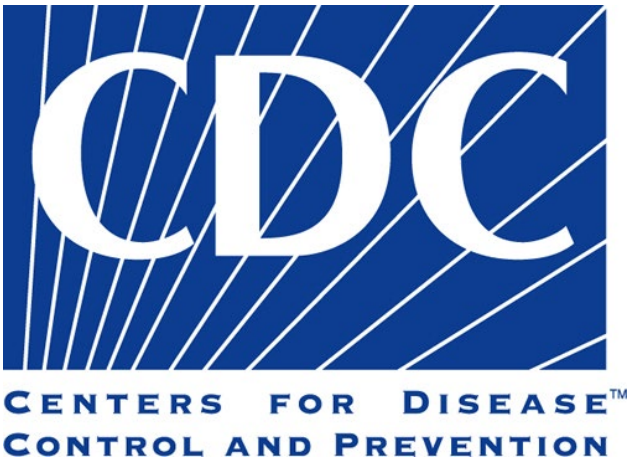

Centers for Disease Control and Prevention

National Center for Emerging and Zoonotic Infectious Diseases

US Public Health Pathogens Genomics Centers of Excellence

CDC-RFA-CK22-2204

05/17/2022

AMENDMENT 1 – This amendment provides a) clarification under the Eligibility Section located on Page 35 and b) Provides a cutoff date for submission of questions of 5/1/2022 at the bottom of page 2 and c) clarifies where Q& A documents will be available for applicant review.

AMENDMENT 2 - This amendment changes pages 35-36 to include full eligibility information. It also corrects funding amounts on pages 3 and 33 from $7,000,000 to $6,200,00 and on pages 4 and 33 from $7,000,000 to $6,000,000. This amendment also amends page 27 from “For research proposed or anticipated, an application must describe the following” to read “An application must describe the following:”

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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-CK22-2204. 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:

US Public Health Pathogens Genomics Centers of Excellence

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 this purpose, research is defined at https://www.gpo.gov/fdsys/pkg/CFR-2007-title42-vol1/pdf/CFR-2007-title42-vol1-sec52-2.pdf. Guidance on how CDC interprets the definition of research in the context of public health can be found at https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html (See section 45 CFR 46.102(d)).

Please note for this particular NOFO, CDC-RFA-CK22-2204, research activities are allowable and will be subject to all applicable laws, regulations and policy requirements. Note research and human subjects protection requirements inserted throughout this NOFO. All instructions pertaining to research should be addressed and followed as indicated in this NOFO. Please refer to the Strategies and Activities for more details.

D. Agency Notice of Funding Opportunity Number:

CDC-RFA-CK22-2204

E. Assistance Listings Number:

93.084

F. Dates:

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

04/17/2022

Recommended but not Required

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows CDC staff to estimate the potential review workload and plan the review.

By the date listed in the Application and Submission Information section of this NOFO, prospective applicants are asked to submit a letter of intent that includes the following information:

Name of the applicant organization
Descriptive title of proposed application
Name, address, and telephone number of the PD(s)/PI(s)
Names of other key personnel
Participating institutions
Number and title of this notice of funding opportunity

The letter of intent should be sent to:
Gregory Anderson, MPH, MS
Extramural Research Program Office
Office of the Associate Director of Science
National Center for HIV, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
1600 Clifton Road, MS US8-1
Atlanta, GA 30333
Telephone: 404-718-8833
Email: GAnderson@cdc.gov

2. Due Date for Applications:

05/17/2022

11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov.

Due Date for Informational Conference Call:

March 31, 2022

Time, 2:00 pm ET; Phone Number 1-866-620-0420; Passcode: 8943360

Questions and answers from the conference call and information on any updates to the NOFO will be posted at www.cdc.gov/amd and on Grants.gov. All questions must be received by 5/1/2022 in order to be included in the Q& A document.

F. Executive Summary:

Summary Paragraph

This NOFO includes three components, two Mandatory and one Optional. The underlying objective of the Pathogen Genomics Centers of Excellence (PGCoE) network NOFO is to foster and improve innovation and technical capacity in pathogen genomics, molecular epidemiology, and bioinformatics to better prevent, control and respond to microbial threats of public health importance. Partnership and collaboration between academia, public health and the private sector is at the core of this objective. The Centers of Excellence network is intended to enable the public health system to better respond to infectious disease threats with resilience, flexibility and the latest practical advances in laboratory technology, scientific computing, and applied research. This cooperative agreement will fund the establishment of several centers of excellence, each consisting of a combination of a health department and one or more academic institutions with the purpose of working together as a network to establish a platform to develop and identify relevant areas of genomics and related technologies, adapt them for use in public health, and pilot their application in actual settings. The network of health departments with their academic partners is expected to also implement three other high-level strategies: education of the public health workforce, including bioinformaticians, microbiologists, and epidemiologists, preparing to respond to infectious threats, and responding to infectious threats.

a. Eligible Applicants:

Open Competition

b. NOFO Type:

CA (Cooperative Agreement)

c. Approximate Number of Awards

6

Mandatory Components (Core, Response Implementation): 6 awards
Optional Component (Lead PGCoE for Education): 1 award (to a recipient of a Mandatory Components (Core, Response Implementation) award)

d. Total Period of Performance Funding:

$185,000,000

e. Average One Year Award Amount:

$6,200,000

$4,000,000 (Mandatory Component, Core); $2,000,000 Mandatory Component (Response Implementation); $1,000,000 (Optional Component)

If applying for both the Mandatory Components (Core, Response Implementation) and Optional Component (Lead PGCoE for Education), a separate Budget and Budget Narrative must be included for each component (Mandatory Component (Core), Mandatory Component (Response Implementation) and Optional Component (Lead PGCoE for Education)).

Awards issued under this NOFO are contingent upon availability of funds and a sufficient number of meritorious applications. Because the nature and scope of the proposed work will vary from application to application, it is also anticipated that the size and duration of each award may

also vary. The total amount awarded and the number of awards will depend upon the number, quality, duration and cost of the applications received.

Average One Year Award Amount for Mandatory Components (Core, Response Implementation) and Optional Component (Lead PGCoE for Education) is as follows:

Year 1:
Average per site for Mandatory Components (Core, Response Implementation): $6,000,000
$4,000,000/award for Mandatory Component (Core) with approximate amounts for each strategy as follows
$3,500,000 for Translation
$400,000 for Education
$100,000 for Response Base

$2,000,000/award for Mandatory Component (Response Implementation)

In addition, one site will be awarded approximately $1,000,000/award for Optional Component (Lead PGCoE for Education)

Throughout the project period, 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 (project period) 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).

f. Total Period of Performance Length:
5

g. Estimated Award Date:
September 30, 2022

h. Cost Sharing and / or Matching Requirements:
No
Cost sharing or matching funds are not required for this program. Although no statutory matching requirement for this NOFO exists, leveraging other resources and related ongoing efforts to promote sustainability is strongly encouraged as long as there is no scientific, budgetary, percent effort or other overlap with any other funded projects.

Part II. Full Text

A. Funding Opportunity Description

1. Background

a. Overview
Rapid advances in genomic technologies are transforming public health, particularly the prevention and control of infectious diseases. "Next-generation sequencing", bioinformatics, and genomic epidemiology are improving understanding of pathogen transmission and clinical

features including of foodborne illness, tuberculosis, influenza, SARS-CoV-2, and antimicrobial drug resistant organisms. Bringing these advances into everyday public health is a priority and can also present a challenge, especially given the continued rapid evolution of genomics, bioinformatics, and related technologies. This NOFO envisions three components:

Mandatory Component (Core; all applications must address) has a three-pronged strategy:

- Translation: developing, identifying, refining, evaluating, piloting, and implementing technologies and practices relevant to public health
- Education: developing practical training for public health professionals
- Response Base: developing capacity to respond to infectious disease threats

Mandatory Component (Response Implementation; all applications must address):

- Responding to infectious disease threats by applying genomic technologies and synthesizing diverse data

Optional Component (Lead PGCoE for Education; applicant may choose to address):

- Lead network educational activities and develop an online training program

All PGCoEs to be supported by this NOFO are expected to address the Mandatory Components (Core, Response Implementation) and one center is also expected to address the Optional Component (Lead PGCoE for Education) by pairing public health agencies with academic centers, utilizing strengths of both. The public health agencies will be the prime recipients of their respective awards and are expected to bring deep understanding of public health priorities and practice as well as needs of the public health workforce. The academic centers (sub-recipients) are expected to bring expertise in microbial genomics and genomic epidemiology and access to innovation and novel, relevant technologies. The intent is for these groups to work synergistically together, accelerating the application of genomics and related technologies in public health, focusing initially on the U.S. but with an eye towards making innovations globally accessible. The PGCoE are expected to work together as a network, and with CDC, its programs, and other partners to implement the strategies and activities described in this NOFO.

The translational strategy will be the main, ongoing focus of the PGCoE network and relies on developing and identifying technologies and approaches that have relevance for public health, adapting and evaluating those for use in public health, piloting those in real-life public health settings and, if applicable, assisting in implementing those in the public health system. In this sense, the PGCoE network is expected to be a U.S. public health system technology “incubator."

The educational strategy (mandatory and optional components) relies on identifying relevant educational needs of public health bioinformaticians, microbiologists, and epidemiologists and developing training to address these needs. Training that is developed will be mostly online and asynchronous, although some in-person training may also be supported.

The response strategy relies on contributing to the overarching response to infectious disease threats in a flexible and rapid manner. This assistance may include, for example, assisting with sequencing or analysis of sequence data, synthesis of data from a variety of sources, and reports of findings.

Statutory Authorities
PUBLIC LAW 117–2, the AMERICAN RESCUE PLAN ACT OF 2021, (PUBL002.PS (congress.gov)), Section 2402;

ARP ***SEC. 2402. FUNDING FOR SARS–COV–2 GENOMIC SEQUENCING AND SURVEILLANCE.***
(a) *In General.—In addition to amounts otherwise available, there is appropriated to the Secretary for fiscal year 2021 out of any money in the Treasury not otherwise appropriated, $1,750,000,000, to remain available until expended, to strengthen and expand activities and workforce related to genomic sequencing, analytics, and disease surveillance.*
(b) *Use Of Funds.—From amounts appropriated by subsection (a), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall—*
(1) *conduct, expand, and improve activities to sequence genomes, identify mutations, and survey the circulation and transmission of viruses and other organisms, including strains of SARS–CoV–2;*
(2) *award grants or cooperative agreements to State, local, Tribal, or territorial public health departments or public health laboratories—*
(A) *to increase their capacity to sequence genomes of circulating strains of viruses and other organisms, including SARS–CoV–2;*
(B) *to identify mutations in viruses and other organisms, including SARS–CoV–2;*
(C) *to use genomic sequencing to identify outbreaks and clusters of diseases or infections, including COVID–19; and*
(D) *to develop effective disease response strategies based on genomic sequencing and surveillance data;*
(3) *enhance and expand the informatics capabilities of the public health workforce; and*
(4) *award grants for the construction, alteration, or renovation of facilities to improve genomic sequencing and surveillance capabilities at the State and local level.*

c. Healthy People 2030
Public Health Infrastructure (https://health.gov/healthypeople/objectives-and-data/browse-objectives/public-health-infrastructure)
Health IT (https://health.gov/healthypeople/objectives-and-data/browse-objectives/health-it)
Global Health (https://health.gov/healthypeople/objectives-and-data/browse-objectives/global-health)
Workforce Development (https://health.gov/healthypeople/objectives-and-data/browse-objectives/public-health-infrastructure/increase-use-core-and-discipline-specific-competencies-drive-workforce-development-phi-r03)

d. Other National Public Health Priorities and Strategies
To increase the use of pathogen genomics in the US public health system as articulated in the American Rescue Plan Act of 2021, Section 2402.

e. Relevant Work
1. Armstrong GL, MacCannell DR, Taylor J, *et al*. Pathogen genomics in public health. N Engl J Med 2019;381:2569-80. This review describes how microbial genomics was impacting public health practice in the United States before the start of the COVID-19 pandemic.
2. Kubota KA, Wolfgang WJ, Baker DJ, *et al*. PulseNet and the changing paradigm of

laboratory-based surveillance for foodborne diseases. Pub Health Rep 2019;134(2 Suppl):22S-28S. PulseNet (https://www.cdc.gov/pulsenet) is a flagship program for molecular surveillance in the United States public health system and switched several years ago from PFGE to whole-genome sequencing.
3. Zhou B, Deng YM, Barnes JR, *et al*. Multiplex Reverse Transcription-PCR for Simultaneous Surveillance of Influenza A and B Viruses. J Clin Microbiol 2017:3492-3501.
4. Shepard SS, Meno S, Bahl J, Wilson MM, Barnes J, Neuhaus E. Viral deep sequencing needs an adaptive approach: IRMA, the iterative refinement meta-assembler. BMC Genomics. 2016 Sep 5;17(1):708.
5. Rambo-Martin BL, Keller MW, Wilson MM, *et al*. Influenza A Virus Field Surveillance at a Swine-Human Interface. mSphere. 2020;5(1):e00822-19. Sequencing is a core part of viral surveillance of influenza in the United States and elsewhere, and also plays a key role in investigations such as those in the third reference.
6. https://www.cdc.gov/amd. The Advanced Molecular Detection (AMD) program has supported the adoption of sequencing in the US public health system since 2014. The AMD web site provides information on some of the many activities supported by the program, both internally at CDC and externally, including support for SARS-CoV-2 sequencing and training.

2. CDC Project Description

Bold indicates period of performance outcome.

CDC-RFA-CK22-2204 Logic Model: US Public Health Pathogens Genomics Centers of Excellence
Bold indicates period of performance outcome

Strategies and Activities	Short-term Outcomes	Intermediate Outcomes	Long-Term Outcomes
Mandatory Component (Core) 1. Translate Innovations to Public Health a) develop networked approaches and support and encourage use of reproducible methods and open standards b) identify gaps in use of genomic epidemiology c) develop, identify, adapt, pilot, and	**Networked function with established "platform" for collaborative work between and beyond centers** **Improved understanding of current state of genomic epidemiology in public health** **Increased use of new and refined laboratory and bioinformatics**	**Greater use of genomic technologies to address infectious public health threats** **Improved interoperability of microbial genomic and other surveillance, clinical and public health relevant information** **Increased use of common tools and applications across network sites and beyond**	Improved prevention of infectious diseases Improved detection and characterization of emerging and re-emerging infectious diseases Improved response to emerging and re-emerging infectious diseases Improved response to outbreaks of infectious diseases

implement technologies and applications for public health d) assist in implementing technologies broadly in the US and aligning with global efforts <u>2. Educate Public Health Workforce</u> Lead or assist in training activities <u>3. Response Base</u> Prepare to respond to infectious disease threats *Mandatory Component (Response Implementation)* Perform sequencing and other applications, analysis, and data synthesis during emergencies from infectious agents *Optional Component (Lead PGCoE for Education)* Identify relevant educational needs, lead education efforts of the network and develop online	**tools** **Increased capacity to sequence pathogens and to analyze genomic data** **Increased capacity to link microbial genomic, clinical, and epidemiologic data and analyze linked data** **Increased speed of adoption of relevant genomic technologies in US public health** **Increased availability of educational materials and approaches** **Networked activity supported by established systems for data sharing, analysis, review, and reporting**	**Improved discovery of transmission, risk factors, and outcomes of pathogens of public health importance** **Increase in US public health personnel with proficiency and expertise in use of genomics and genomic epidemiology** **Greater alignment of US and global microbial genomics and genomic epidemiology efforts** **Rapid scale-up of genomic epidemiology capabilities in emergencies from infectious agents**	Lower burden of infectious diseases Improved national-level capacity and coordination against infectious disease threats Improved use of microbial genomic and epidemiologic data in global public health

training			

i. Purpose

This NOFO will implement a Mandatory Component (Core) with three-pronged strategy: 1) translation of pathogen genomic technologies and innovations into the U.S. public health system; 2) training of the public health workforce in genomics and genomic epidemiology; and 3) preparation for response to infectious threats. If and when needed this NOFO will implement Mandatory Component (Response Implementation) to respond to infectious threats. This NOFO will also implement an Optional Component (Lead PGCoE for Education) to lead education activities of the network and develop online training.

ii. Outcomes

The overall outcomes will focus on:

- Establishing "platform" for collaborative work between and beyond centers
- Improving understanding of the current state of genomic epidemiology in public health
- Increasing use of new and refined laboratory and bioinformatics tools
- Increasing capacity to sequence pathogens and to analyze genomic data
- Increasing capacity to link microbial genomic, clinical, and epidemiologic data and analyze linked data
- Increasing speed of adoption of relevant genomic technologies in US public health
- Increasing availability of educational materials and approaches
- Establishing systems for data sharing, analysis, review and reporting
- Greater use of genomic technologies to address public health threats
- Improving interoperability of microbial genomic and other surveillance, clinical and public health relevant systems and information
- Increasing use of common tools and applications across network sites and beyond
- Improving discovery of transmission, risk factors, and outcomes of pathogens of public health importance
- Increasing in US public health personnel with proficiency and expertise in use of genomics and genomic epidemiology
- Greater alignment of US and global microbial genomics and genomic epidemiology efforts
- Rapid scale-up of genomic epidemiology capabilities in emergencies from infectious agents

iii. Strategies and Activities

Each funded prime recipient is expected to develop, with an academic partner or partners, a U.S. Pathogen Genomics Center of Excellence (PGCoE) to pursue three crosscutting strategies (Mandatory Component (Core)): 1) translation of innovations to public health; 2) education of the public health workforce; and 3) preparation for response to infectious disease threats. In addition, each funded prime recipient is expected to propose a strategy of response to infectious disease threats (Mandatory Component (Response Implementation) to be funded and

implemented if and when needed. In addition, one prime recipient will be funded to be the Lead PGCoE for Education and lead the network in workforce education activities (Optional Component (Lead PGCoE for Education)). The Mandatory Component (Core) Translation and Response Base strategies and the Mandatory Component (Response Implementation) may contain research activities. The Mandatory Component (Core) Education strategy and the Optional Component (Lead PGCoE for Education) may not include research activities.

The PGCoEs are expected to operate collaboratively as a network and will be expected to collaborate with CDC and CDC-funded entities, including other partners and health departments. This collaboration is intended to ensure synergy and policy coordination toward achieving the expected outcomes consistent with this cooperative agreement. The network is intended to actively assist stakeholders in CDC-supported partnerships (e.g., other grants, cooperative agreements), support communication channels, and provide peer-to-peer technical assistance (TA) to relevant entities, that include other state and local public health departments, academic partners, the community, and other stakeholders.

A coordinating group for the PGCoE network will include representatives of each funded site and CDC personnel. The coordinating group will consider emergent public health priorities and advancements in public health genomics, coordinate implementation and operation of the network activities among the sites and within the scope of the cooperative agreement, and foster coordination across PGCoEs and with CDC programs. The coordinating group will not include consensus decision making and will not provide advice or recommendations to CDC. Over the period of performance of the cooperative agreement, a networked approach with collaboration across sites will be expected. Specific projects may involve one or several sites, and there may be "core" projects in which all sites are participants. Activities of the network will fall within five broad topic areas:

1. Wet laboratory methods development and validation, proficiency testing, technologies, and applications
2. Bioinformatics technologies and applications, as well as related technologies
3. Data standardization/data security/data stewardship/data integration and reporting/data linkage/data science/data analytics/data visualization including of genomic, epidemiologic, clinical, biological, environmental, geospatial, behavioral, social and other types of data together
4. Genomic surveillance, monitoring, analysis, data synthesis, and response
5. Field applications and investigations

To ensure that PGCoE activities align with the CDC mission, collaboration between the PGCoE personnel and CDC technical advisors, including from programs focused on specific pathogens or groups of pathogens, is required. Project plans will be assessed at least annually by appropriate CDC technical advisors; to the extent projects are proposed that may implicate research activities governed by applicable laws, regulations and policies, those proposals are expected to comply with those laws, regulations and policies.

Applicants should propose activities for each of the three main strategies of the (Mandatory Component (Core) and for the strategy of the Mandatory Component (Response Implementation). Applicants interested in being considered for the Optional Component (Lead PGCoE for Education) should propose how they would lead the network in workforce education activities.

The Project Narrative and Budgets should focus in a detailed way on site-specific projects in the first year. Applicants are encouraged to propose projects that highlight and build upon particular areas of expertise of the PGCoE applicant partners (health department and academic). The application should discuss ways that these projects could be further developed and implemented over the period of performance and across the network and beyond. Applications may address host genomics, if the main focus is for its use in understanding and responding to infectious disease threats. The Project Narrative and Budget for the first year should include a landscape analysis on gaps, needs, and opportunities for relevant genomics (and related) technologies in the U.S. public health system. This landscape analysis will contribute to a Roadmap for pathogen genomics (and related technologies) and genomic epidemiology in public health.

Work of the network is intended to meet the needs of public health and to align with the strategic direction of CDC programs, and to incorporate new technologies and approaches from the rapidly evolving field of genomics. Therefore, the network and individual PGCoEs are expected to be agile and flexible in identifying, implementing, and amending specific activities, to the extent consistent with the terms of this cooperative agreement. Annually, by way of the PGCoE cooperative agreement continuation planning and process, projects will be evaluated and amended as necessary in light of public health priorities, advancement in the field and emerging issues and infectious threats.

Applicants should describe how the network will benefit from the applicant's expertise within the five broad topic areas for network activities.

Applicants should also describe how the network will benefit from their unique scientific environment, subject populations, or collaborative arrangements.

The Project Narrative should follow the format specified in the H. Other Information section of this NOFO. The protection of human subjects should also be described in the Strategies and Activities section of the Project Narrative, including a single institutional review board (IRB) plan, using the Public Health Service (PHS) Human Subjects and Clinical Trials Information format (a sample of the format can be found on page 238 at https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general-forms-g.pdf**).**

Protections for Human Subjects and Animals
If any proposed research involves human subjects but does not involve one of the eight categories of research that are exempt under 45 CFR Part 46, the proposal must include the justification for the involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the eight categories of research that are exempt under 45 CFR Part 46, include the following: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on the content of the Human Subjects section, please refer to https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general-forms-g.pdf.

Activities involving the use of animals conducted under this NOFO shall be in compliance with the PHS Policy on Humane Care and Use of Laboratory Animals, the current edition of the "Guide for the Care and Use of Laboratory Animals (the Guide), the Animal Welfare Act and Regulations (Title 9 Code of Federal Regulations part 1), and all applicable local, state, or other federal regulations. The PGCoE and any sub-awardee shall have an approved Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare (OLAW), at the time of contract award. Accreditation of the PGCoE or sub-awardee by the Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC) is preferred. If animal species regulated by the United States Department of Agriculture (USDA) are to be used, the PGCoE or sub-awardee shall be registered with the Secretary of Agriculture of the United States in accordance with the following Federal regulations 7 U.S.C 2136 and 9 CFR sections 2.25-2.28 respectively.

Applicants are required to respond to all three strategies of the Mandatory Component (Core) and to the one strategy of the Mandatory Component (Response Implementation). Applicants may choose to respond to the Optional Component (Lead PGCoE for Education).

A separate Narrative and Budget are required each component and strategy as follows:

I. Mandatory Component (Core)
    a. Translation (one narrative and budget)
    b. Education (one narrative and budget)
    c. Response Base (one narrative and budget)

II. Mandatory Component (Response Implementation) (one narrative and budget)
III. Optional Component (Lead PGCoE for Education) (one narrative and budget)

Mandatory Component (Core)

Strategy 1: Translation. Translate innovations in pathogen genomics and genomic epidemiology to public health

a) Develop networked approaches and support and encourage the use of reproducible methods and open standards.

Work with the other centers as part of a network. Provide representation to the coordinating group. Establish processes and procedures that will allow for coordinated efforts within and beyond the network of centers, such as data use agreements, memoranda of understanding, and

IRB protocols.

b) Identify gaps in and opportunities for use of genomic epidemiology in public health.

All applicants should indicate how they will perform a landscape analysis for the following **5 broad areas** relevant to genomic epidemiology. Recipients will be expected to coordinate with other centers and will receive technical assistance and input from CDC, including pathogen-focused programs on these landscape analyses.

1. Wet laboratory methods development and validation, proficiency testing, technologies, and applications
2. Bioinformatics technologies and applications, as well as related technologies
3. Data standardization/data security/data stewardship/data integration and reporting/data linkage/data science/data analytics/data visualization including of genomic, epidemiologic, clinical, biological, environmental, geospatial, behavioral, social and other types of data together
4. Genomic surveillance, monitoring, analysis, data synthesis, and response
5. Field applications and investigations

c) Develop, identify, adapt, pilot, and implement technologies and applications for public health. This may include relevant genomic and other "-omics" (e.g., host genomics, transcriptomics, proteomics, metabolomics) technologies and applications.

The PGCoE network is expected to function as a technology and innovation "incubator" for pathogen genomics in public health. To this end, all PGCoEs are expected to establish and maintain a research and evaluation "platform" that allows them to readily develop or identify, adapt, pilot, evaluate, and implement technologies and applications within **5 broad areas**:

1. Wet laboratory methods development and validation, proficiency testing, technologies, and applications
2. Bioinformatics technologies and applications, as well as related technologies
3. Data standardization/data security/data stewardship/data integration and reporting/data linkage/data science/data analytics/data visualization including of genomic, epidemiologic, clinical, biological, environmental, geospatial, behavioral, social and other types of data together
4. Genomic surveillance, monitoring, analysis, data synthesis, and response
5. Field applications and investigations

Applicants should describe their capacity to conduct activities in these five broad topic areas, and how their specialized expertise within the five main topic areas relevant to pathogen genomics may contribute to the overall capacity of the network.

Applicants should also describe how the network will benefit from the applicant's unique scientific environment, subject populations, or collaborative arrangements.

Sites should describe how they will establish a research program that will allow them, in an ongoing and flexible way, to develop or identify, adapt, pilot, evaluate, and implement technologies and applications for use in public health that align with the activities set out in this cooperative agreement. This should include provision for human subjects research protocols that will allow enrollment of participants, collection of specimens, banking of specimens, testing of banked specimens, and collection of clinical and other participant data. The proposed research projects should be guided by public health needs. Applicants should also clearly articulate how the research program will ensure compliance with applicable regulatory requirements for proposed research activities.

Applicants should propose an initial research and non-research project or projects that include all 5 of these broad topic areas. Applicants are expected to propose activities in all 5 broad topic areas, but to highlight in the application the areas in which they have particular expertise. Applications should focus in a detailed way on site-specific projects in the first year. The application should discuss ways that this project or projects could be further developed over the period of performance and across the network and beyond.

Applications should describe projects in the Project Narrative using the format specified in the H. Other Information. section of this NOFO.

Applications should include working with other network sites to evaluate novel bioinformatics platforms.

The following are examples of types of projects that might be considered. These are only provided as examples and applicants should not limit themselves to proposals that fall within the scope of these:

- Data integration and analytics. Integrating genomic data with epidemiologic data and analyzing the two types of data together are high priorities for US public health. A site may propose to pilot and scale up methods for better achieving this integration. Such a project could be used, for example, to evaluate technologies for integrating data or might serve to evaluate what aspects of this integration are most valuable to public health.
- Increasing the availability and accessibility of genomic data. Projects that improve the ability of sites to make public health genomic data (and its metadata) available for use by other organizations (e.g., researchers, industry) or that make the data or analyses of the data more accessible to public health workers or to the general public would fall within the scope of this cooperative agreement.
- Other methods for improving the use of genomics in public health. Applicants are encouraged to think creatively about projects that could result in the improved use of genomics and other relevant, related technologies in public health.

Applicants should consider the following when selecting and proposing their activities:

- Potential for public health impact: An overarching objective of the cooperative agreement is to improve the use of pathogen genomics in the U.S. public health system (i.e., federal,

state, territorial, local, and tribal public health agencies). As such, projects whose results have the potential to improve public health either immediately, or in the future, will be prioritized. A framework assessing potential public-health impact is given below *("Framework for evaluating potential public health impact").* The network will have leeway to support some projects that will advance more upstream (i.e., more basic science) priorities in the absence of clear public health benefit, but these are expected to be a minor part of the project portfolio.

- Scalability: For many of the anticipated projects, the ultimate impact will depend on the ability to alter public health practice in the United States and elsewhere. Projects that can be integrated into routine public health workflows and that make use of equipment and other infrastructure already commonly found in public health agencies are most likely to be scalable. Projects that are difficult to implement or that require technical support not typically found in public health agencies are not necessarily scalable.
- Applicability beyond the U.S. setting: Whereas the primary objective of this cooperative agreement is to improve U.S. public health, it is desired that it also yields products or findings that can have an impact beyond the United States.
- Scope of implementation: Projects need not be ones with potential to be implemented separately in many sites. For example, a proposal to develop or expand a web site or service that is useful to public health in making use of genomic data would be of interest.

d) Assist in implementing technologies broadly in the U.S. and aligning with global efforts.

The application should discuss ways that projects could be further developed and implemented over the period of performance and across the network and beyond.

Strategy 2: Education. Educate the Public Health Workforce.
a.) Lead or assist in training activities

b.) Educate state, local, territorial and other non-Federal public health workforce in pathogen genomics and genomic epidemiology
All centers will be expected, in collaboration with the Lead PGCoE for Education (see Optional Component (Lead PGCoE for Education) described below) and with CDC, to contribute to development of online training resources and other training activities.

- Lead an online course or training. Provide a high-level outline of the curriculum for the course(s) and describe how the proposed courses are relevant to public health practice.
- Assist in training. Describe expertise or resources that the applicant could bring to the network to assist in an educational project led by a different center.
- Other educational activities may be proposed as well.

Strategy 3: Response Base. Prepare to Respond to Infectious Threats

a.) Prepare to respond to infectious threats and respond to infectious threats

Applications should describe foundational activities such as preparing data use agreements, memoranda of understanding and IRB protocols to allow rapid scale-up of efforts across the network.

Mandatory Component (Response Implementation): Perform sequencing and other applications, analysis, and data synthesis during emergencies from infectious agents.

Response implementation consistent with the terms of this cooperative agreement may be funded via post-award supplements should infectious threat conditions warrant.

Implement activities in response to an infectious threat. Plan the types of experiments, research studies, and non-research activities that could be done in the event of an infectious threat, including analyzing and synthesizing data to inform public health action.

Applications should include working with other network sites to analyze and synthesize pathogen genomic and other diverse data and preparing informational reports. The network is expected to make informational reports public. This data synthesis activity will provide an objective overview of recent information for use by local, state, and federal public health agencies. These network data synthesis reports are not intended to provide recommendations.

Applications should describe response implementation activities in **5 broad areas**:

1. Wet laboratory methods development and validation, proficiency testing, technologies, and applications
2. Bioinformatics technologies and applications, as well as related technologies
3. Data standardization/data security/data stewardship/data integration and reporting/data linkage/data science/data analytics/data visualization including of genomic, epidemiologic, clinical, biological, environmental, geospatial, behavioral, social and other types of data together
4. Genomic surveillance, monitoring, analysis, data synthesis, and response
5. Field applications and investigations

Specific activities, consistent with the terms of this cooperative agreement, may include but are not limited to the following:

- In collaboration with relevant subject-matter groups from CDC, develop or adapt methods for sequencing the pathogen or for applying other molecular subtyping.
- Contribute to pathogen sequencing efforts or analysis of sequence data.
- Enroll study participants, test clinical specimens, test banked specimens, collect clinical, epidemiologic and other data.
- Develop and integrate bioinformatic solutions to rapidly analyze, interpret, visualize, integrate, and share pathogen genomic information.

- Expand networks of partnerships across public health, academia and the private sector that can be rapidly engaged for infectious threats.
- Perform ongoing analysis of genomic and epidemiologic surveillance data as well as other relevant information such as surveillance data from other countries and information in preprints and publications.
- Interpret all these data for their implications for public health.
- Provide regular and timely reports to public health and, as appropriate, relevant third parties, including advisory committees (e.g., CDC Board of Scientific Counselors), in response to infectious threats.

These activities should provide coordinated, rapid, and scalable actions in responding to infectious threats. Following initial award, a Network Response Plan will be developed collaboratively with the coordinating group.

Applicants should describe how they would use their expertise in areas that may be useful during responses to infectious threats.

The following are examples of contributions such a network *might have provided* had one been in place during past infectious disease threats. During such responses, the network will be expected to work in collaboration with the relevant federal/state/local public health agencies so that these actions may more directly impact the response. Applicants are encouraged to consider, in addition to these examples, how their expertise would be useful during infectious disease threats.

- SARS-CoV-2 emergence:
    - Working with state/local public health agencies to sequence samples as part of surveillance or outbreak investigations, either in the public health agency's laboratory or at an outside laboratory.
    - Analyzing publicly available data on circulating SARS-CoV-2 variants at the national, state, or local level, and presenting these data in ways that make them useful to public health.
    - Projecting the course of variant emergence in the United States.
    - Reviewing available data on emerging variants from a variety of sources, including publications, pre-prints, and other relevant public or non-public sources.
    - Creating regular, publicly available summaries of these various sources of information to be used by public health agencies and other interested parties.
    - Assessing the role of host genomics factors in infection, transmission, disease severity and outcomes.
- Zika emergence in the Americas
    - Assistance to US states and partners (including overseas partners) in sequencing specimens and analysis of available genomic data.
    - Assessment of the risk of importation of the virus.
- Emergence of *Candida auris*
    - Assistance with sequencing and analysis of the data.

- Real-time summary of *C. auris* sequence data submitted to the National Center for Biotechnology Information (NCBI). This could be a simple webpage that is auto populated and resides with the centers of excellence.
- Development and piloting of new workflows for sequencing and analysis of the sequence data. For example, the project could evaluate measures of genomic relatedness and whether those can be used to infer transmission between healthcare facilities.

Optional Component (Lead PGCoE for Education)

In order to apply for Lead PGCoE (Optional Component (Lead PGCoE for Education)), an applicant must apply for both of the Mandatory Components (Core and Response Implementation).

The Work Plan for the Optional Component (Lead PGCoE for Education) must address the following activities:

- Identify relevant educational needs for the public health workforce, with focus on microbiologists, bioinformaticians, and epidemiologists
- Lead education efforts of the network
  - Provide leadership for educational activities of the network.
  - Pilot and evaluate educational materials, including online training.
- Develop online training
  - Act as the host for the network's online training. In this capacity, the site will need to operate or have access to a robust online educational platform and have resources that enable the network members to create training courses or modules for the platform.
  - Engage with CDC, relevant partner organizations (e.g., Association of Public Health Laboratories, Council of State and Territorial Epidemiologists, American Society for Microbiology, National Association of County and City Health Officials, American Public Health Association, Public Health Alliance for Genomic Epidemiology), and other health departments and academic institutions to expand training, cross-appointments, sharing of best practices and uses of genomic data.
  - Develop and/or work to offer online, freely available training platform focused specifically on the use of genomics in public health. Training should address the needs of microbiologists, bioinformaticians, and epidemiologists working in public health.
  - Include, as part of training, the opportunity to receive continuing education credits in the relevant disciplines (e.g., PACE, CME, or other accreditation).

Addendum: Framework for evaluating potential public health impact

In developing their applications, applicants should consider the following questions which get at the potential public health impact of particular projects. The term “intervention” below refers to what is being proposed, be it a diagnostic protocol, a surveillance tool, data system, or any other

proposed outcome.

- *Would the intervention have a direct impact on public health?* This is usually the easiest type of justification to explain. This impact may be immediate, as with an intervention that enabled early detection of outbreaks, or delayed, as in one that slows transmission of infectious diseases.
- *Would the intervention result in better data for decision-making?* For example, a project might improve the collection of data that would be useful in establishing a baseline for surveillance. Or it might generate data that's useful making decisions about vaccination or other public health interventions.
- *Would the intervention improve preparedness for emerging infectious diseases or other public-health emergencies?* Some of the products funded by AMD will hopefully never be used—those developed to prepare for public health emergencies. Nonetheless, preparedness is clearly an import part of the mission of CDC and state and local public health agencies.
- *Would the intervention improve efficiency in the public-health system?* Proposals that reduce costs, increase through-put, decrease waste, or otherwise improve efficiency in the public health system are of interest to the AMD program.
- *Is the proposed intervention a prerequisite for other public health work to come?* Occasionally, the intervention by itself will not improve public health but needs to be evaluated or implemented before another important intervention can be developed.

1. Collaborations

a. With other CDC programs and CDC-funded organizations:

Recipients are expected to collaborate with CDC programs that are relevant to the projects the network is pursuing. These programs are typically focused on specific pathogens or groups of pathogens and are responsible for developing and coordinating national strategy for control and response to those pathogens. CDC's Office of Advanced Molecular Detection will facilitate the involvement of the relevant CDC programs with the centers of excellence network. Applicants should describe the extent of any current collaboration with CDC programs in the areas of pathogen genomics and genomic epidemiology. Recipients should seek to ensure their proposed activities are not duplicating activities already funded by other CDC grants, contracts, and cooperative agreements or implemented by other CDC-supported organizations and may coordinate with CDC to make this determination.

Recipients should collaborate with each other to function with other PGCoEs as a network.

b. With organizations not funded by CDC:

Recipients are expected to collaborate with one or more academic centers with strong programs in pathogen genomics or genomic epidemiology. Recipients will need to be able to subaward to those centers and include a clear description of the work that is expected to be conducted by the sub-recipients in the recipient's initial application to this NOFO. Applications should include input from both the public health agency and their intended academic partner(s). Applicants should describe the extent of current collaboration with the academic center(s). Applicants must file a letter of support from the academic center(s), name the file "Academic Letter of Support", and upload it as a PDF file at www.grants.gov.

The network will function as a platform for innovation in pathogen genomics and genomic epidemiology and will be expected to collaborate with organizations such as other health departments and academic institutions, including those that may receive Advanced Molecular Detection funding, as long as there is no scientific, budgetary, percent effort or other overlap with other funded entities.

Optional Component (Lead PGCoE for Education) applicants are expected to engage with partner organizations (e.g., Association of Public Health Laboratories, Council of State and Territorial Epidemiologists, American Society for Microbiology, National Association of County and City Health Officials, American Public Health Association, Public Health Alliance for Genomic Epidemiology) and other health departments and academic institutions to expand training, cross-appointments, sharing of best practices and uses of genomic data.

2. Target Populations

This program overall does not target specific populations. However, specific projects focused on specific pathogens, for example, should target populations most impacted by those pathogens. Outcomes of this program will benefit the U.S. and public health workforce and public.

a. Health Disparities

The program encourages projects that address disparities as evidenced by relevant data to be associated with race, ethnicity, gender identity, sexual orientation, geography, socioeconomic status, disability status, primary language, health literacy, and other relevant dimensions. The Translation strategy of this NOFO emphasizes analysis of linked pathogen genomic and epidemiologic data. This activity will improve discovery of transmission, risk factors, and outcomes of pathogens in specific populations, and allow prevention strategies to be targeted to populations at greatest risk.

CDC supports efforts to improve the health of populations disproportionately affected by infectious diseases by maximizing the health impact of public health services, reducing disease incidence, and advancing health equity.

A health disparity occurs when a health outcome is seen to a greater or lesser extent between populations. Health disparities in infectious diseases are inextricably linked to a complex blend of social determinants that influence which populations are most disproportionately affected by these infections and diseases.

Social determinants are conditions in the places where people live, learn, work, and play that affect a wide range of health and quality-of life-risks and outcomes (https://www.cdc.gov/socialdeterminants/index.htm). These include conditions for early childhood development; education, employment, and work; food security, health services, housing, income, and social exclusion. Health equity is a desirable goal that entails special efforts to improve the health of those who have experienced social or economic challenges. It requires:

- Continuous efforts focused on elimination of health disparities, including disparities in health and in the living and working conditions that influence health, and
- Continuous efforts to maintain a desired state of equity after health disparities are eliminated.

Applicants should use data, including social determinants data, to identify communities within their jurisdictions that are disproportionately affected by infectious diseases and related diseases and conditions, and plan activities to help eliminate health disparities. In collaboration with partners and appropriate sectors of the community, applicants should consider social determinants of health in the development, implementation, and evaluation of program specific efforts and use culturally appropriate interventions and strategies that are tailored for the communities for which they are intended.

iv. Funding Strategy

This NOFO intends to fund recipients that are well suited (i.e., have the necessary technical expertise, infrastructure, academic partnership, and management capabilities) and have the potential to make substantial contributions to the activities and outcomes in the logic model. This NOFO has 2 Mandatory Components (Mandatory Component (Core) and Mandatory Component (Response Implementation)) and one Optional Component (Lead PGCoE for Education). The Mandatory (Core) component has 3 strategies. All recipients for the Mandatory Components must engage in all three strategies of the Mandatory Component (Core) and the single strategy of the Mandatory Component (Response Implementation). Applicants may choose to also apply to be the Lead PGCoE for Education (Optional Component (Lead PGCoE for Education)). Depending on the applications received and fund availability, CDC intends to fund one recipient as the Lead PGCoE for Education.

Applicants must clearly state in the Project Abstract Summary if they are applying to only the Mandatory Components (Core, Response Implementation), or if they are also applying to the Optional Component (Lead PGCoE for Education). When including this information in the Project Abstract Summary, please indicate one of the following: a) "This application is only for the Mandatory Components (Core, Response Implementation)" or b) "This application is for the Mandatory Components (Core, Response Implementation) and also includes the Optional Component (Lead PGCoE for Education)."

Applications must include a separate project narrative, budget, and work plan for each component, titled: "Mandatory Component (Core)", "Mandatory Component (Response Implementation)" and "Optional Component (Lead PGCoE for Education)." Applicants must apply for all three strategies of the Mandatory Component (Core). For the Mandatory Component (Core), the budget and the work plan must be broken out by each strategy.

The Mandatory Components (Core, Response Implementation) will be scored and rank ordered separately from the Optional Component (Lead PGCoE for Education). Applicants may therefore be awarded either the Mandatory Components (Core, Response Implementation) alone, or, for one applicant, both the Mandatory Components (Core, Response Implementation) and the Optional Component, depending on the score and rank for each component.

Funding will be awarded for activities selected on a yearly basis according to priorities for the network after obtaining prior approval from the CDC Grants Services Office and following all grants administration requirements.

Funding strategy within the period of performance will be as follows:

- Year 1: recipients will be funded to participate in the coordinating group, perform a landscape analysis to identify gaps, needs, and opportunities for genomics and other "-omics" technologies and applications in public health, contribute to a Roadmap for pathogen genomics (and related technologies) and genomic epidemiology in public health, participate in network activities and collaborative work, and to conduct individual site projects.
- Years 2-5: recipients will be funded to implement individual, multi-site, and network-wide projects and collaborative activities. Priorities and funding decisions will take into consideration the Roadmap for pathogen genomics in public health that will be informed by the landscape analysis performed during the first year of the performance period.

All components included in the application must be addressed in the Project Narratives, Work Plans, and Budget Narratives as described below. The Project Narratives, Work Plans, and Budget Narratives should address the strategy(ies) specified for each component in the Project Abstract Summary.

Work proposed by an applicant can be complementary to, but must not be duplicative of, work funded through any other mechanism or source during the period of performance.

Component Funding: A component is a discrete set of activities with an associated budget. CDC will use component funding to provide funding for activities proposed in an application that received merit review but were not selected for funding in the initial award but may be funded at a later point in the budget period as programmatically necessary and as funding becomes available. Please review the following key points about component funding:

Each component must be a discrete set of activities with an associated budget. Distinguishable component budget narratives are required.

Applicants should submit the anticipated components on an SF-424A form as part of their application which shows all components for the budget period.

Any component that is not funded at the time of a new award may be deemed "Approved but Unfunded (ABU)". There is no guarantee that all components will be funded in a budget period as ABU components are subject to the availability of funds and infectious threat conditions that warrant the component.

Coronavirus Disease 2019 (COVID-19) Funds: N/A

b. Evaluation and Performance Measurement

i. CDC Evaluation and Performance Strategy

Applicants should propose an evaluation plan, data analysis plan, and timeline.

CDC will provide technical assistance on the selection of performance measures, implementing the measures, and identifying feasible data sources for the performance measures. CDC and recipients will have 6 months to finalize performance measures.

Recipients are responsible for gathering and analyzing data for performance measures.

Evaluation and performance measurement for the various PGCoE activities include quantitative and qualitative measures.

Performance measures for the three Mandatory Component (Core) strategies and one Mandatory (Response Implementation) strategy and, as applicable, for the Optional Component (Lead PGCoE for Education) may include, but are not limited to, those listed below. Applicants are not required to use the examples provided below. Applicants are welcome to propose measures in addition to those examples provided below if the proposed process and outcome measures align to the work plan and logic model.

PROCESS MEASURES for strategies and activities:

Translate Innovations to Public Health

- Participation in PGCoE Coordinating Group meetings and calls
- Active engagement and coordination with CDC programs
- Completion of agreements and protocols such as memoranda of understanding, data use agreements, IRB protocols.
- For studies, preparation of protocols and enrollment of participants

Educate Public Health Workforce

- Performance of an evaluation to determine gaps and educational needs for the public health workforce
- Development of online training materials
- Pilot evaluation of training materials

Prepare to Respond to Infectious Disease Threats

- Preparation of agreements and processes for activation of this activity in emergencies due to infectious threats

OUTCOME MEASURES: Short-term outcomes
Networked function with established "platform" for collaborative work between and beyond centers

- Completion of data use agreements, memoranda of understanding, IRB protocols in place for collaborative activities

Improved understanding of current state of genomic epidemiology in public health

- Completed landscape report on the state of genomic epidemiology in public health in the U.S.
- Roadmap for pathogen genomics (and related technologies) and genomic epidemiology in public health

Increased use of new and refined laboratory and bioinformatics tools

- Types and uses of bioinformatic tools utilized for analysis of public health data during period of performance compared to prior to the initiation of cooperative agreement activities

Increased capacity to sequence pathogens and to analyze genomic data

- Number and type of pathogens and number of samples sequenced during period of performance compared to prior to the initiation of cooperative agreement activities
- For specific pathogens, number and proportion of cases reported to public health with sequence data available during period of performance compared to prior to the initiation of cooperative agreement activities

Increased capacity to link microbial, clinical, and epidemiologic data and analyze linked data

- Number and proportion of pathogen sequences linked to epidemiologic data during period of performance compared to prior to the initiation of cooperative agreement activities
- Number of methods and technologies used to link microbial, clinical, and epidemiologic data compared to prior to the initiation of cooperative agreement activities
- Time from collection to linkage of microbial, clinical, and epidemiologic data for routine surveillance activities, during period of performance compared to prior to the initiation of cooperative agreement activities

Increased speed of adoption of relevant genomic technologies in U.S. public health

- Number of U.S. public health labs utilizing new technologies during period of performance compared to prior to the initiation of cooperative agreement activities

Increased availability of educational materials and approaches

- Report on the education needs for public health microbiologists, bioinformaticians, and epidemiologists
- Online training curriculum in pathogen genomics and genomic epidemiology

Networked activity supported by established systems for data sharing, analysis, review and reporting

- Completed agreements, protocols, and standard operating procedures for response activities by the network

OUTCOME MEASURES: Long-term outcomes
Greater use of genomic technologies to address infectious public health threats

- Number of public health departments performing pathogen sequencing or other related technologies

Improved interoperability of microbial genomic and other surveillance, clinical, and public health relevant information

- Number of pathogen programs with systems for systematically linking pathogen genomic, clinical, and other data during period of performance compared to prior to the initiation of cooperative agreement activities
- Uses of linked pathogen, clinical, and other data

Increased use of common tools and applications across network sites and beyond

- Number of Centers of Excellence and of U.S. public health organizations participating in use of common tools and applications during period of performance compared to prior to the initiation of cooperative agreement activities
- Types of common tools and applications being used and how they are being used

Improved discovery of transmission, risk factors, and outcomes of pathogens of public health importance

- New transmission mechanisms, risk factors, and clinical outcomes detected for pathogens of public health importance
- Number of publications and other communications that report discovery of transmission mechanisms, risk factors, and clinical outcome

Increase in U.S. public health personnel with proficiency and expertise in use of genomics and genomic epidemiology

- Number of participants who have completed online training courses and other activities

Greater alignment of U.S. and global microbial genomics and genomic epidemiology efforts

- Types and functions of international partnerships

Rapid scale-up of genomic epidemiology capabilities in response to infectious threats

- Collaboration with CDC to define evaluation and performance measures for this activity.

Resource Sharing Plan(s)
HHS/CDC policy requires that recipients of grant awards make research resources and data readily available for research purposes to qualified individuals within the scientific community after publication. Please see: https://www.cdc.gov/grants/additional-requirements/ar-25.html

As provided in the Additional Requirement (AR), CDC requires recipients for projects and programs that involve data collection or generation of data with federal funds to develop and submit a Data Management Plan (DMP) for each collection of public health data.

Applicants responding to this Notice of Funding Opportunity should include a detailed DMP in the Resource Sharing Plan(s) section of the application. The AR-25 outlines the components of a DMP and provides additional information for applicants regarding the requirements for data

accessibility, storage, and preservation.

The DMP should be developed during the project planning phase prior to the initiation of collecting or generating public health data and will be submitted with the application. The submitted DMP will be evaluated for completeness and quality at the time of submission.

Applicants must propose a Data Management Plan (DMP) in their application for finalization within 6 months after the award. In the DMP, applicants will describe how they intend to manage, preserve, and make data generated or collected with CDC funding accessible to CDC. To the extent allowed under grant award and applicable regulations, CDC may get a copy of data produced under the award for federal purposes. The DMP may be in narrative or table form and must include:

- A description of the data to be collected or generated in the proposed project;
- The standards to be used for the collected or generated data;
- Mechanisms for, or limitations to, providing access to the data, including a description for the provisions for the protection of privacy, confidentiality, security, and intellectual property, or other rights;
- Statement of the use of data standards that ensure all documentation that describes the method of collection, what the data represent, and
- Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified; and,

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 the 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)
- 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.

Given the wide range of potential activities and evolving landscape of genomics in public health, and because proposed recipient activities may be collaborative across the network and planned in collaboration with CDC programs, evaluation plans will be tailored after recipients are selected and refined with yearly work plan development. Additional guidance on the development of evaluation and performance measurement plans may be provided by CDC, as needed.

c. Organizational Capacity of Recipients to Implement the Approach

Applications must describe the organizational capacity and the unique and specialized technical expertise needed to implement the award. Applicants must describe how they are well suited to implement the activities proposed in their work plan and significantly contribute toward the bolded outcomes defined in the logic model within the NOFO period of performance. Applicants will represent partnerships of public health and academic organizations. A strong working relationship between these organizations will be crucial to the success of the program. Applicants must describe in what ways the partner academic institution(s) has the appropriate investigators and environment/facilities to successfully undertake and complete the research objectives outlined in the Project Narrative section of this NOFO.

An application must describe the following:

Personnel

- Ongoing record of accomplishments that have advanced their field(s)
- Complementary and integrated expertise for proposed collaborative projects.
- Experience and capacity to collaborate between health departments and academia.
- Experience and capacity to collaborate across laboratory and epidemiology-focused groups.
- Leadership approach, governance, and organizational structure and how these are appropriate for the project.

Environment

- The scientific environment and how it will contribute to the success of the project.
- The institutional support, equipment, and other physical resources and how it will benefit the project.
- Unique features of the scientific environment, subject populations, or collaborative arrangements.

- An existing or planned partnership with an academic institution or institutions as required by this NOFO.
- The nature of the partnership with an academic institution or institutions and the commitment of the partner or partners to participate in proposed activities; this information should be detailed in a Letter of Support from the academic institution(s).

Management and administrative capacities

- Experience and capacity to design and implement the evaluation plan.
- Experience and capacity to sub-award funds.
- Project management structure sufficient to achieve the project outcomes, including having appropriate policies and procedures in place. This includes, but is not limited to, program and staffing management, financial reporting systems, communication, technological and data systems required to implement activities in an effective and expedited manner, physical infrastructure and equipment, and workforce capacity.

Strategy-specific criteria for the Mandatory Components (Core, Response Implementation)

Technical capacities for Mandatory Component (Core) Strategy 1 Translation: ***Translate Innovations to Public Health***. Applications should describe technical capabilities as related to:

- Sequencing using next generation sequencing methods. Applicants (specifically, the public health department) should have at least one year of sequencing experience.
- Computing environment and how it will meet the needs of the project.
- A track record in innovating in molecular epidemiology. A track record for innovation may include one or more of the following 5 broad areas:

    1. Wet laboratory methods development and validation, proficiency testing, technologies, and applications
    2. Bioinformatics technologies and applications, as well as related technologies
    3. Data standardization/data security/data stewardship/data integration and reporting/data linkage/data science/data analytics/data visualization including of genomic, epidemiologic, clinical, biological, environmental, geospatial, behavioral, social and other types of data together
    4. Genomic surveillance, monitoring, analysis, data synthesis, and response
    5. Field applications and investigations

- Understanding public health practice in the United States.
- Application of microbial genomics to public health
- Obtaining Institutional Review Board approvals for human subjects research protocols

Technical capacities for Mandatory Component (Core) Strategy 2 Education: ***Educate the Public Health Workforce***. Applications should describe technical capabilities as related to:

- Experience in providing the type of training proposed

Technical capacities for Mandatory Component (Core) Strategy 3 Response: ***Prepare to respond to Infectious Threats***. Applications should describe technical capabilities as related to:

- Experience in responding to emergencies due to infectious threats
- Expertise and capacity to contribute to responses to infectious threats

Technical capacities for Mandatory Component (Response Implementation): Respond to Infectious Threats: Applications should describe technical capabilities as related to:

- Experience in responding to emergencies due to infectious threats
- Expertise and capacity to contribute to responses to infectious threats

Strategy-specific criteria for the Optional Component (Lead PGCoE for Education)

Technical capacities for Optional Component (Lead PGCoE for Education) ***Lead PGCoE for Education*** include the following. Applications should describe technical capabilities as related to:

- Performing needs assessments
- Expertise in genomics or relevant technologies and in training in this field
- Online education systems, including platforms suitable for "massive online open courses." The academic partner should have or obtain access to a robust online educational system that can host courses, including those developed by, or in collaboration with, other centers.
- The ability to offer formal continuing education credits in fields relevant to public health epidemiology and laboratory practice.
- Ability to offer courses developed by the network at no or minimal cost to participants.
- Capacity to organize and coordinate training activities

All applicants should include the following attachments for the application:

- **An Academic Letter of Support from the partnering academic organization(s) that articulates the nature of the partnership and the partner's commitment to participate in the proposed activities. The file should be named "Academic Letter of Support" and uploaded as a .pdf at www.grants.gov.**

d. Work Plan

A Work Plan template (see example below) must be provided for the Mandatory Components (Core, Response Implementation) and, as applicable, for the Optional Component (Lead PGCoE for Education). Under the Mandatory Component (Core), the work plan must be divided by strategy. Activities proposed under the respective work plans must align with the approach (logic

model, strategies, activities, outcomes, and evaluation/performance measures) outlined throughout this funding announcement.

The applicant must provide a detailed work plan for the first year and a high-level work plan for subsequent years. Application narratives must use the format specified in the H. Other Information section of the NOFO.

Post-award, the proposed work plan and activities may be adjusted within the scope and terms of this NOFO in collaboration with CDC to ensure compliance with applicable grant regulations and policies, to avoid duplicative work within the network and to prioritize highest priority efforts to address the objectives of this NOFO.

In the first year of the performance period all PGCoEs are expected to contribute to a landscape analysis of gaps, needs, and opportunities for genomics (and related) technologies in the U.S. public health system. This landscape analysis will help contribute to the development of a Roadmap for pathogen genomics (and related technologies) and genomic epidemiology in public health. The Roadmap will be one factor taken into consideration in setting priorities and making funding decisions for the network. Applicants should be able to revise work plans as emerging needs arise and/or upon discussion with CDC program staff after prior approval from the Office of Grants Services and following all grants administration requirements.

Period of Performance Outcome: *[from Outcomes section and/or logic model]*		**Outcome Measure:** *[from Evaluation and Performance Measurement section]*	
Strategies and Activities	**Process Measure** *[from Evaluation and Performance Measurement section]*	**Responsible Position / Party**	**Completion Date**
1.			
2.			
3.			
4.			
5.			
6			

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.

For all work plans supported through this funding opportunity, recipients should strive to collaborate with CDC project officers and technical monitors to align work towards pathogen genomic innovation, workforce development, and response in the United States, consistent with the scope of the NOFO and terms of the cooperative agreement.

Additional CDC routine monitoring and accountability activities may include:

- Reviewing and approving the recipient's annual work plan and detailed budget
- Providing administrative support to help the recipient meet U.S. Government financial and reporting requirements
- Organizing regular calls and meetings with the recipient to monitor project implementation progress
- Organizing regular calls and meetings with the recipient to assess expenditure in relation to approved work plan and to modify as necessary
- Ensuring all human subjects research protocols have been approved by an Office of Human Research Protections-registered IRB in accordance with the requirements of the Common Rule before human subjects work is initiated, and that IRB approvals are maintained throughout the study period, when applicable.
- Ensuring all OMB-Paperwork Reduction Act (PRA) approvals have been obtained, as necessary, throughout the lifespan of the NOFO.
- Ensuring all animal use protocols are reviewed by the CDC Animal Care and Use Program Office and Institutional Animal Care and Use Committee per CDC policies.

f. CDC Program Support to Recipients

In a cooperative agreement, CDC staff are substantially involved in the program activities, above and beyond routine grant monitoring.

CDC activities may include, but are not limited to:

- Provide general coordination for all Centers of Excellence and the overall network.
- Provide coordination specifically for Centers of Excellence crosscutting activities such as use of bioinformatics platforms
- Provide program-specific guidance on national strategy for control and response for specific pathogens
- Develop, facilitate, and participate in collaborative multi-site relationships as needed to support the successful completion of network activities
- Provide consultation and scientific and technical assistance as necessary in the operation of the PGCoE network. This may include:
    - Facilitating the development of protocols and procedure manuals
    - Assisting sites with local human subject requirements
    - Training recipient personnel
    - Assisting in the design of projects
    - Assisting in developing Data Management Plans
    - Assisting in analysis and interpretation of data
    - Assisting in disseminating results
    - Coordinating and facilitating communications within the network
    - Facilitating and coordinating the development of information exchange. CDC will consult with sites to assist evolution of PGCoE-related information systems to conform with applicable (e.g., HHS, CDC) standards
    - Laboratory testing
    - Obtaining determination of research or non-research from the Associate Director for Science for the respective CDC program when CDC scientists are engaged in the research.
    - Obtaining IRB approval from the CDC Institutional Review Board for research involving human subjects when CDC is engaged.
    - Obtaining Office of Management and Budget approval per the Paperwork Reduction Act, if necessary.
    - Assisting recipient Principal Investigators, as needed, in complying with their responsibilities described in the United States Government Policy for Institutional Oversight of Life Science Dual Use Research of Concern (DURC) http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf.
    - Ensuring compliance with the Office of Laboratory Animal Welfare (OLAW) requirements.

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:
U50

3. Fiscal Year:

2022
Estimated Total Funding:
$185,000,000

4. Approximate Total Fiscal Year Funding:
$37,000,000
This amount is subject to the availability of funds.

5. Approximate Period of Performance Funding:
$185,000,000

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

7. Expected Number of Awards:
6
Mandatory Components (Core, Response Implementation): 6 awards
Optional Component (Lead PGCoE for Education): 1 award (to a recipient of a Mandatory Components (Core, Response Implementation) award)

8. Approximate Average Award:
$6,200,000
Per Budget Period

$4,000,000 (Mandatory Component, Core); $2,000,000 Mandatory Component (Response Implementation); $1,000,000 (Optional Component)

If applying for both the Mandatory Components (Core, Response Implementation) and Optional Component (Lead PGCoE for Education), a separate Budget and Budget Narrative must be included for each component (Mandatory Component (Core), Mandatory Component (Response Implementation) and Optional Component (Lead PGCoE for Education)).

Awards issued under this NOFO are contingent upon availability of funds and a sufficient number of meritorious applications. Because the nature and scope of the proposed work will vary from application to application, it is also anticipated that the size and duration of each award may also vary. The total amount awarded and the number of awards will depend upon the number, quality, duration and cost of the applications received.

Average One Year Award Amount for Mandatory Components (Core, Response Implementation) and Optional Component (Lead PGCoE for Education) is as follows:

Year 1:
Average per site for Mandatory Components (Core, Response Implementation): $6,000,000
$4,000,000/award for Mandatory Component (Core) with approximate amounts for each strategy as follows

$3,500,000 for Translation
$400,000 for Education
$100,000 for Response Base

$2,000,000/award for Mandatory Component (Response Implementation)

In addition, one site will be awarded approximately $1,000,000/award for Optional Component (Lead PGCoE for Education)

Throughout the project period, 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 (project period) 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).

9. Award Ceiling:
$0
Per Budget Period

10. Award Floor:
$0
Per Budget Period

11. Estimated Award Date:
September 30, 2022
Throughout the project period, 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 (project period) 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).

12. Budget Period Length:
12 month(s)

13. Direct Assistance
Direct Assistance (DA) is not 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:
00 (State governments)

01 (County governments)

02 (City or township governments)

07 (Native American tribal governments (Federally recognized))

2. Additional Information on Eligibility

1. To be deemed responsive, applications must include an Academic Letter of Support from at least one academic partner organization. If an applicant fails to submit at least one letter of support from an academic partner organization, the application will be deemed non-responsive and will receive no further review.

2. Applicants must clearly state in the Project Abstract Summary if they are applying to only the Mandatory Components (Core, Response Implementation), or if they are applying to both the Mandatory Components (Core, Response Implementation) and Optional Component (Lead PGCoE for Education). When including this information in the Project Abstract Summary, please indicate one of the following: a) "This application is only for the Mandatory Compnents (Core, Response Implementation)" or b) "This application is for the Mandatory Component (Core, Response Implementation) and also includes the Optional Component (Lead PGCoE for Education)." If an applicant fails to clearly state which component are being applied for in the Project Abstract Summary, the application will be deemed non-responsive and will receive no further review.

State, local, Tribal, or territorial public health departments or public health laboratories per ARP Sec. 2402:

"FUNDING FOR SARS–COV–2 GENOMIC SEQUENCING AND SURVEILLANCE. (a) *In General.—In addition to amounts otherwise available, there is appropriated to the Secretary for fiscal year 2021 out of any money in the Treasury not otherwise appropriated, $1,750,000,000, to remain available until expended, to strengthen and expand activities and workforce related to genomic sequencing, analytics, and disease surveillance.* (b) *Use Of Funds.—From amounts appropriated by subsection (a), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall—* (1) *conduct, expand, and improve activities to sequence genomes, identify mutations, and survey the circulation and transmission of viruses and other organisms, including strains of SARS–CoV–2;* (2) *award grants or cooperative agreements to State, local, Tribal, or territorial public health departments or public health laboratories—*

(A) to increase their capacity to sequence genomes of circulating strains of viruses and other organisms, including SARS–CoV–2;

(B) to identify mutations in viruses and other organisms, including SARS–CoV–2;

(C) to use genomic sequencing to identify outbreaks and clusters of diseases or infections, including COVID–19; and

(D) to develop effective disease response strategies based on genomic sequencing and surveillance data;

(3) enhance and expand the informatics capabilities of the public health workforce; and

(4) award grants for the construction, alteration, or renovation of facilities to improve genomic sequencing and surveillance capabilities at the State and local level."

3. Justification for Less than Maximum Competition

4. Cost Sharing or Matching

Cost Sharing / Matching Requirement:
No
Cost sharing or matching funds are not required for this program. Although no statutory matching requirement for this NOFO exists, leveraging other resources and related ongoing efforts to promote sustainability is strongly encouraged as long as there is no scientific, budgetary, percent effort or other overlap with any other funded projects.

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: For applications due on or after April 4, 2022, applicants must have a unique entity identifier (UEI) at the time of application submission (SF-424, field 8c). In preparation for the federal government's April 4, 2022 transition to the Unique Entity Identifier (UEI) from the Data Universal Numbering System (DUNS), applicants must obtain a UEI. 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. Entities registering in SAM.gov prior to April 4, 2022 must still obtain a DUNS number before registering in SAM.gov registration. Additional information is available on the GSA website, SAM.gov, and Grants.gov-Finding the UEI.

a. Data Universal Numbering System:

All applicant organizations must obtain a Data Universal Numbering System (DUNS) number to register in SAM.gov prior to April 4, 2022. A DUNS number is a unique nine-digit identification number provided by Dun & Bradstreet (D&B).

The applicant organization may request a DUNS number by telephone at 1-866-705-5711 (toll free) or internet at http:// fedgov.dnb. com/ webform/ displayHomePage.do. The DUNS number will be provided at no charge.

If funds are awarded to an applicant organization that includes sub-recipients, those sub-

recipients must provide their DUNS 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	Data Universal Number System (DUNS) (Required until April 4, 2022)	1. Click on http:// fedgov.dnb.com/ webform 2. Select Begin DUNS search/request process 3. Select your country or territory and follow the instructions to obtain your DUNS 9-digit # 4. Request appropriate staff member(s) to obtain DUNS number, verify & update information under DUNS number	1-2 Business Days	To confirm that you have been issued a new DUNS number check online at (http:// fedgov.dnb.com/ webform) or call 1-866-705-5711
2	System for Award Management (SAM) formerly Central	1. Retrieve organizations DUNS number (required until April 4, 2022) 2. Go to SAM.gov and designate an E-Biz POC (You will need to have an active	3-5 Business Days but up to 2 weeks and must be renewed once a year	For SAM Customer Service Contact https://fsd.gov/ fsd-gov/ home.do Calls: 866-606-8220

	Contractor Registration (CCR)	SAM account before you can register on grants.gov). The UEI is generated as part of your registration.		
3	Grants.gov	1. Set up an individual account in Grants.gov using organization new DUNS number to become an authorized organization representative (AOR) 2. Once the account is set up the E-BIZ POC will be notified via email 3. Log into grants.gov using the password the E-BIZ POC received and create new password 4. This authorizes the AOR to submit applications on behalf of the organization	Same day but can take 8 weeks to be fully registered and approved in the system (note, applicants MUST obtain a DUNS number and SAM account before applying on grants.gov)	Register early! Log into grants.gov and check AOR status until it shows you have been approved

2. Request Application Package

Applicants may access the application package at www.grants.gov.

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)

Number Of Days from Publication 30
04/17/2022
Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows CDC staff to estimate the potential review workload and plan the review.

By the date listed in the Application and Submission Information section of this NOFO, prospective applicants are asked to submit a letter of intent that includes the following

information:

Name of the applicant organization
Descriptive title of proposed application
Name, address, and telephone number of the PD(s)/PI(s)
Names of other key personnel
Participating institutions
Number and title of this notice of funding opportunity

The letter of intent should be sent to:
Gregory Anderson, MPH, MS
Extramural Research Program Office
Office of the Associate Director of Science
National Center for HIV, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
1600 Clifton Road, MS US8-1
Atlanta, GA 30333
Telephone: 404-718-8833
Email: GAnderson@cdc.gov

b. Application Deadline

Number Of Days from Publication 60

05/17/2022
11:59 pm U.S. Eastern Standard 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.

CDC encourages inquiries concerning this NOFO.
Programmatic Technical Contact
Eleanor Click, MD, PhD
Project Officer
Office of Advanced Molecular Detection
National Center for Emerging and Zoonotic Diseases
Centers for Disease Control and Prevention
1600 Clifton Rd NE, M/S H16-5
Telephone: (404) 639-8698
Email:pgcoecoag@cdc.gov

Scientific Research Contact
Amy Yang, PhD
Extramural Research Program Office
Office of the Associate Director for Science
National Center for HIV, Viral Hepatitis, STD and TB Prevention

Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
1600 Clifton Road, MS US8-1
Atlanta, GA 30333
Telephone: 404-718-8836
Email: AYang@cdc.gov

Peer Review Contact
Gregory Anderson, MPH, MS
Extramural Research Program Office
Office of the Associate Director for Science
National Center for HIV, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
1600 Clifton Road, MS US8-1
Atlanta, GA 30333
Telephone: 404-718-8833
Email: GAnderson@cdc.gov
March 31, 2022

Due Date for Information Conference Call
Time, 2:00 pm ET; Phone Number 1-866-620-0420; Passcode: 8943360
Questions and answers from the conference call and information on any updates to the NOFO will be posted at www.cdc.gov/amd and on Grants.gov. All questions must be received by 5/1/2022 in order to be included in the Q& A document.

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 DUNS.

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:
Recommended but not Required
Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows CDC staff to estimate the potential review workload and plan the review.

By the date listed in the Application and Submission Information section of this NOFO, prospective applicants are asked to submit a letter of intent that includes the following information:

Name of the applicant organization
Descriptive title of proposed application
Name, address, and telephone number of the PD(s)/PI(s)

Names of other key personnel
Participating institutions
Number and title of this notice of funding opportunity

The letter of intent should be sent to:
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Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
1600 Clifton Road, MS US8-1
Atlanta, GA 30333
Telephone: 404-718-8833
Email: GAnderson@cdc.gov

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 file 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.

Applicants must clearly state in the Project Abstract Summary if they are applying to only the Mandatory Components (Core, Response Implementation) or if they are applying to both the Mandatory Components (Core, Response Implementation) and Optional Component (Lead PGCoE for Education). When including this information in the Project Abstract Summary, please indicate one of the following: a) “This application is only for the Mandatory Components (Core, Response Implementation)” or b) “This application is for the Mandatory Components (Core, Response Implementation) and also includes the Optional Lead PGCoE for Education Component.”

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.

Please see the H. Other Information section of this NOFO for page limits and format for the Project Narrative.

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. Target Populations and Health Disparities

Applicants must describe the specific target population(s) in their jurisdiction and explain how such a target will 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 Target Populations and Health Disparities requirements as described in the CDC Project Description.

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/od/science/integrity/reducePublicBurden/.
- 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.

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 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 upload it as a PDF file

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.

Additional budget instructions:

For the application, provide one single file entitled "Budget Narrative" that includes individual and complete line item budgets and detailed justification narratives for each:

- Mandatory Component (Core) strategy Translation
- Mandatory Component (Core) strategy Education
- Mandatory Component (Core) strategy Response Base
- Mandatory Component (Response Implementation)
- Optional Component (Lead PGCoE for Education) strategy Lead PGCoE for Education (if applying for this Optional Component (Lead PGCoE for Education))

The applicant must provide a detailed budgets for the first year and high-level budgets for subsequent years.

Applicants should consider and include requests for travel that may be necessary for proposed activities, including specifically (in the Mandatory Components (Core) strategy Translation and the Mandatory Component (Response Implementation)) travel to the bi-annual PGCoE coordinating group meeting and to the Annual Network Meeting. Travel that is approved and funded by CDC will be considered a required activity of the cooperative agreement.

13. Pilot Program for Enhancement of Employee Whistleblowers Protections

Pilot Program for Enhancement of Employee Whistleblower Protections: All applicants will be subject to a term and condition that applies the terms of 48 Code of Federal Regulations

(CFR) section 3.908 to the award and requires that recipients inform their employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. 4712.

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 andadditional guidance on lobbying 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.

Please note for this particular NOFO, CDC-RFA-CK22-2204, research activities are allowable and will be subject to all applicable laws, regulations and policy requirements. Note research and human subjects protection requirements inserted throughout this NOFO. All instructions pertaining to research should be addressed and followed as indicated in this NOFO. Please refer to the Strategies and Activities section for more details.

The Mandatory Component (Core) Translation strategy and the Mandatory Component (Response Implementation) may include research activities.

Additional Funding Restrictions:

1) Applications submitted under this notice of funding opportunity must not include activities that overlap with simultaneously funded research under other awards (no scientific, budgetary or percent effort overlap allowed).

2) Please note: Certain grants or recipients are not eligible for expanded authorities. In addition, one or more expanded authority may be overridden by a special term or condition of the award. The Notice of Award (NoA) will indicate the applicability of expanded authorities by reference to the HHS Grants Policy Statement or through specific terms and conditions of the award. Therefore, recipients must review the NoA to determine whether and to what extent they are, or are not, permitted to use expanded authorities.

3) Funds relating to the conduct of research involving human subjects will be restricted until the appropriate assurances and Institutional Review Board (IRB) approvals are in place. Copies of all current local IRB approval letters and local IRB approved protocols (and CDC IRB approval letters, if applicable) will be required to lift restrictions. If multiple collaborating institutions will be involved, please include in the human subjects section of the Project Narrative your single IRB (sIRB) Plan:

- Describe how you will comply with the single IRB review requirement under the Revised Common Rule at 45 CFR 46.114 (b) (cooperative research). If available, provide the name of the IRB that you anticipate will serve as the sIRB of record.
- Indicate that all identified engaged institutions or participating sites will agree to rely on the proposed sIRB and that any institutions or sites added after award will rely on the sIRB.
- Briefly describe how communication between institutions and the sIRB will be handled.
- Indicate that all engaged institutions or participating sites will, prior to initiating the study, sign an authorization/reliance agreement that will clarify the roles and responsibilities of the sIRB and participating sites.
- Indicate which institution or entity will maintain records of the authorization/reliance agreements and of the communication plan.
- Note: Do not include the authorization/reliance agreement(s) or the communication plan(s) documents in your application.
- Note: If you anticipate research involving human subjects but cannot describe the study at the time of application, include information regarding how the study will comply with the single Institutional Review Board (sIRB) requirement prior to initiating any multi-site study in the delayed onset study justification.

4) Funds relating to the conduct of activities involving vertebrate animals will be restricted until the appropriate assurances and Institutional Animal Care and Use Committee (IACUC) approvals are in place. Copies of all current local IACUC approval letters and local IACUC approved protocols will be required to lift restrictions.

5) Projects that involve the collection of information, identical record keeping or reporting from 10 or more individuals and are funded by a cooperative agreement and constitute a burden of time, effort, and/or resources expended to collect and/or disclose the information will be subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA).

6) On September 24, 2014, the Federal government issued a policy for the oversight of life

sciences “Dual Use Research of Concern” (DURC) and required this policy to be implemented by September 24, 2015. This policy applies to all New and Renewal awards issued on applications submitted on or after September 24, 2015, and to all non-competing continuation awards issued on or after that date. CDC grantee institutions and their investigators conducting life sciences research subject to the Policy have a number of responsibilities that they must fulfill. Institutions should reference the policy, available at http://www.phe.gov/s3/dualuse , for a comprehensive listing of those requirements. Non-compliance with this Policy may result in suspension, limitation, or termination of US Government (USG) funding, or loss of future USG funding opportunities for the non-compliant USG-funded research project and of USG funds for other life sciences research at the institution, consistent with existing regulations and policies governing USG funded research and may subject the institution to other potential penalties under applicable laws and regulations.

7) Please note the requirement for inclusion of a Data Management Plan (DMP) in applications described in AR-25 in the Additional Requirements section of this NOFO (https://www.cdc.gov/grants/additional-requirements/ar-25.html) . Funding restrictions may be imposed, pending submission and evaluation of a Data Management Plan.

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. All application attachments must be submitted using a PDF file format. 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 the Grants.gov Online User Guide.

https://www.grants.gov/help/html/help/index.htm?callingApp=custom#t=GetStarted%2FGetStarted.htm

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:** 40

Significance
Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Strategy-specific Criteria for Mandatory Component (Core)

Translation

- To what extent are the proposed projects ones that, if successful, are likely to be scalable and have the potential to impact public health practice in the United States?
- To what extent do the proposed projects under this section have the potential to impact public health (see "Framework for evaluating potential public-health impact", above) either in the short term or long term?

Education

- To what extent do the proposed topics and activities have relevance for public health in the United States?

Response Base

- To what extent has the applicant provided examples of how they might prepare for a response to an infectious threat?

Strategy-specific Criteria for Mandatory Component (Response Implementation)

- To what extent has the applicant provided examples of how they might contribute to a response to infectious threats using expertise in genomics?

Innovation
Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Strategy-specific Criteria for the Mandatory Component (Core)

Translation

- To what extent do the proposed projects represent novel ideas for how to improve public health in the US?
- To what extent is the proposed project to achieve the translational objective of the cooperative agreement—i.e., bringing relevant genomics (and related) technologies into the US public health system?

Education

- To what extent are the proposed courses/trainings innovative?

Response Base

- To what extent are the contributions that the applicant is proposing likely to result in effective preparation for an infectious threat?

Strategy-specific Criteria for the Mandatory Component (Response Implementation)

- To what extent are the contributions that the applicant is proposing novel?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility, and will particularly risky aspects be managed? If the project involves clinical research, are there plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Strategy-specific Criteria for Mandatory Component (Core)

Translation

- To what extent could the proposed activities be feasibly implemented in the network?
- To what extent would the activities, if successful within the network, be scalable for broader use in the US public health system?

Education

- To what extent are the proposed topics and activities relevant to public health practice?

Response Base

- To what extent does the applicant suggest activities that will realistically prepare to contribute to a response to an infectious threat?

Strategy-specific Criteria for Mandatory Component (Response Implementation)

- To what extent does the applicant suggest activities that will realistically contribute to a response to an infectious threat?

Strategy-specific criteria for the Optional Component (Lead PGCoE for Education):

Determine Education Needs

- To what extent has the applicant provided examples of how they might determine the education needs for the public health workforce, with particular emphasis on the needs of microbiologists, bioinformaticians, and epidemiologists?

Lead Education Efforts for the Network and Develop Online Training

- To what extent has the applicant provided examples of how they would lead education efforts of the network?
- To what extent has the applicant described a plan for developing online training for the public health workforce, particularly microbiologists, bioinformaticians, and epidemiologists?

Additional Review Criteria

As applicable for the project proposed, *reviewers will evaluate* the following additional items while determining scientific and technical merit, and in providing an overall impact/priority score given to the Approach section of this NOFO.

Protections for Human Subjects

If the research involves human subjects but does not involve one of the eight categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the eight categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on the review of the Human Subjects section, please refer to https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general-forms-g.pdf.

Inclusion of Women, Minorities, and Across the Lifespan

When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children and older adults (>65 years). For additional information on review of the Inclusion section, please refer to the policy on the Inclusion of Women and Racial and

Ethnic Minorities in Research (https://www.cdc.gov/grants/additional-requirements/ar-2.html) and the policy on the Inclusion of Persons Under 21 in Research (https://www.cdc.gov/grants/additional-requirements/ar-28.html).

Vertebrate Animals
The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following four points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 4) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section (https://grants.nih.gov/grants/olaw/VASchecklist.pdf).

Biohazards
Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Dual Use Research of Concern
Reviewers will identify whether the project involves one of the agents or toxins described in the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern, and, if so, whether the applicant has identified an IRE to assess the project for DURC potential and develop mitigation strategies if needed.

For more information about this Policy and other policies regarding dual use research of concern, visit the U.S. Government Science, Safety, Security (S3) website at: http://www.phe.gov/s3/dualuse. Tools and guidance for assessing DURC potential may be found at: http://www.phe.gov/s3/dualuse/ Documents/durc-companion-guide.pdf.

ii. Evaluation and Performance Measurement **Maximum Points:** 25

To what extent does the applicant describe clear monitoring and evaluation procedures and how evaluation and performance measurement will be incorporated into planning, implementation, and reporting of project activities?

To what extent does the applicant describe in sufficient detail key evaluation questions, and data sources and analysis methods?

Did the applicant include a preliminary Data Management Plan (DMP)?

iii. Applicant's Organizational Capacity to Implement the Approach **Maximum Points:** 35

Personnel
Are the PD/PIs, collaborators, and other researchers well suited to the project? Have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

To what extent does the applicant describe experience and capacity to collaborate across laboratory and epidemiology-focused groups?

To what extent does the applicant provide evidence of partnership with an academic organization(s) (i.e., an Academic Letter of Support from the academic partner(s)) that clearly articulates the nature of the partnership and the partner's commitment to participate in the proposed activities?

To what extent does the applicant describe a track record of collaborating with the partner academic organization(s) or do they describe ways that they will be able to collaborate successfully?

To what extent does the applicant describe a track record of collaborating and of collaborating in a network or do they describe ways that they will be able to collaborate successfully within a network?

Strategy-specific Criteria for the Mandatory Component (Core):

Translation

- To what extent does the applicant have a track record in innovating in pathogen genomics and genomic epidemiology? Innovation could include one or more of the following 5 broad areas:

1. Wet laboratory methods development and validation, proficiency testing, technologies, and applications
2. Bioinformatics technologies and applications, as well as related technologies
3. Data standardization/data security/data stewardship/data integration and reporting/data linkage/data science/data analytics/data visualization including of genomic, epidemiologic, clinical, biological, environmental, geospatial, behavioral, social and other types of data together
4. Genomic surveillance, monitoring, analysis, data synthesis, and response
5. Field applications and investigations

Education

- To what extent does the applicant have experience in providing the type of training that they propose?

Response Base

- To what extent does the applicant have experience in preparing protocols, data sharing agreements, and other items that would be useful in preparation for a response to an infectious threat?

Strategy-specific Criteria for the Mandatory Component (Response Implementation):

- To what extent does the applicant have experience in responding to infectious threats?
- To what extent does the applicant have expertise and capacity that will be useful in contributing to response to infectious threats?

Strategy-specific Criteria for the Optional Component (Lead PGCoE for Education)

Determine education needs

- To what extent does the applicant have relevant experience in performing needs assessments?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Strategy-specific Criteria for the Mandatory Component (Core):

Translation

- Does the applicant (health department) have at least one year of experience with sequencing using next generation methods?
- To what extent does the application describe a computing environment adequate to complete the proposed project?

Strategy-specific Criteria for the Mandatory Component (Response Implementation):

- To what extent does the applicant describe access to resources they would need to assist in response to an infectious threat?

Strategy-specific criteria for the Optional Component (Lead PGCoE for Education)

Provide leadership in education efforts and develop an online course

- To what extent does the site have the relevant resources to act as host for an online training program?
- To what extent does the site have an existing online presence?
- Can the site support continuing education credits for disciplines within public health?

Budget **Maximum Points:** 0

The budget will be reviewed but not scored.

Applications will be evaluated for scientific and technical merit by an appropriate peer review group (Special Emphasis Panel or SEP), in accordance with CDC peer review policy and procedures for research, using the stated review criteria. As part of the scientific peer review, all applications:

- Will undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review), will be discussed and assigned an overall impact/priority score.
- Will receive a written critique.

Applications will compete for available funds with all other recommended applications submitted in response to this NOFO. Mandatory Components (Core, Response Implementation) will be scored and rank ordered separately from Optional Components (Lead PGCoE for Education). Applicants may therefore be awarded either the Mandatory Components (Core, Response Implementation) alone, or, for one applicant, both the Mandatory Components (Core, Response Implementation) and Optional Component, depending on the score and rank for each component.

c. Phase III Review

Applications will be evaluated during the peer review process on the strength and capacity of the applicant and how well they address the intent of the NOFO, the strength of the proposed design and approach to accomplish the program priorities, and the feasibility of completing the proposed effort within the time frame of the project period and within the proposed budget, among other scored peer review criteria as described in Section E. Review and Selection Process 1.b. Phase II Review, above.

Following phase II peer review, recommended applications will receive an additional level of review (phase III). During phase III review, the following will be considered in making funding recommendations in priority order:

Scientific merit of the proposed project as determined by Special Emphasis Panel (SEP) review.

Diversity in areas of expertise for investigators and key personnel within the applicant organization and its proposed partner academic organization(s) as determined by experience described in the application (e.g., publication record, experience in wet laboratory, bioinformatics, data linkage, data visualization, analytics, field applications and investigations, online training).

Geographic diversity of applicants as defined by HHS region. Recipients should not all be from a single region.

Demographic diversity of the population served by the applicant.

CDC will provide justification for any decision to fund out of rank order based solely on the priorities listed above.

The review process for non-competitive continuation and supplemental applications will be outlined in future guidance for those proposed activities, consistent with applicable grant regulations and policies.

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 are expected to be announced by September 1, 2022 at the earliest and awarded by September 30, 2022.

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 the DUNS, 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.

2. Administrative and National Policy Requirements

Organization Specific ARs:
AR-8: Public Health System Reporting Requirements
AR-15: Proof of Non-profit Status
AR 23: Compliance with 45 C.F.R. Part 87

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.

The full text of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards, 45 CFR 75, can be found at: https://www.ecfr.gov/cgi-bin/text-idx?node=pt45.1.75

Should you successfully compete for an award, recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy).This includes taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons

with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on your specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and taking appropriate steps to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment, see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html.
- For guidance on administering your project in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

3. Reporting

Reporting provides continuous program monitoring and identifies successes and challenges that recipients encounter throughout the project period. 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)	6 months into award	Yes
Annual Performance Report (APR)	No later than 120 days before end of budget period. Serves as yearly continuation application.	Yes
Data on Performance Measures	N/A	No
Federal Financial Reporting Forms	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 target 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 publically 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.

Recipients may request that as much as 75% of their estimated unobligated funds be carried over into the next budget period.

Research activities must be reported annually on the standard Research Performance Progress Report (RPPR) form (*https://grants.nih.gov/grants/rppr/index.htm*).

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.

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.

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).

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 $25,000.

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:
Eleanor

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

Address:
1600 Clifton Rd NE, M/S H16-5

Telephone:
(404) 639-8698

Email:
pgcoecoag@cdc.gov

Grants Management Office Information

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

First Name:
Freda

Last Name:
Johnson
Grants Management Specialist
Department of Health and Human Services
Office of Grants Services

Address:

Telephone:
770-488-3107

Email:
wve2@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** can upload as PDF files 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

Memorandum of Agreement (MOA)

Memorandum of Understanding (MOU)

Bona Fide Agent status documentation, if applicable

IRB determination/approval letters (for proposed research activities)
Documentation of Relevant Accomplishments: this may include abstracts, publications, bibliographies, number of students trained or training opportunities provided, etc.

Appendices submitted via Grants.gov should be uploaded in a PDF file format, and should be clearly titled such as "Curriculum vitaes," "Letters of Support," "Indirect Cost Rate Agreement," "IRBs," etc. Multiple documents of the same type (such as organizational charts, letters of support, CVs, IRBs) should be scanned in as one file. Do not provide a separate attachment for each individual letter or CV.

Applicants should file a letter of support from the academic center(s), name the file "Academic Letter of Support", and upload it as a PDF file at www.grants.gov. If an applicant fails to submit at least one of letter of support from an academic partner organization, the application will be deemed non-responsive and will receive no further

review.

The Project Narrative for the **Mandatory Component (Core) strategy Translation** should describe research and other activities organized into separate sections for each of the 5 broad areas:

1. Wet laboratory methods development and validation, proficiency testing, technologies, and applications
2. Bioinformatics technologies and applications, as well as related technologies
3. Data standardization/data security/data stewardship/data integration and reporting/data linkage/data science/data analytics/data visualization including of genomic, epidemiologic, clinical, biological, environmental, geospatial, behavioral, social and other types of data together
4. Genomic surveillance, monitoring, analysis, data synthesis, and response
5. Field applications and investigations

For each of these 5 broad areas, the narrative should include the following sections in the following order:

- Background
- Activities
    - Purpose
    - Outcomes
    - Significance
    - Innovation
    - Approach (including Specific Aims)
    - Collaborations
    - Target Populations
    - Human Subjects Protections/ PHS Human Subjects and Clinical Trials information
    - Inclusion of Women, Minorities, and Ages across the Lifespan in Research
    - Vertebrate Animal Protections
    - Biohazards/Dual Use Research of Concern
- Resource Sharing Plan (including Data Management Plan)
- Evaluation and Performance Measurement Plan
- Organizational Capacity of Applicant to Implement the Approach (including Investigator qualifications and institutional Environment to successfully complete objectives)
- Work Plan
- Bibliography and References Cited

The Project Narrative for the **Mandatory Component (Core) strategy Education** should include the following sections:

- Background
- Approach

- Application Evaluation and Performance Plan
- Organizational Capacity of Applicants to Implement the Approach
- Work Plan

The Project Narrative for the **Mandatory Component (Core) strategy Response Base** should describe preparation for research and other activities organized into separate sections for each of the 5 broad areas:

1. Wet laboratory methods development and validation, proficiency testing, technologies, and applications
2. Bioinformatics technologies and applications, as well as related technologies
3. Data standardization/data security/data stewardship/data integration and reporting/data linkage/data science/data analytics/data visualization including of genomic, epidemiologic, clinical, biological, environmental, geospatial, behavioral, social and other types of data together
4. Genomic surveillance, monitoring, analysis, data synthesis, and response
5. Field applications and investigations

Preparation activities may include but are not limited to preparation of IRB protocols, memoranda of understanding, and data sharing and use agreements.

The project narrative should include the following sections:

- Background
- Approach
- Application Evaluation and Performance Plan
- Organizational Capacity of Applicants to Implement the Approach
- Work Plan

The Project Narrative for the **Mandatory Component (Response Implementation)** should describe research and other activities organized into separate sections for each of the 5 broad areas:

1. Wet laboratory methods development and validation, proficiency testing, technologies, and applications
2. Bioinformatics technologies and applications, as well as related technologies
3. Data standardization/data security/data stewardship/data integration and reporting/data linkage/data science/data analytics/data visualization including of genomic, epidemiologic, clinical, biological, environmental, geospatial, behavioral, social and other types of data together
4. Genomic surveillance, monitoring, analysis, data synthesis, and response
5. Field applications and investigations

Plan and prepare a response to infectious threats, with activities in the 5 broad areas listed above.

Activities may include but are not limited to sequencing and other applications, analysis, and synthesis of data.

- Background
- Approach
- Application Evaluation and Performance Plan
- Organizational Capacity of Applicants to Implement the Approach
- Work Plan

The Project Narrative for the **Optional Component (Lead PGCoE for Education) strategy Lead CoE for Education** should include the following sections:

- Background
- Approach
- Application Evaluation and Performance Plan
- Organizational Capacity of Applicants to Implement the Approach
- Work Plan

See additional instructions for each of these narrative sections throughout this NOFO and in Section D.10. and Section D.11, above.

PAGE LIMIT:
Disregard page limits stated under Section D.10 for "Program Narrative," (but do follow other page and type format instructions). Maximum number of pages for the Mandatory Components (Core, Response Implementation) Project Narrative file is 75 (excluding budget, budget narrative, appendices, and required forms). Maximum number of pages for the Optional Component (Lead PGCoE for Education) is 25 (excluding budget, budget narrative, appendices, and required forms). If Project Narrative exceeds the page limit, only the first pages which are within the page limit will be reviewed.

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 compendium published by the General Services Administration (available on-line in searchable format as well as in printable format as a .pdf file) that describes domestic assistance programs administered by the Federal Government.

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.

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.

DUNS: The Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number is a nine-digit number assigned by Dun and Bradstreet Information Services. When applying for Federal awards or cooperative agreements, all applicant organizations must obtain a DUNS number as the Universal Identifier. DUNS number assignment is free. If requested by telephone, a DUNS number will be provided immediately at no charge. If requested via the Internet,

obtaining a DUNS number may take one to two days at no charge. If an organization does not know its DUNS number or needs to register for one, visit Dun & Bradstreet at http://fedgov.dnb.com/ webform/displayHomePage.do.

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: Differences in health outcomes and their determinants among segments of the population as defined by social, demographic, environmental, or geographic category.

Health Equity: Striving for the highest possible standard of health for all people and giving special attention to the needs of those at greatest risk of poor health, based on social conditions.
Health Inequities: Systematic, unfair, and avoidable differences in health outcomes and their determinants between segments of the population, such as by socioeconomic status (SES), demographics, or geography.

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: Both the meaningful involvement of a community's members in all stages of the program process and the maximum involvement of the target population that the intervention will benefit. Inclusion ensures that the views, perspectives, and needs of affected communities, care providers, and key partners are considered.

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 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).

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.

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: Conditions in the environments in which people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.

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.

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.

AMD: Advanced Molecular Detection

PGCoE: Pathogen Genomics Center of Excellence

Infectious Disease and Infectious Disease Threats: are synonymous in this document