SMART milestones) based on technical review feedback and discussions with CDC on first recipient post award call.
10) Recipients are expected to meet all deadlines for:
    a. Revision of Work Plan
    b. Quarterly milestone progress status
    c. Submission of success stories
    d. Submission of summary documents and/or presentations (that describe activities, successes, challenges, and evaluation data) as described under specific activities

Strategies and Activities:

Tier I: Core activities for all recipients applying for C-CORE funding. Applicants must apply for funding to address all required core activities.

0) Strategy to Address Required Tasks

a) Address Required Tasks in project guidance.

☒ Required ☐ Optional

Area A: Surveillance, Detection, and Response

1) Strengthen internal health department engagement in designing responses (Tier 1)

a) Enhance CDR engagement to review data and design multi-level interventions.

i) Develop, implement and/or strengthen an internal written plan and implementation of activities in the plan to enhance ongoing routine engagement across the health department to review cluster data, identify investigation needs, and design network and systems level interventions.

ii) This enhanced engagement plan should, at a minimum, include facilitating meaningful participation in monthly CDR leadership and coordination group from HIV program leadership, staff from HIV surveillance, prevention, partner services, and linkage to care programs, as well as other relevant staff (e.g., from hepatitis, harm reduction/overdose prevention, or STI programs).

iii) Key roles of the CDR leadership and coordination group should include: 1) reviewing HIV molecular and time-space data monthly to identify and prioritize clusters of rapid HIV transmission for further investigation and response, and 2) developing and facilitating implementation of tailored actions to investigate and respond to prioritized clusters at network and systems levels (to improve HIV prevention and care services and address social

determinants of health), in addition to addressing identified needs of individual cluster members).

iv) The development, enhancement, and implementation of this plan will likely be informed by the strategies and experiences of enhanced CDR cross-disciplinary engagement shared on recipient calls and during the consultation described in Strategy 5, activity b(ii) (below).

v) Health departments that already have broad participation and meaningful engagement in monthly CDR leadership and coordination group to review data, prioritize clusters, and develop multi-level and tailored cluster response actions should propose specific ways to strengthen, formalize, and document this internal leadership and cross disciplinary engagement at the recipient health department, and if appropriate, also consider supporting similar efforts at local health departments where clusters have been detected.

vi) Document strategies used and successes and challenges experienced with enhancing cross-disciplinary CDR engagement and multi-level response planning in a format that can be shared with and translated to other jurisdictions (e.g., in a project brief or a presentation on a CDC-funded CDR Implementation Learning Collaborative (ILC) call or at the ILC summit).

(a) Applicant's implementation plan for this activity should describe existing CDR experience and capacity in addition to proposal for implementing the activity. Specifically, the implementation plan should include all of following: 1) current CDR staffing structure and capacity, 2) a description of current internal CDR engagement processes and experiences (type of staff and from what program areas participate in routine as well as escalated response planning and coordination), 3) the proposed plan to strengthen and document enhanced internal CDR engagement activities in response planning, including any CDR staff training plans.

☒ Required ☐ Optional

Applicants may apply for funding to address the enhanced activities described below in addition to required Tier I core activities.

2) Design and implement evaluation plan of multi-level response outcomes and impact (Tier 2)

a) Design and pilot use of an adaptable cluster response evaluation plan

i) During the first half of the budget period, prospectively design an evaluation plan/framework, including process, outcome, and impact metrics to evaluate (common/anticipated) response activities. Evaluation plan/framework should be applicable to both sexual and injection drug use-related priority clusters and able to be adapted and deployed during a cluster response.

(a) A key benefit of CDR is the ability to focus on changes that impact networks and systems and not just individuals. The evaluation plan must include strategies and considerations for measuring response impact on networks and systems. The evaluation plan should also: 1) use SMART goals (or similar goal-setting method) to define progress/success and include a tracking sheet, dashboard, or other IT tool to manage/summarize key output and outcome measures/indicators, 2) consider both quantitative and qualitative data

(e.g., obtaining feedback from cluster network members or service providers on topics such as experiences with response activities, feasibility and acceptability and impact of response interventions, and 3) consider collecting and monitoring data (e.g., client demographics, geographic access to services, social determinants of health) to inform equitable implementation of response and assess measures of equity and/or impact on health disparities.

(b) Submit developed evaluation plan to CDC.

(c) Applicant's implementation plan for this activity should describe current CDR evaluation experience and capacity in addition to proposed plan for this activity.

☒ Required ☐ Optional

b) Pilot use of an adaptable cluster response evaluation plan

i) During the second half of the budget period, pilot adaptation and implementation of proposed evaluation plan as part of responding to one or more priority clusters.

(a) High and moderate morbidity jurisdictions can consider reducing the threshold to respond to molecular clusters to include those with at least three (rather than five) new diagnoses within the previous 12 months as needed to facilitate opportunities to pilot evaluation plan.

(b) Report to CDC pilot evaluation results as well as evaluation plan implementation successes, challenges, and limitations.

☒ Required ☐ Optional

3) Develop, implement, and evaluate CDR innovations to inform CDR implementation (Tier 2)

a) Pilot an innovative response demonstration project adaptable to other jurisdictions

i) Proposed innovation should focus on piloting and evaluating strategies to better reach, understand, and engage the affected network and communities (not just the known/named network) through interventions such as: conducting rapid qualitative assessments with network members and providers who serve them to inform response activities; adapting outreach approaches to CDR context (e.g., venue or cluster interviewing; social network strategies for testing and/or PrEP referrals); innovative use of incentives (e.g., to facilitate treatment or partner services engagement among cluster members and/or facilitate testing and PrEP linkage among network members or affected community).

ii) The proposed innovation and evaluation should be initiated within the budget period, however, depending on the scope of the innovation, evaluation activities may extend into the next budget period. If successful, recipient should anticipate collaborating with one or more Tier 1 recipients in future budget periods to translate this promising practice to that jurisdiction. Funding can be proposed to establish, implement, promote, and evaluate the innovation, but not for ongoing staffing, incentives or other programmatic costs beyond the pilot and evaluation period.

iii) Applicants are strongly encouraged to propose an innovation that centers around health equity or addresses social determinants of health.

iv) The implementation and evaluation plan for the pilot will be finalized in consultation with CDC.

v) Report to CDC implementation successes, challenges, and any evaluation data (process, outcome, impact measures) and share any developed SOPs, tools, and/or scripts.

☒ Required ☐ Optional

b) *Pilot an (additional) innovative CDR demonstration project*

i) Proposed innovation could include piloting and evaluating an additional strategy to better reach, understand, and engage the affected network and communities as described in Strategy 3, Activity a, or could focus on other CDR-driven innovations to address identified gaps in services, social determinants of health identified as facilitating rapid transmission, or to address other locally identified CDR-related needs, such as:

(a) An innovative collaboration with a local health care provider (e.g., FQHC, Ryan White-funded health center, etc.) to address one or more key service or service utilization gaps identified through a cluster/outbreak investigation. This activity could take on a range of approaches, including but not limited to staff training, revised workflows, modifying EHR/EMR prompts, or establishing or expanding low threshold services. Innovations proposed can address topic areas such as stigma, outreach, status neutral services, syndemics, and housing.

(b) An innovative collaboration with community partner(s) to address one or more social determinants of health that have been identified as contributing to locally identified cluster(s) (e.g., expand housing options or referral systems for network members or affected communities).

(c) Strategies to enhance CDR collaborations with local health departments to improve CDR-related engagement, coordination, access to and review of CDR-related data, and multi-level response activities.

(d) Innovations to improve cluster detection or data timeliness, cluster prioritization strategies (e.g., evaluate different prioritization matrices), and/or data visualization (that are not otherwise funded through DHP's flagship cooperative agreement).

(e) Innovative syndemic approaches to integrating delivery of interventions to network members or people with similar characteristics that make them susceptible to HIV infection (e.g., hepatitis, STIs, mpox, injection drug users).

(f) Innovations to facilitate expedited, "red carpet", or "low barrier" health care appointments for cluster and network members.

(g) Use of self-testing for affected networks.

(h) Strategies to increase HIV resistance testing and reporting in one or more medium to high morbidity local jurisdictions.

(i) Collaboration with an academic partner to pilot consent protocols for research re-use of public health data

(j) Applicants are welcome to propose piloting other CDR innovations.

ii) Proposed innovation and evaluation should be initiated within the budget period, however, depending on the scope of the innovation, evaluation activities may extend into the next budget period. If successful, the recipient should anticipate collaborating with other funding recipients in future budget periods to translate this promising practice to other jurisdictions. Funding can be proposed to establish, promote, and evaluate the innovation but not for ongoing staffing, diagnostic or treatment-related costs.

iii) If appropriate, applicants may want to consider using rapid cycle continuous quality improvement (CQI) or similar methodologies when implementing their proposed innovation. CQI methodologies are appropriate in scenarios where it makes sense to pilot innovations and potential improvements in a stepwise fashion of rapid implementation and assessment until desired outcomes are met. Innovations such as piloting strategies to increase provider ordering of molecular testing or to increase PrEP referrals or uptake among populations impacted by rapid transmission may lend themselves well to CQI methodologies.

iv) Share with CDC and other recipients the implementation successes, challenges, and any evaluation data (process, outcome, impact measures), and share any developed SOPs, tools, and/or scripts.

v) In addition to describing applicants plan to implement the proposed innovation plan, the implementation plan for this activity should include a rationale for and current capacity to implement the proposed innovation.

☐ Required ☒ Optional

c) *Pilot an additional innovative demonstration project based on guidance for Strategy 3, Activity a) or b).*

☐ Required ☒ Optional

Area C: Communication, Coordination, and Partnerships

4) Enhance CDR Community Engagement and Communication (Tier 1)

a) Enhance community response planning and implementation engagement.

i) Implement and evaluate at least three of the following activities to enhance and expand meaningful CDR community engagement in response planning and implementation that, if successful, could be adapted to other jurisdictions. These implementation and evaluation plans should focus on activities that are not already required in DHP's new flagship

cooperative agreement (PS24-0047) and that the applicant health department has not already implemented.

(a) Develop, implement, and evaluate processes to routinely consult and collaborate with community partners when considering additional investigation needs, developing plans for how to respond to clusters at individual, network, and systems levels, and to engage in an ongoing way with specific cluster responses.

(b) Engage HIV planning group to establish a CDR subcommittee where the health department can provide CDR updates and obtain input on a range of CDR-related activities (e.g., messaging strategies to cluster members, community messaging strategies about CDR work, data security enhancements). Evaluate engagement.

(c) With meaningful engagement of community partners, coalitions, or HIV planning councils, conduct a comprehensive review of current health department (HD) HIV data security and data sharing policies and procedures (including molecular HIV data) and identify opportunities to strengthen HD protections of molecular sequence and other HIV data while incorporating community input. Document and evaluate community engagement process, community perspectives expressed, and any aspects of strengthened data protections that address expressed community perspectives.

    i. **Tier 2 applicants are strongly encouraged to propose implementing this specific Tier 1 sub-activity**.)

(d) Substantively expand and enhance plain-language communications about CDR to community members by developing, disseminating or implementing, and evaluating a presentation, fact sheet, webpage, video, Disease Investigation Specialists (DIS) script, or other related product or approach.

(e) Develop an annual report with input from community partners to summarize CDR activities, including successes, challenges, improvements in service delivery, and community perspectives.

(f) Propose a substantive alternative CDR community engagement activity that meets locally identified needs.

ii) Engagement should include people with HIV, representatives of local populations most affected by HIV, and organizations and service providers who represent and/or serve them.

iii) Evaluation plans should be written and could include description of activities, outputs, outcomes, impact, and challenges with enhanced community engagement activities, and should consider inclusion of perspectives from community members and partners.

iv) Share with CDC other C-CORE recipients a summary of your community engagement activities and evaluation results (e.g., via recipients' webinar, presentation at C-CORE recipients' meeting and/or ILC summit, or a written summary report) and also report out these activities to your community partners as appropriate (eg., HIV Planning Group)

v) Applicant's implementation plan for this activity should describe current CDR community engagement experience and capacity in addition to proposed scope of work for this activity.

☒ Required ☐ Optional

b) Develop and implement CDR provider education programming.

i) Develop and implement CDR provider educational program that focuses on one or both of the following topics:

(a) Increasing healthcare and other service provider engagement in response planning and implementation (i.e., education/training that is aimed at healthcare and service providers who are or will likely be engaged in active cluster response work, such as providing input on potential additional investigation needs and developing and implementing plans for how to respond at the individual, network, and systems levels, among specific clusters)

(b) Increasing HIV health care providers' understanding of CDR and related topics more broadly

1. This more general CDR provider training program could take many forms such as provider detailing or collaborating with an AIDS Education and Training Center (AETC) to offer a training that provides continuing education credits (CEUs).

2. Depending on the scope of the educational program, it may be more appropriate to develop the program in the current budget period and implement it in the next budget period.

3. Education program could include topics such as: what CDR is; how laboratory test results are shared with the HD and used for surveillance activities; the importance of drug resistance testing and how antiretroviral therapy can be rapidly initiated while waiting on resistance test results; strategies to explain to patients what information is shared with HDs for surveillance and how this data is used; and guidance on how to protect patient confidentiality in the event of a subpoena for medical records.

4. Consider marketing the training to providers who have not been ordering HIV drug resistance tests as a strategy to increase availability of molecular data for CDR activities.

ii) Provide CDC with a copy of any training materials developed or used and evaluation results (e.g., pre/post-assessments).

☐ Required ☒ Optional

5) Support cross-jurisdictional sharing and translation of CDR promising practices (Tier 1)

a) Identify CDR promising practices and develop translation and adaptation tools

i) Identify 2-3 CDR promising practices in applicant's jurisdiction that lend themselves to being adapted and translated to other jurisdictions. Describe these promising practices/innovations and why applicant considers them promising practices suitable for

translation to (some) other HDs. Descriptions of selected promising practices will be presented at the C-CORE recipient meeting, where other C-CORE recipients will be able to ask questions and consider if any of these promising practices may be suitable for adaptation and translation to their jurisdiction. In applicant implementation plan for this activity, include a brief description of proposed promising practices and why considered a promising practice suitable for translation.

(a) Promising practices can be related to program structure or protocols, data integration, data visualization, cluster prioritization, response planning, community engagement, response implementation/intervention, response evaluation, etc.

ii) Develop tools and guidance to facilitate adapting and implementing at least one of these best practices in another jurisdiction. Tool and guidance development will occur after one of these promising practices has been selected by another C-CORE recipient as a practice they plan to adapt and implement. Applicants are encouraged to use implementation and evaluation frameworks (e.g., CFIR, RE-AIM) when developing guidance and tools. Consider barriers and facilitators to implementation, tools needed, and organization or systems modifications needed to facilitate implementation. CDC will provide additional guidance for this activity during the budget period. Note: Adaptation and translation tools and guidance will be developed in this budget period (ELC Budget Period 1), however it is anticipated that the full implementation and evaluation of the promising CDR practice selected by another recipient will occur in ELC Budget Period 2 (BP2).

iii) Share with CDC any developed tools or guidance for adapting the innovation to another jurisdiction.

☒ Required ☐ Optional

b) Consult with paired jurisdiction for CDR knowledge sharing and translation

i) In Fall of 2024, after the C-CORE recipient meeting, CDC will pair up recipients to collaborate on Strategy 5. Pairings may be guided by the promising practice each recipient selects to implement from among all the promising practices proposed from other recipient jurisdictions.

ii) During the first half of the budget period, and after the C-CORE recipient meeting the paired jurisdictions will participate in a 1–2-day consultation (ideally in-person) with their paired jurisdiction to:

(a) Share CDR strategies, innovations, experiences, and lessons learned.

(b) Discuss strategies, experiences, and challenges engaging relevant health department programs in ongoing CDR work (e.g., reviewing cluster data, identifying additional investigation needs, and designing cluster-specific network and systems level interventions to address identified gaps and challenges). These discussions may inform recipient's implementation of Strategy 1, Activity a.

(c) If either recipient has selected to implement a promising practice from the HD they have been paired with, consultation can also include planning for translation, adaptation, and implementation of translation activity described in Strategy 5, Activity a(i) and development of associated adaptation and translation tools described in Strategy 5, Activity a(ii).

(d) Based on insights from consultation, revise plans to implement other activities if indicated (e.g., Strategy 1 (Activity a), Strategy 4 (Activity a), and Strategy 5 (Activity a(ii) and c(ii)).

☒ Required ☐ Optional

c) Develop a written plan to adapt and pilot implementation and evaluation of selected CDR promising practice from paired jurisdiction. Note: Implementation, and evaluation of promising practice is anticipated to occur in BP2.

i) After the C-CORE recipient meeting in Fall of 2024, select one CDR promising practice (from among the promising practices presented by other recipient HDs) that your jurisdiction could implement in BP2.

ii) Draft a written plan to adapt, implement, and evaluate selected promising practice in BP2

(a) Steps in adapting, implementing, and evaluating selected promising practice may include: establish an implementation committee, develop a timeline and work plan, obtain leadership support, conduct any needed assessments, identify necessary adaptations, develop protocol, develop an evaluation plan, train staff, consult with paired partner jurisdiction, pilot implementation, evaluate (potentially using RE-AIM or CQI methodology), make any needed modification, etc.

(b) Applicants are encouraged to consider using implementation and evaluation frameworks (e.g., CFIR, RE-AIM) to guide this work, including consideration of barriers and facilitators to implementation, organizational and systems supports and modifications that can facilitate implementation, and tools to evaluate implementation and impact.

(c) Share written plan with CDC; share plans and experiences to date with other jurisdictions via recipient call.

(d) Implementation and evaluation will take place in subsequent budget period.

☒ Required ☐ Optional

d) Write a CDR-related manuscript

i) Write a manuscript about CDR activities in your jurisdiction (e.g., describe a prioritized cluster and your response activities; describe your jurisdiction's CDR community engagement activities; describe an overview of your CDR program and lessons learned). about CDR activities in your jurisdiction (e.g., describe a prioritized cluster and your

response activities; describe your jurisdiction's CDR community engagement activities; describe an overview of your CDR program and lessons learned).

☐ Required ☒ Optional

Collaborations:

a. With CDC-Funded Programs

Recipients will be expected to work with HIV programs funded through DHP's flagship cooperative agreement (PS24-0047) CDC-funded capacity-building assistance and training providers, CDC DHP staff, and other organizations funded by CDC to support HIV CDR work (e.g., CDR Implementation Learning Collaborative).

b. With Organizations External to CDC

Recipient HIV programs will be expected to collaborate with their CDC-assigned partner jurisdiction (also funded for HIV C-CORE). Recipient HIV programs will be expected to collaborate with external organizations as needed to facilitate implementation of proposed Work Plan. These organizations might include but are not limited to: academic partners, local health departments, health care and social services organizations, HIV planning groups, other local government entities and community-based organizations in the selected jurisdiction, and AIDS Education and Training Centers.

Populations of Focus:

Persons identified as part of HIV clusters and outbreaks and persons in sexual and drug using networks experiencing rapid transmission; populations disproportionately affected by rapid HIV transmission; HIV clinical and social service providers.

Evaluation and Performance Measurement:

Performance progress will be collected verbally via monthly recipient calls, through ELC required quarterly milestones progress reporting (in ELC CAMP), through submission to CDC of developed plans, tools, and evaluation summaries as described under specific activities, and through presentations of activities, successes, and challenges to other C-CORE recipients and jurisdictions also as described under specific activities.

Recipients may be given additional optional opportunities to share or present their work (e.g., CDR ILC calls or summit; division-wide seminars, or on peer-to-peer C-CORE networking calls.

Performance measures included here are representative and may not be final at the time of NOFO publication. Please see the CK-24-0002 Performance Measure Guidance document for all final measures and descriptions.

a. ACTIVE Performance Measures

N/A

b. PASSIVE Indicators

N/A

ELC Logic Model

