Centers for Disease Control and Prevention

NATIONAL CENTER FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION

Health Promotion and Disease Prevention Research Centers: 2025 Special Interest Project Competitive Supplements (SIPS)

RFA-DP-25-126

02/28/2025

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Overview

Participating Organization(s)

Centers for Disease Control and Prevention

Components of Participating Organizations

Components of Participating Organizations:
National Center for Chronic Disease Prevention and Health Promotion

Notice of Funding Opportunity (NOFO) Title

Health Promotion and Disease Prevention Research Centers: 2025 Special Interest Project Competitive Supplements (SIPS)

Activity Code

U48

Notice of Funding Opportunity Type

New

Agency Notice of Funding Opportunity Number

RFA-DP-25-126

Assistance Listings Number(s)

93.135

Category of Funding Activity

HL - Health

NOFO Purpose

This Notice of Funding Opportunity (NOFO) will provide supplemental funding to the CDC Health Promotion and Disease Prevention Research Centers (RFA-DP-24-004) to conduct Special Interest Research Projects (SIPs) to inform public health practice. Recipients will conduct high-quality applied health promotion and disease prevention research in real-world

settings to identify, design, test, assess, evaluate, disseminate, and translate interventions (i.e., programs, practices, policies, or strategies) to prevent and reduce risk for the leading causes of illness, disability, and death in the United States.

Key Dates

Publication Date:
To receive notification of any changes to RFA-DP-25-126, return to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notification Emails" link. An email address is needed for this service.

Letter of Intent Due Date:
02/05/2025

Application Due Date:
02/28/2025

On-time submission requires that electronic applications be error-free and made available to CDC for processing from the NIH eRA system on or before the deadline date. Applications must be submitted to and validated successfully by Grants.gov no later than 11:59 PM U.S. Eastern Time.

Applicants will use a system or platform to submit their applications through Grants.gov and eRA Commons to CDC. ASSIST, an institutional system to system (S2S) solution, or Grants.gov Workspace are options. ASSIST is a commonly used platform because it provides a validation of all requirements prior to submission and prevents errors.

For more information on accessing or using ASSIST, you can refer to the ASSIST Online Help Site at: https://era.nih.gov/erahelp/assist. Additional support is available from the NIH eRA Service desk via http://grants.nih.gov/support/index.html.

- E-mail: commons@od.nih.gov
- Phone: 301-402-7469 or (toll-free) 1-866-504-9552
- Hours: Monday - Friday, 7 a.m. to 8 p.m. Eastern Time, excluding Federal holidays

Note: HHS/CDC grant submission procedures do not provide a grace period beyond the application due date time to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e., error correction window).

Scientific Merit Review:
03/24/2025

Secondary Review:
06/27/2025

Estimated Start Date:
09/30/2025

Expiration Date:
03/28/2025

Required Application Instructions

It is critical that applicants follow the instructions in the How to Apply - Application Guide except where instructed to do otherwise in this NOFO. Conformance to all requirements (both in the Application Guide and the NOFO) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

Page Limitations: Pages that exceed the page limits described in this NOFO will be removed and not forwarded for peer review, potentially affecting an application's score.

Applications that do not comply with these instructions may be delayed or may not be accepted for review.

Telecommunications for the Hearing Impaired: TTY 1-888-232-6348

Executive Summary

Purpose: This Notice of Funding Opportunity (NOFO) invites applications from CDC Health Promotion and Disease Prevention Research Centers (PRCs), selected for funding under RFA-DP-24-004, to apply for supplemental funding to conduct Special Interest Research Projects (SIPs) to inform public health practice. PRCs will conduct high-quality applied health promotion and disease prevention research projects in real-world settings to identify, design, test, evaluate, disseminate, and translate interventions (i.e., programs, practices, policies, or strategies) to prevent and reduce risk for the leading causes of illness, disability, and death in the United States.

Mechanism of Support: Cooperative Agreement

Funds Available and Anticipated Number of Awards: The estimated total funding (including direct and indirect costs) for the period of performance (9/30/2024 - 9/29/2029) is $21,858,000. It is anticipated that up to 12 awards will be made under this NOFO. Awards issued under this NOFO are contingent upon the availability of funds and receipt of a sufficient number of meritorious applications. Because the nature and scope of the proposed research projects will vary from application to application, it is anticipated that the total amount awarded, and the number of awards will depend upon the quality and cost of the applications.

- **Budget and Period of Performance.** The estimated total funding (direct and indirect) for the first 12-month budget period, 9/30/2025 - 9/29/2026, is $5,902,000. See Section VIII. Other Information - Special Interests Project Descriptions for the funding amount and period of performance for each individual SIP.
- **Application Research Strategy Length:** Page limits for the Research Strategy are clearly specified in Section IV. Application and Submission Information of this announcement.
- **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III. Eligibility Information are eligible to apply.

- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support.
- **NOTE:** CDC does not make awards to individuals directly, only to institutions / organizations. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply.
- **Number of PDs/PIs.** The SIP PI/PD may be anyone that meets the qualifications from within the selected recipient PRC institution (RFA-DP-24-004). The PI/PD named on RFA-DP-24-004 Notice of Award MUST be included as a Co-PI on the SIP, if not already proposed as the SIP PI/PD. Additional SIP PIs/PDs are permitted, but they also must be referred to as SIP Co-PIs/PD.
- Number of Applications. Applicants may apply to more than one SIP listed in Section **VIII: Other Information** - Special Interests Project Descriptions; however, a separate application is required for each SIP. Only one application per SIP per institution is allowed (e.g., multiple applications for the same SIP (listed in Section VIII) from the same institution are NOT permitted). Each SIP application, and SF 424 (R&R) must be submitted as a New Application (field 8) and must include the correct SIP number in Field 4.a (Federal Identifier), and the SIP Title Field 4.b (Agency Routing Identifier), as listed below and in Section VIII. Special Interest Project Descriptions. **PLEASE NOTE: Effective April 4, 2022, applicants must have a Unique Entity Identifier (UEI) at the time of application submission.** The UEI replaced the Data Universal Numbering System (DUNS) and is generated as part of SAM.gov registration. Current SAM.gov registrants have already been assigned their UEI and can view it in SAM.gov and Grants.gov. Additional information is available on the GSA website, SAM.gov, and Grants.gov-Finding the UEI.
- **Application Type.** New
- **Special Date(s).** The Pre-Application Informational Call will be scheduled in early 2025. Call-in information will be provided on the CDC PRC home page (Prevention Research Centers | CDC)
- **Application Materials.** See Section IV: Application and Submission Information for application materials.
- **Hearing Impaired:** Telecommunications for the hearing impaired are available at: TTY: 1-888-232-6348

Section I. Funding Opportunity Description

Statutory Authority

The activities of this NOFO are supported under Section 1706 of the Public Health Service Act, as amended (42 USC 300u-5). The eligible applicants (academic research centers) are further defined in Section 799B of the Public Health Service Act (42 USC 295p). Funding for this activity is current through the Consolidated Appropriations Act 2023, Joint Explanatory Statement on H.R. 2617

1. Background and Purpose

Prevention research includes applied public health research (to develop and evaluate health promotion and disease prevention and control strategies that are community- and population-based). It can involve identifying strategies to inform the design of interventions, testing developed interventions for efficacy and effectiveness, or conducing dissemination and implementation research to increase understanding of strategies to implement and sustain interventions in public health practice. Applied public health promotion and disease prevention research may focus on primary, secondary, or tertiary prevention; or may improve health and prevent disease through approaches that involve changes to individual behavior, policy or environmental structure, health systems, or socio-economic factors. Applied public health researchers engage communities and key partners to conduct high-quality research that supports the development and evaluation of health promotion and disease prevention interventions, dissemination of new science, and translation of proven effective interventions into public health practice and policy for population health benefit.

The Prevention Research Center (PRC) Program was established by Congress in 1984 (Public Law 98-551) to conduct research in health promotion, disease prevention, and methods of appraising health hazards and risk factors. Congress mandated that the centers be located at academic health centers capable of providing multidisciplinary faculty with expertise in public health, relationships with professionals in other relevant fields, graduate training and demonstrated curricula in disease prevention, and a capability for residency training in public health or preventive medicine. The PRCs also serve as demonstration sites for the use of new and innovative applied public research and activities for disease prevention and health promotion. CDC administers the PRC Program and provides leadership, technical assistance, and oversight. Funded PRCs can compete for Special Interest Research Projects (SIPs) sponsored by CDC, HHS, and other federal agencies, to conduct research and other activities in priority areas to inform public health practice.

CDC created the SIP program in 1993 as a supplemental funding mechanism to support health promotion and disease prevention research that would benefit from a multidisciplinary group of researchers. SIPs are supplemental funding awards that focus on topics of interest or gaps in knowledge or research and can also support the development of state and local public health interventions and policies. PRCs are uniquely positioned to oversee, coordinate, and rapidly initiate applied public health research that promotes the field of health promotion and disease prevention due to their established relationships with multidisciplinary faculty and community partners. SIP topics are aligned with public health priorities, such as the Healthy People 2030 Objectives—HHS's national objectives for improving Americans' health. SIPs are sponsored and primarily funded by CDC Centers, Institutes, and Offices (CIOs).

SIPs can focus on various topics or a gap in scientific evidence, such as:

- Major causes of death and disability in the United States.
- Improving public health practice within communities.
- Cultivating effective state and local public health programs.
- Developing and evaluating disease prevention and health promotion interventions.

- Disseminating new science and translating proven effective prevention interventions into public health practice and policy for community-wide benefit.

SIPs can have different structures including funding one or multiple PRCs to conduct community-based applied prevention research projects:

- Single PRC: The SIP supports one PRC to conduct a specific research project.
- Multiple PRCs: The SIP supports two or more PRCs to conduct different dimensions of a research project or to test strategies in different populations.
- Thematic Research Networks: The SIP supports multiple PRCs that collaborate on research of a specific health issue.

Institutions (successful PRC applicants) selected for funding under RFA-DP-24-004 are encouraged to apply for SIPs that expand and strengthen their PRC's mission and increase their applied public health research activities to contribute to preventing and reducing risk for the leading causes of illness, disability, and death in the United States.

Healthy People 2030 and other National Strategic Priorities
The 2025 SIP research activities align with the following Healthy People 2030 topic areas: cancer, Nutrition and Healthy Eating; Physical Activity; Diabetes; Heart Disease and Stroke; Overweight and Obesity

Below are the HP 2030 health topics and the associated SIPs:

Cancer

C-08: Reduce the prostate cancer death rate

C-11: Increase the proportion of cancer survivors living 5 years or longer after diagnosis.

C-R01: Increase quality of life for cancer survivors**.**

AHS-08: Increase the proportion of adults who get recommended evidence-based preventive health care

Diabetes

D-01: Increase the proportion of eligible people completing CDC-recognized type 2 diabetes prevention programs

D-02: Reduce the proportion of adults who don't know they have prediabetes

Overweight and Obesity

NWS-04: Reduce the proportion of children and adolescents with obesity

NWS-03: Reduce the proportion of adults with obesity

NWS-06: Increase fruit consumption by people aged 2 years and over

NWS-07: Increase vegetable consumption by people aged 2 years and older

NWS-10: Reduce consumption of added sugars by people aged 2 years and over

NWS-12: Reduce consumption of sodium by people aged 2 years and over

Physical Activity

PA-01: Reduce the proportion of adults who do no physical activity in their free time

PA-08: Increase the proportion of adolescents who do enough aerobic and muscle-strengthening activity

PA-09 Increase the proportion of children who do enough aerobic physical activity

Heart Disease and Stroke

HDS-01: Increase overall cardiovascular health in adults

HDS-04: Reduce the proportion of adults with high blood pressure

HDS-06: Reduce cholesterol in adults

Infectious Diseases

Public Health Impact
Accomplishing the objectives of these projects will result in improvements in the delivery and outcomes of public health programs and practice. The PRCs will use equitable and participatory evidence-based, community-engaged approaches to 1) fill critical gaps in chronic disease prevention and health promotion research, and 2) identify effective strategies to reduce or eliminate health disparities and health inequities. Public Health Impact is described for each Special Interest Project in Section VIII. Other Information, Special Interest Project Descriptions.

Relevant Work
As appropriate, this information will be provided for each SIP in the individual descriptions contained in Section VIII. Other Information - Special Interests Project Descriptions of this announcement.

2. Approach

As appropriate, the information that follows (up to Section II. Award Information) will be provided for each SIP in the individual descriptions contained in **Section VIII. Other Information - Special Interests Project Descriptions.**
Special Interests Project descriptions in this announcement will include:

- Objectives/Outcomes
- Public Health Priorities
- Study design and methods
- Target Population
- Collaboration/Partnerships
- Recruitment Plan
- Annual Action Plan
- Evaluation/Performance Measurement
- Data Management Plan
- Dissemination and Translation Plan
- Public Health Impact
- References

See individual SIPS proposals in the **Section VIII. Other Information - Special Interests Project Descriptions** for more detailed information of the requirements of each research projects.
SIP recipients may be asked to participate in the PRC Program Evaluation Reporting System (PERS) to collect data that are used to evaluate Special Interest Projects, CDC Award Management Platform (AMP), or other CDC-led program evaluation data collection activities/systems (e.g., success stories, newsletters, issue briefs, and PRC profiles, and the Pathway to Practice resource center).

Objectives/Outcomes
Recipients are expected to achieve expected objectives and outcomes during the reporting/funding period as described in **Section VIII. Other Information - Special Interest Project Descriptions.**

Population of Focus
Applicants should clearly identify the population and communities they will address in the Research Plan as described for each SIP in **Section VIII. Other Information - Special Interest Project Descriptions.**

Collaboration/Partnerships
It is anticipated that Recipients will collaborate internally and with external partners (organizations, individuals, community members, governmental, non-governmental and private sector partners) on SIP projects. Additional information on specific collaborations/partnership are described for each SIP in **Section VIII. Other Information - Special Interest Project Descriptions.**

Evaluation/Performance Measurement
Recipients may be asked to report data and information to CDC to support monitoring and evaluation activities, as described for each SIP in **Section VIII. Other Information - Special Interest Project Descriptions.**

Translation Plan
Applicants will be expected to describe how the results from the research will be adopted by other institutions or implemented and sustained by partners that translate after project completion, as described for each SIP in **Section VIII. Other Information - Special Interest Project Descriptions.**

3. Funding Strategy

N/A

Section II. Award Information

Funding Instrument Type:
CA (Cooperative Agreement)
A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, scientific or program staff will assist, guide, coordinate, or participate in project activities.

Application Types Allowed:

New - An application that is submitted for funding for the first time. Includes multiple submission attempts within the same round.

Estimated Total Funding:
$21,858,000
Please refer to Section VIII. Other Information - Special Interests Project Descriptions for the number of awards under each individual SIP.

Anticipated Number of Awards:
12
Please refer to Section VIII. Other Information - Special Interests Project Descriptions for the number of awards under each individual SIP.

Awards issued under this NOFO are contingent on the availability of funds and submission of a sufficient number of meritorious applications.

Award Ceiling:
$5,902,000
Per Budget Period

Award Floor:
$0
Per Budget Period

Total Period of Performance Length:
4 year(s)

Throughout the Period of Performance, CDC's commitment to continuation of awards will depend on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and CDC’s determination that continued funding is in the best interest of the Federal government.

HHS/CDC grants policies as described in the HHS Grants Policy Statement (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf) will apply to the applications submitted and awards made in response to 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.

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:
25 (Others (see text field entitled "Additional Information on Eligibility" for clarification))

2. Foreign Organizations

Foreign Organizations **are not** eligible to apply.

Foreign components of U.S. Organizations are not eligible to apply.

For this announcement, applicants may include collaborators or consultants from foreign institutions. All applicable federal laws and policies apply.

3. Additional Information on Eligibility

Applicants must be approved for funding under CDC Notice of Funding Opportunity RFA-DP-24-004 Health Promotion and Disease Prevention Research Centers in order to apply for SIP supplemental funding under this announcement. On the SIP applicant's SF424 (R&R), the institution's legal name, EIN, and UEI (sections 8a, b and c of SF424) must match the information of the institution selected for funding under RFA-DP-24-004 as listed in the Notice of Award. Special eligibility may apply to each SIP that will be listed in the NOFO.

The 20 institutions currently approved for funding under CDC RFA-DP-24-004 as CDC Prevention Research Centers (PRCs) are:

CDC Grant # PRC Recipient

U48 DP006809 Emory University

U48 DP006803 Georgia State University

U48 DP006785 Harvard School of Public Health

U48 DP006802 Morehouse School of Medicine

U48 DP006778 New York University School of Medicine

U48 DP006816 San Diego State University

U48 DP006799 University of Arizona

U48 DP006814 University of Arkansas for Medical Sciences

U48 DP006806 University of California, San Francisco

U48 DP006812 University of Iowa

U48 DP006808 University of Massachusetts Medical School Worcester

U48 DP006791 University of Michigan at Ann Arbor

U48 DP006787 University of Minnesota

U48 DP006807 University of North Carolina at Chapel Hill

U48 DP006801 University of Pennsylvania

U48 DP006792 University of Pittsburgh

U48 DP006779 University of Rochester

U48 DP006780 University of South Carolina at Columbia

U48 DP006789 University of Utah

U48 DP006793 University of Wisconsin-Madison

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

For an application to be considered it must be responsive to the information below:

- Submitted by an institution currently approved for funding as a CDC PRC under CDC RFA-DP-24-004.
- The institution name and EIN of the SIP applicant must match the information of the institution funded under RFA-DP-24-004 as listed in the Notice of Award, SF424 R&R, Section 8a. and b.
- The proposed budget does not exceed the budget ceiling amount for each SIP listed in Section VIII. Other Information - Special Interest Project Descriptions.
- Special eligibility requirement(s) may apply to each SIP as listed in **Section VIII. Other Information - Special Interest Project Descriptions** of the NOFO announcement.

If an application is incomplete or does not meet the responsiveness criteria in the special eligibility requirements listed in this section or in **Section VIII. Other Information - Special Interest Project Descriptions**, it will be deemed non-responsive and will not enter into the peer review process.

6. Required Registrations

Applicant organizations must complete the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. Applicants must have a valid Unique Entity Identifier (UEI) number in order to begin each of the following registrations.

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

(Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: NCAGE Tool / Products / NCS Help Center (nato.int).

System for Award Management (SAM) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, SAM.gov.

Grants.gov

eRA Commons

All applicant organizations must register with Grants.gov. Please visit www.Grants.gov at least 30 days prior to submitting your application to familiarize yourself with the registration and submission processes. The one-time registration process will take three to five days to complete.

However, it is best to start the registration process at least two weeks prior to application submission.

All Senior/Key Personnel (including Program Directors/Principal Investigators (PD/PIs) must also work with their institutional officials to register with the eRA Commons or ensure their existing Principal Investigator (PD/PI) eRA Commons account is affiliated with the eRA commons account of the applicant organization. All registrations must be successfully completed and active before the application due date. Applicant organizations are strongly encouraged to start the eRA Commons registration process at least four (4) weeks prior to the application due date. ASSIST requires that applicant users have an active eRA Commons account in order to prepare an application. It also requires that the applicant organization's Signing Official have an active eRA Commons Signing Official account in order to initiate the submission process. During the submission process, ASSIST will prompt the Signing Official to enter their Grants.gov Authorized Organizational Representative (AOR) credentials in order to complete the submission, therefore the applicant organization must ensure that their Grants.gov AOR credentials are active.

7. Universal Identifier Requirements and System for Award Management (SAM)

All applicant organizations **must obtain** a Unique Entity Identifier (UEI) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The UEI number is a twelve-digit number assigned by SAM.gov. An AOR should be consulted to determine the appropriate number. If the organization does not have a UEI number, an AOR should register through SAM.gov. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a UEI number.

Additionally, organizations must maintain the registration with current information at all times during which it has an application under consideration for funding by CDC and, if an award is made, until a final financial report is submitted or the final payment is received, whichever is later.

SAM.gov is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at SAM.gov and the SAM.gov Knowledge Base.

If an award is granted, the recipient organization **must** notify potential sub-recipients that no organization may receive a subaward under the grant unless the organization has provided its UEI number to the recipient organization.

8. Eligible Individuals (Project Director/Principal Investigator) in Organizations/Institutions

Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. CDC does not make awards to individuals directly. Individuals from organizations that are uniquely prepared to examine research relevant to undeserved groups, including sexual

orientation and gender identity minorities as well as individuals with disabilities are always encouraged to apply.

9. Cost Sharing

This NOFO does not require cost sharing as defined in the HHS Grants Policy Statement (http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

10. Number of Applications

As defined in the HHS Grants Policy Statement, (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf), applications received in response to the same Notice of Funding Opportunity generally are scored individually and then ranked with other applications under peer review in their order of relative programmatic, technical, or scientific merit. HHS/CDC will not accept any application in response to this NOFO that is essentially the same as one currently pending initial peer review unless the applicant withdraws the pending application.

Section IV. Application and Submission Information

1. Address to Request Application Package

Applicants will use a system or platform to submit their applications through Grants.gov and eRA Commons to CDC. ASSIST, an institutional system to system (S2S) solution, or Grants.gov Workspace are options. ASSIST is a commonly used platform because, unlike other platforms, it provides a validation of all requirements prior to submission and prevents errors.

To use ASSIST, applicants must visit https://public.era.nih.gov where you can login using your eRA Commons credentials, and enter the Notice of Funding Opportunity Number to initiate the application, and begin the application preparation process.

If you experience problems accessing or using ASSIST, you can refer to the ASSIST Online Help Site at: https://era.nih.gov/erahelp/assist. Additional support is available from the NIH eRA Service desk via: http://grants.nih.gov/support/index.html

- Email: commons@od.nih.gov
- Phone: 301-402-7469 or (toll-free) 1-866-504-9552.
  Hours: Monday - Friday, 7 a.m. to 8 p.m. Eastern Time, excluding Federal holidays.

2. Content and Form of Application Submission

Application guides for FORMS-H application packages are posted to the How to Apply - Application Guide page.

It is critical that applicants follow the instructions in the SF-424 (R&R) Application Guide How to Apply - Application Guide except where instructed in this Notice of Funding Opportunity to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review. The package associated with this NOFO includes all applicable mandatory and optional forms. Please note that some forms marked optional in the application package are

required for submission of applications for this NOFO. Follow the instructions in the SF-424 Application Guide to ensure you complete all appropriate "optional" components.

When using ASSIST, all mandatory forms will appear as separate tabs at the top of the Application Information screen; applicants may add optional forms available for the NOFO by selecting the Add Optional Form button in the left navigation panel.

3. Letter of Intent

Due Date for Letter Of Intent 02/05/2025

Although a letter of intent (LOI) 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 peer review.
By the date listed above and in Part 1. Overview Information, prospective applicants are asked to submit an LOI electronically that includes the following information:

- Name of Institution Submitting Application
- SIP number and title
- Descriptive title of proposed SIP
- Name, address, and telephone number of the Lead PD/PI for the SIP Application
- Participating institutions, if applicable
- Number and title of this notice of funding opportunity: RFA-DP-25-126: Health Promotion and Disease Prevention Research Centers -2025 Special Interest Projects (SIPS) Competitive Supplements

The LOI should be emailed to the CDC Scientific Program Official with subject line "NOFO # RFA-DP-25-126" and the SIP proposal number which applicant will apply (i.e., SIP 25-001).

Natalie Darling, MPH

Scientific Program Official Extramural Research Program Operations and Services (ERPOS)

Email: researchnofo@cdc.gov

4. Required and Optional Components

A complete application has many components, both required and optional. The forms package associated with this NOFO in Grants.gov includes all applicable components for this NOFO, required and optional. In ASSIST, all required and optional forms will appear as separate tabs at the top of the Application Information screen.

5. PHS 398 Research Plan Component

The SF424 (R&R) Application Guide includes instructions for applicants to complete a PHS 398 Research Plan that consists of components. Not all components of the Research Plan apply to all Notices of Funding Opportunities (NOFOs). Specifically, some of the following components are for Resubmissions or Revisions only. See the SF 424 (R&R) Application Guide at How to Apply

- Application Guide for additional information. Please attach applicable sections of the following Research Plan components as directed in Part 2, Section 1 (Notice of Funding Opportunity Description).

Follow the page limits stated in the SF 424 unless otherwise specified in the NOFO. As applicable to and specified in the NOFO, the application should include the bolded headers in this section and should address activities to be conducted over the course of the entire project, including but not limited to:

1. **Introduction to Application** (for Resubmission and Revision ONLY) - provide a clear description about the purpose of the proposed research and how it addresses the specific requirements of the NOFO.
2. **Specific Aims** – state the problem the proposed research addresses and how it will result in public health impact and improvements in population health.
3. **Research Strategy** – the research strategy should be organized under 3 headings: Significance, Innovation, and Approach. Describe the proposed research plan, including staffing and timeline.
4. **Progress Report Publication List** (for Continuation ONLY)

Other Research Plan Sections

5. **Vertebrate Animals**
6. **Select Agent Research**
7. **Multiple PD/PI Leadership Plan**
8. **Consortium/Contractual Arrangements**
9. **Letters of Support**
10. **Resource Sharing Plan(s)**
11. **Other Plan(s)**
12. **Authentication of Key Biological and/or Chemical Resources**
13. **Appendix**

All instructions in the SF424 (R&R) Application Guide at How to Apply - Application Guide must be followed along with any additional instructions provided in the NOFO.

Applicants that plan to collect public health data must submit a Data Management Plan (DMP) in the Other Plan(s) section of the PHS 398 Research Plan Component of the application. A DMP is required for each collection of public health data proposed. Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds.

The DMP may be outlined in a narrative format or as a checklist but, at a minimum, should include:

- A description of the data to be collected or generated in the proposed project;
- Standards to be used for the collected or generated data;
- Mechanisms for providing access to and sharing of the data (include a description of provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights - this section should address access to identifiable and de-identified data);

- A statement (required) of any limitations you may encounter with sharing data collected or generated under this award with CDC (such as legal, regulatory, policy, or technical concerns);
- Statement of the use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use; and
- Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified (this section should address archiving and preservation of identifiable and deidentified data).

The AR-25 outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation. https://www.cdc.gov/grants/additional-requirements/ar-25.html

CDC OMB approved templates may be used (e.g. NCCDPHP template https://www.cdc.gov/nccdphp/dch/media/files/Data-Management-Plan-template.docx

Other examples of DMPs may be found here: USGS, http://www.usgs.gov//products/data-and-tools/data-management/data-management-plans

Application guides for FORMS-H application packages are posted to the How to Apply - Application Guide page.

6. Appendix

Do not use the appendix to circumvent page limits. A maximum of 10 PDF documents are allowed in the appendix. Additionally, up to 3 publications may be included that are not publicly available. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

7. Page Limitations

All page limitations described in this individual NOFO must be followed. For this specific NOFO, the Research Strategy component of the Research Plan narrative is limited to 18 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 30 pages for all appendices. Pages that exceed page limits described in this NOFO will be removed and not forwarded for peer review, potentially affecting an application's score.

8. Format for Attachments

Designed to maximize system-conducted validations, multiple separate attachments are required for a complete application. When the application is received by the agency, all submitted forms and all separate attachments are combined into a single document that is used by peer reviewers and agency staff. Applicants should ensure that all attachments are uploaded to the system.

CDC requires all text attachments to the Adobe application forms be submitted as PDFs and that all text attachments conform to the agency-specific formatting requirements noted in the SF424 (R&R) Application Guide at .How to Apply - Application Guide.

Application guides for FORMS-H application packages are posted to the How to Apply - Application Guide page.

9. Submission Dates & Times

Part I. Overview Information contains information about Key Dates. Applicants are strongly encouraged to allocate additional time and submit in advance of the deadline to ensure they have time to make any corrections that might be necessary for successful submission. This includes the time necessary to complete the application resubmission process that may be necessary, if errors are identified during validation by Grants.gov and the NIH eRA systems. The application package is not complete until it has passed the Grants.gov and NIH eRA Commons submission and validation processes. Applicants will use a platform or system to submit applications.

ASSIST is a commonly used platform because it provides a validation of all requirements prior to submission. If ASSIST detects errors, then the applicant must correct errors before their application can be submitted. Applicants should view their applications in ASSIST after submission to ensure accurate and successful submission through Grants.gov. If the submission is not successful and post-submission errors are found, then those errors must be corrected and the application must be resubmitted in ASSIST.

Applicants are able to access, view, and track the status of their applications in the eRA Commons.

Information on the submission process is provided in the SF-424 (R&R) Application Guidance and ASSIST User Guide at https://era.nih.gov/files/ASSIST_user_guide.pdf.

Note: HHS/CDC grant submission procedures do not provide a grace period beyond the grant application due date time to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e., error correction window).

Applicants who encounter problems when submitting their applications must attempt to resolve them by contacting the NIH eRA Service desk at:
Toll-free: 1-866-504-9552; Phone: 301-402-7469
http://grants.nih.gov/support/index.html
Hours: Mon-Fri, 7 a.m. to 8 p.m. Eastern Time (closed on Federal holidays)

Problems with Grants.gov can be resolved by contacting the Grants.gov Contact Center at:
Toll-free: 1-800-518-4726
https://www.grants.gov/support
support@grants.gov
Hours: 24 hours a day, 7 days a week; closed on Federal holidays

It is important that applicants complete the application submission process well in advance of the due date time.

After submission of your application package, applicants will receive a "submission receipt" email generated by Grants.gov. Grants.gov will then generate a second e-mail

message to applicants which will either validate or reject their submitted application package. A third and final e-mail message is generated once the applicant's application package has passed validation and the grantor agency has confirmed receipt of the application.

Unsuccessful Submissions: If an application submission was unsuccessful, the **applicant** must:

1. Track submission and verify the submission status (tracking should be done initially regardless of rejection or success).

    a. If the status states "rejected," be sure to save time stamped, documented rejection notices, and do #2a or #2b

2. Check emails from both Grants.gov and NIH eRA Commons for rejection notices.

    a. If the deadline has passed, he/she should email the Grants Management contact listed in the Agency Contacts section of this announcement explaining why the submission failed.

    b. If there is time before the deadline, correct the problem(s) and resubmit as soon as possible.

Due Date for Applications 02/28/2025

Electronically submitted applications must be submitted no later than 11:59 p.m., ET, on the listed application due date.

10. Funding Restrictions

Expanded Authority:

For more information on expanded authority and pre-award costs, go to https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf and speak to your GMS.

All HHS/CDC awards are subject to the federal regulations, in 45 CFR Part 75, terms and conditions, and other requirements described in the HHS Grants Policy Statement. Pre-award costs may be allowable as an expanded authority, but only if authorized by CDC.

Public Health Data:

CDC requires that mechanisms for, and cost of, public health data sharing be included in grants, cooperative agreements, and contracts. The cost of sharing or archiving public health data may also be included as part of the total budget requested for first-time or continuation awards.

Data Management Plan:

Fulfilling the data-sharing requirement must be documented in a Data Management Plan (DMP) that is developed during the project planning phase prior to the initiation of generating or collecting public health data and must be included in the Other Plan(s) section of the PHS 398 Research Plan Component of the application.

Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds (for example, but not limited to, any statutory limitations prohibiting data sharing, privacy and confidentiality considerations, embargo issues).

Applications submitted without the required DMP may be deemed ineligible for award unless submission of DMP is deferred to a later period depending on the type of award, in which case, funding restrictions may be imposed pending submission and evaluation.

Recipients who fail to release public health data in a timely fashion will be subject to procedures normally used to address lack of compliance (for example, reduction in funding, restriction of funds, or award termination) consistent with 45 CFR 74.62 or other authorities as appropriate. For further information, please see: https://www.cdc.gov/grants/additional-requirements/ar-25.html

Human Subjects:

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 the proposed research project involves more than one institution and will be conducted in the United States, awardees are expected to use a single Institutional Review Board (sIRB) to conduct the ethical review required by HHS regulations for the Protections of Human Subjects Research, and include a single IRB plan in the application, unless review by a sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy or a compelling justification based on ethical or human subjects protection issues or other well-justified reasons is provided. Exceptions will be reviewed and approved by CDC in accordance with Department of Health and Human Services (DHHS) Regulations (45 CFR Part 46), or a restriction may be placed on the award. For more information, please contact the scientific/research contact included on this NOFO.

Note: The sIRB requirement applies to participating sites in the United States. Foreign sites participating in CDC-funded, cooperative research studies are not expected to follow the requirement for sIRB.

11. Intergovernmental Review

This NOFO is not subject to executive order 12372, Intergovernmental Review of Federal Programs. No action is needed.

12. Other Submission Requirements and Information

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 under "Other Attachment Forms." The document should be labeled: "Report on Programmatic, Budgetary, and Commitment Overlap."

Application Submission

Applications must be submitted electronically following the instructions described in the SF 424 (R&R) Application Guide. **PAPER APPLICATIONS WILL NOT BE ACCEPTED.**

Applicants must complete all required registrations before the application due date. Section III.6 "Required Registrations" contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically (http://grants.nih.gov/grants/guide /url_ redirect.htm? id=11144).

Important reminders:
All Senior/Key Personnel (including any Program Directors/Principal Investigators (PD/PIs) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF 424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to CDC.

It is also important to note that for multi-project applications, this requirement also applies to the individual components of the application and not to just the Overall component.

The applicant organization must ensure that the UEI number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management (SAM). Additional information may be found in the SF424 (R&R) Application Guide.

If the applicant has an FWA number, enter the 8-digit number. Do not enter the letters "FWA" before the number. If a Project/Performance Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the Project/Performance Site operates under and appropriate Federal Wide Assurance for the protection of human subjects and complies with 45 CFR Part 46 and other CDC human

subject related policies described in Part II of the SF 424 (R&R) Application Guide and in the HHS Grants Policy Statement.

See more resources to avoid common errors and submitting, tracking, and viewing applications:

- http://grants.nih.gov/grants/ElectronicReceipt/avoiding_errors.htm
- http://grants.nih.gov/grants/ElectronicReceipt/submit_app.htm
- https://era.nih.gov/files/ASSIST_user_guide.pdf
- http://era.nih.gov/erahelp/ASSIST/

Upon receipt, applications will be evaluated for completeness by the CDC Office of Grants Services (OGS) and responsiveness by OGS and the Center, Institute or Office of the CDC. Applications that are incomplete and/or nonresponsive will not be reviewed.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the CDC mission (https://www.cdc.gov/about/divisions-offices/index.html), all applications submitted to the CDC in support of public health research are evaluated for scientific and technical merit through the CDC peer review system.

Overall Impact
Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria
Reviewers will consider each of the review criteria below in the determination of scientific merit and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

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 public health be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s)
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?

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?

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 research project is in the early stages of development, will the strategy establish feasibility, and will particularly risky aspects be managed?

If the project involves human subjects and/or 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?

If applicable, how will populations with health disparities be considered and addressed in the design and implementation of the proposed research activities?

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?

To what extent will findings be disseminated to communities and populations of focus in an appropriate and accessible manner?

2. 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, but *will not give separate scores* for these items.

Protections for Human Subjects
If the research involves human subjects but does not involve one of the six 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 six 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 review of the Human Subjects section, please refer to the HHS/CDC Requirements under AR-1 Human Subjects Requirements (https://www.cdc.gov/grants/additional-requirements/ar-1.html).

Inclusion of Women, Minorities, and Children
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. 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/women/research/index.htm) 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/VAChecklist.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/Pages/companion-guide.aspx.

3. Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact/priority score.

Sub-awards and Community Involvement
Reviewers will consider an applicant's proposed plan to competitively award subcontracts. An

open process is available to all qualified entities including nonprofit organizations, small businesses, and for-profit organizations. Community-based collaborative efforts relevant to the SIPs objective and public health priorities may also be involved.

Applications from Foreign Organizations
N/A

Resource Sharing Plan(s)
Reviewers will comment on whether the Resource Sharing Plan(s) (e.g. Sharing Model Organisms) or the rationale for not sharing the resources, is reasonable.

Budget and Period of Support
Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research. The applicant can obtain budget preparation guidance for completing a detailed justified budget on the CDC website, at the following Internet address: https://www.cdc.gov/grants/applying/application-resources.html. Following this guidance will also facilitate the review and approval of the budget request of applications selected for award.

The budget can include both direct costs and indirect costs as allowed.

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 modified total direct costs 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.

Indirect costs on training grants are limited to a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and sub-awards in excess of $25,000.

If requesting indirect costs in the budget based on a federally negotiated rate, a copy of the indirect cost rate agreement is required. Include a copy of the current negotiated federal indirect cost rate agreement or cost allocation plan approval letter.

4. Review and Selection Process

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

- Will undergo a selection process in which all responsive applications will be discussed and assigned an overall impact/priority score.
- Will receive a written critique.

Applications will be assigned to the appropriate HHS/CDC Center, Institute, or Office. Applications will compete for available funds with all other recommended applications submitted in response to this NOFO. Following initial peer review, recommended applications will receive a second level of review. The following will be considered in making funding recommendations:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

Specific funding preferences are listed for each SIP proposal (see **Section VIII. Other Information - Special Interest Project Descriptions**) in this announcement.

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 with 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 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 review of risk may impact award eligibility.

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 45 CFR Part 75, subpart F, 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. Additionally, we may ask for additional information prior to the award based on the results of this risk review.

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.

5. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) and other pertinent information via the eRA Commons.

Section VI. Award Administration Information

1. Award Notices

Any applications awarded in response to this NOFO will be subject to the UEI, SAM Registration, and Transparency Act requirements. If the application is under consideration for funding, HHS/CDC will request "just-in-time" information from the applicant as described in the HHS Grants Policy Statement (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

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

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the Grants Management Officer is the authorizing document and will be sent via email to the recipient's business official.

Recipient must comply with any funding restrictions as described in Section IV.11. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be allowable as an expanded authority, but only if authorized by CDC.

2. CDC Administrative Requirements

Overview of Terms and Conditions of Award and Requirements for Specific Types of Grants. See CDC General Terms and Conditions.

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

Generally applicable ARs:

AR-1: Human Subjects Requirements

AR-2: Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research

AR-9: Paperwork Reduction Act Requirements

AR-10: Smoke-Free Workplace Requirements

AR-11: Healthy People 2030

AR-12: Lobbying Restrictions

AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities

AR-14: Accounting System Requirements

AR-16: Security Clearance Requirement

AR-22: Research Integrity

AR-24: Health Insurance Portability and Accountability Act Requirements

AR-25: Data Management and Access

AR-26: National Historic Preservation Act of 1966

AR-28: Inclusion of Persons Under the Age of 21 in Research

AR-29: Compliance with EO13513, "Federal Leadership on Reducing Text Messaging while Driving", October 1, 2009

AR-30: Information Letter 10-006, - Compliance with Section 508 of the Rehabilitation Act of 1973

AR-31: Research Definition

AR-32: Appropriations Act, General Provisions

AR-33: United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern

AR-37: Prohibition on certain telecommunications and video surveillance services or equipment for all awards issued on or after August 13, 2020

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

3. Additional Policy Requirements

The following are additional policy requirements relevant to this NOFO:

HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items and Printing Publications: This policy supports the Executive Order on Promoting Efficient Spending (EO 13589), the Executive Order on Delivering and Efficient, Effective, and Accountable Government (EO 13576) and the Office of Management and Budget Memorandum on Eliminating Excess Conference Spending and Promoting Efficiency in Government (M-35-11). This policy applies to all new obligations and all funds appropriated by Congress. For more information, visit the HHS website at:

https://www.hhs.gov/grants/contracts/contract-policies-regulations/efficient-spending/index.html.

Federal Funding Accountability and Transparency Act of 2006: 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 grants, contracts, loans and other assistance and payments through a single, publicly accessible website, www.usaspending.gov. For the full text of the requirements, please review the following website: https://www.fsrs.gov/.

Plain Writing Act: The Plain Writing Act of 2010, Public Law 111-274, was signed into law on October 13, 2010. The law requires that federal agencies use "clear Government communication that the public can understand and use" and requires the federal government to write all new publications, forms, and publicly distributed documents in a "clear, concise, well-organized" manner. For more information on this law, go to: https://www.plainlanguage.gov/.

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

Copyright Interests Provision: This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. Applicants may include reasonable publication costs and costs associated with submission, curation, management of data, and special handling instructions as allowable expenses in all research budgets. 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 without any embargo or delay after publication. Also at the time of submission, Recipient and/or Recipient's submitting author must also post the manuscript through PMC without any embargo or delay after publication. 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.

Language Access for Persons with Limited English Proficiency: Recipients of federal financial assistance from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. Recipients of federal financial assistance must take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency.

Dual Use Research of Concern: On September 24, 2014, the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern was released. Recipients (foreign and domestic) receiving CDC funding on or after September 24, 2015, are subject to this policy. Research funded by CDC, involving the agents or toxins named in the policy, must be reviewed to determine if it involves one or more of the listed experimental effects and if so, whether it meets the definition of DURC. This review must be completed by an Institutional Review Entity (IRE) identified by the funded institution.

Recipients also must establish an Institutional Contact for Dual Use Research (ICDUR). The award recipient must maintain records of institutional DURC reviews and completed risk mitigation plans for the term of the research grant, cooperative agreement or contract plus three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation.

If a project is determined to be DURC, a risk/benefit analysis must be completed. CDC will work collaboratively with the award recipient to develop a risk mitigation plan that the CDC must approve. The USG policy can be found at http://www.phe.gov/s3/dualuse.

Non-compliance with this Policy may result in suspension, limitation, restriction or termination of 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.

Data Management Plan(s): CDC requires that all new collections of public health data include a Data Management Plan (DMP). For purposes of this announcement, "public health data" means digitally recorded factual material commonly accepted in the scientific community as a basis for public health findings, conclusions, and implementation.

This requirement ensures that CDC is in compliance with the following; Office of Management and Budget (OMB) memorandum titled "Open Data Policy–Managing Information as an Asset" (OMB M-13-13); Executive Order 13642 titled "Making Open and Machine Readable the New Default for Government Information"; and the Office of Science and Technology Policy (OSTP) memorandum titled "Increasing Access to the Results of Federally Funded Scientific Research" (OSTP Memo).

The AR-25 https://www.cdc.gov/grants/additional-requirements/ar-25.html outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.

Certificates of Confidentiality: Institutions and investigators are responsible for determining whether research they conduct is subject to Section 301(d) of the Public Health Service (PHS) Act. Section 301(d), as amended by Section 2012 of the 21st Century Cures Act, P.L. 114-255 (42 U.S.C. 241(d)), states that the Secretary shall issue Certificates of Confidentiality (Certificates) to persons engaged in biomedical, behavioral, clinical, or other research activities in which identifiable, sensitive information is collected. In furtherance of this provision, CDC-supported research commenced or ongoing after December 13, 2016 in which identifiable, sensitive information is collected, as defined by Section 301(d), is deemed issued a Certificate and therefore required to protect the privacy of individuals who are subjects of such research. Certificates issued in this manner will not be issued as a separate document, but are issued by application of this term and condition to this award. See Additional Requirement 36 to ensure compliance with this term and condition. The link to the full text is at: https://www.cdc.gov/grants/additional-requirements/ar-36.html.

4. Cooperative Agreement Terms and Conditions

CDC staff will serve as consultants on this project, and will provide technical assistance, as requested, on project activities such as evaluation design, data collection and analysis, and data interpretation and dissemination of results. CDC staff may be co-authors on manuscripts. However, CDC staff will not have contact with human subjects or data collected from human subjects.

The PD(s)/PI(s) will have the following responsibility:

- The SIP PI/PD may be anyone that meets the qualifications from within the selected recipient PRC institution (RFA-DP-24-004).
- The PI/PD named on RFA-DP-24-004 Notice of Award MUST be included as a Co-PI on the SIP, if not already proposed as the SIP PI/PD.
- Additional SIP PIs/PDs are permitted but must be referred to as SIP Co-PIs/PD.
- Obtaining appropriate Institutional Review Board approvals for research involving human subjects for all participating institutions.
- Adhering to the rights and responsibilities of the PD/PI as described in each SIP description under Section VIII, Award Administration, of this NOFO
- Coordinating all CDC-required reporting submissions and prior approval requests with the PRC PI.
- Participating in the PRC Network as applicable.

HHS/CDC Responsibilities:

- CDC staff have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described in each Special Interest Project description contained in Section VIII, Award Administration, of this NOFO
- Additional responsibilities include:

- Assisting the PI, as needed, in complying with the Investigator responsibilities described in the Policy on Public Health Research and Non-research Data Management and Access

SIP Sponsor (Project Scientist) will:

- Be identified as the CDC Project Scientist
- Provide technical assistance and consultation on research design and methodology, program implementation, measurement selection, dissemination of study findings, and translation of project
- Monitor progress of the approved project objectives
- Promote dissemination of promising practices, programs, interventions, and other results from the research in collaboration with the PRC Program

PRC Program Project Officer (PO) will:

- Be named in the Notice of Award as the Project Officer
- Provide administrative and technical assistance to the CDC SIP sponsors and award recipient
- Make recommendations on requests for changes in scope, objectives, and/or budgets that deviate from the approved peer-reviewed application
- Assist SIP Project Scientist with monitoring performance against approved project objectives
- Promote dissemination of promising practices, programs, interventions, and other results from the research in collaboration with the SIP Sponsor

ERPOS Scientific Program Official (SPO) will:

- Be named in the Notice of Award as the Scientific Program Official
- Provide normal overall scientific oversight and assure overall scientific and programmatic stewardship of the award
- Collaborate with the PRC Program to monitor performance against approved project objectives
- Ensure assessment of the public health impact of the research conducted under this NOFO

5. Reporting

Recipients will be required to complete Research Performance Progress Report (RPPR) in eRA Commons at least annually (see https://grants.nih.gov/grants/rppr/index.htm; https://grants.nih.gov/grants/forms/report_on_grant.htm) and financial statements as required in the HHS Grants Policy Statement.

A final progress report, invention statement, equipment inventory list and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the HHS Grants Policy Statement.

Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity depend upon the availability of funds, 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 Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later.

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 recipients:
1) Information on executive compensation when not already reported through the SAM Registration; and
2) Similar information on all sub-awards/ subcontracts/ consortiums over $25,000. It is a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipients of applicable CDC grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over $25,000. See the HHS Grants Policy Statement (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

A. Submission of Reports

The Recipient Organization must submit:

Annual Performance Report (APR)/RPPR is due 120 days before the end of the current budget period, or the date identified in the guidance that CDC distributes. The RPPR form (https://grants.nih.gov/grants/rppr/index.htm; https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf) is to be completed on the eRA Commons website. The progress report will serve as the non-competing continuation application. Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds, 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.

Annual Federal Financial Report (FFR) SF-425 (Reporting | Grants | CDC) is required and must be submitted to the Payment Management System accessed through the FFR navigation link in eRA Commons or directly through PMS **within 90 days after the budget period ends.**

Closeout Reports: a final progress report, invention statement, equipment/inventory report, and the **Final FFR (SF-425)** are required **120 days after the end of the period of performance.**

B. Content of Reports

1. Annual Performance Report (APR)/RPPR: The recipient's continuation application/progress report should include:

- Description of Progress during Annual Budget Period: Current Budget Period Progress reported on the RPPR form in eRA Commons (https://grants.nih.gov/grants/rppr/index.htm). Detailed narrative report for the current budget period that directly addresses progress towards the Measures of Effectiveness included in the current budget period proposal.
- Research Aims: list each research aim/project

  a) Research Aim/Project: purpose, status (met, ongoing, and unmet), challenges, successes, and lessons learned

  b) Leadership/Partnership: list project collaborations and describe the role of external partners.

- Translation of Research (1 page maximum). When relevant to the goals of the research project, the PI should describe how the significant findings may be used to promote, enhance, or advance translation of the research into practice or may be used to inform public health policy. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers, and other potential users. The PI should identify the research findings that were translated into public health policy or practice and how the findings have been or may be adopted in public health settings. Or, if they cannot be applied yet, this section should address which research findings may be translated, how these findings can guide future research or related activities, and recommendations for translation. If relevant, describe how the results of this project could be generalized to populations and communities outside of the study. Questions to consider in preparing this section include:

- How will the scientific findings be translated into public health practice or inform public health policy?
- How will the project improve or effect the translation of research findings into public health practice or inform policy?
- How will the research findings help promote or accelerate the dissemination, implementation, or diffusion of improvements in public health programs or practices?
- How will the findings advance or guide future research efforts or related activities?

- Public Health Relevance and Impact (1 page maximum). This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project relate beyond the immediate study to improved practices, prevention or intervention techniques, inform policy, or use of technology in public health. Questions to consider in preparing this section include:
- How will this project lead to improvements in public health?
- How will the findings, results, or recommendations been used to influence practices, procedures, methodologies, etc.?

- How will the findings, results, or recommendations contribute to documented or projected reductions in morbidity, mortality, injury, disability, or disease?

- Current Budget Period Financial Progress: Status of obligation of current budget period funds and an estimate of unobligated funds projected provided on an estimated FFR.

- New Budget Period Proposal:
- Detailed operational plan for continuing activities in the upcoming budget period, including updated Measures of Effectiveness for evaluating progress during the upcoming budget period. Report listed by Research Aim/Project.
- Project Timeline: Include planned milestones for the upcoming year (be specific and provide deadlines).

- New Budget Period Budget: Detailed line-item budget and budget justification for the new budget period. Use the CDC budget guideline format.

- Publications/Presentations: Include publications/presentations resulting from this CDC grant only during this budget period. If no publication or presentations have been made at this stage in the project, simply indicate "Not applicable: No publications or presentations have been made."

- IRB Approval Certification: Include all current IRB approvals to avoid a funding restriction on your award. If the research does not involve human subjects, then please state so. Please provide a copy of the most recent local IRB and CDC IRB, if applicable. If any approval is still pending at time of APR due date, indicate the status in your narrative.

- Update of Data Management Plan: The DMP is considered a living document that will require updates throughout the lifecycle of the project. Investigators should include any updates to the project's data collection such as changes to initial data collection plan, challenges with data collection, and recent data collected. Applicants should update their DMP to reflect progress or issues with planned data collection and submit as required for each reporting period.

- Additional Reporting Requirements:

1. **Yearly Non-Competing Grant Progress Report**

- Dissemination of research results refers to sharing information with practice, academic, and community audiences
- Translation of Research findings refers to implementation of research or scientific findings into public health programs or practice
- New Budget Period Proposal: Detailed Operational Plan refers to the Annual Action Plan. Refer to Section VIII. Special Interest Project Descriptions, Annual Action Plan, for additional information
- Publications/Presentations/Tools/Other Products:

- Include peer-reviewed publications and presentations, evaluated research and practice tools, and other products from the SIP, along with other publications and presentations resulting from this award during the budget period

- **Final Reports**
    - Dissemination of research results refers to sharing information with practice, academic, and community audiences
    - Translation of Research findings refers to implementation of research or scientific findings into public health programs or practice
    - Publications/Presentations/Tools/Other Products:
        - Include peer-reviewed publications and presentations, evaluated research and practice tools, and other products from the SIP, along with other publications and presentations resulting from this award during the budget period

- Additional Reporting Requirements
    - Refer to Section VIII. Special Interest Project Descriptions, Project Activities and Submission Requirements for additional information
    - SIP recipients may be asked to participate in the CDC Award Management Platform (AMP) to collect data that are used to evaluate Special Interest Projects, or other CDC-led program evaluation data collection activities/systems

- Annual Federal Financial Report (FFR)
    - FFRs should report separate un-obligated balances for each PRC award and SIP award(s)

2. Annual Federal Financial Reporting The Annual Federal Financial Report (FFR) SF-425 is required and must be submitted through the Payment Management System (PMS) within 90 days after the end of the budget period. The FFR should only include those funds authorized and disbursed during the timeframe covered by the report. The Final FFR (SF-425) 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 in a timely manner may adversely affect the future funding of this project. If the information cannot be provided by the due date, you are required to submit a letter explaining the reason and date by which the Grants Officer will receive the information.

Additional resources on the Payment Management System (PMS) can be found at https://pms.psc.gov.

Recipients must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, recipients must submit a Final FFR (SF-425), final progress report, and Final Invention Statement and Certification

within 120 days after the end of the period of performance. Failure to submit timely and accurate final reports may affect future funding to the organization or awards under the direction of the same Project Director/Principal Investigator (PD/PI).

Organizations may verify their current registration status by running the "List of Commons Registered Organizations" query found at: https://era.nih.gov/registration_accounts.cfm. Organizations not yet registered can go to https://commons.era.nih.gov/commons/ for instructions. It generally takes several days to complete this registration process. This registration is independent of Grants.gov and may be done at any time.

The individual designated as the PI on the application must also be registered in the Commons. The PI must hold a PI account and be affiliated with the applicant organization. This registration must be done by an organizational official or their delegate who is already registered in the Commons. To register PIs in the Commons, refer to the eRA Commons User Guide found at: https://era.nih.gov/docs/Commons_UserGuide.pdf.

3. Final Reports: Final reports should provide sufficient detail for CDC to determine if the stated outcomes for the funded research have been achieved and if the research findings resulted in public health impact based on the investment. The recipient's final report should include:

Research Aim/Project Overview: The PI should describe the purpose and approach to the project, including the outcomes, methodology and related analyses. Include a discussion of the challenges, successes and lessons learned. Describe the collaborations/partnerships and the role of each external partner.

Translation of Research Findings: The PI should describe how the findings will be translated and how they will be used to inform policy or promote, enhance or advance the impact on public health practice. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers and other potential end users. The PI should also provide a discussion of any research findings that informed policy or practice during the course of the Period of Performance. If applicable, describe how the findings could be generalized and scaled to populations and communities outside of the funded project.

Public Health Relevance and Impact: This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project related beyond the immediate study to improved practices, prevention or intervention techniques, or informed policy, technology or systems improvements in public health.

Publications; Presentations; Media Coverage: Include information regarding all publications, presentations or media coverage resulting from this CDC-funded activity. Please include any additional dissemination efforts that did or will result from the project.

Final Data Management Plan: Applicants must include an updated final Data Management Plan that describes the data collected, the location of where the data is stored (example: a repository), accessibility restrictions (if applicable), and the plans for long term preservation of the data.

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.

7. 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.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

Grants.gov Customer Support (Questions regarding Grants.gov registration and submission, downloading or navigating forms)
Contact Center Phone: 800-518-4726
https://www.grants.gov/support
Email: support@grants.gov
Hours: 24 hours a day, 7 days a week; closed on Federal holidays

eRA Commons Help Desk (Questions regarding eRA Commons registration, tracking application status, post submission issues, FFR submission)
Phone: 301-402-7469 or 866-504-9552 (Toll Free)
TTY: 301-451-5939
https://www.era.nih.gov/need-help
Email: commons@od.nih.gov
Hours: Monday - Friday, 7am - 8pm U.S. Eastern Time; closed on Federal holidays

Note: Include NOFO number (RFA-DP25-126) in the email subject line when submitting questions.

Scientific Research Contact:

Natalie J. Darling MPH

Scientific Program Official Extramural Research Program Operations and Services

Centers for Disease Control and Prevention

4770 Buford Highway, NE Mailstop F-80 Atlanta, GA 30341

770-488-5740

Email: researchnofo@cdc.gov

Peer Review Contact

Catherine (Katie) Barrett, PhD

Scientific Review Official Extramural Research Program Operations and Services (ERPOS),

National Center for Chronic Disease Prevention and Health Promotion & National Center on Birth Defects and Developmental Disabilities Centers for Disease Control and Prevention

Email: ohi6@cdc.gov |

Financial/Grants Management Contact

Ahmad Chabkoun

Grants Management Specialist

Office of Grants Services (OGS)

Office of Financial Resources (OFR)

Centers for Disease Control and Prevention

Email: jwg6@cdc.gov | Telephone: 404.498.4164

Section VIII. Other Information

Other CDC Notices of Funding Opportunities can be found at www.grants.gov.

All awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement.

Authority and Regulations

Awards are made under the authorization of Sections of the Public Health Service Act as amended and under the Code of Federal Regulations.

The activities of this NOFO are supported under Section 1706 of the Public Health Service Act, as amended (42 USC 300u-5). The eligible applicants (academic research centers) are further defined in Section 799B of the Public Health Service Act (42 USC 295p).

SPECIAL INTEREST PROJECT DESCRIPTION

Project Title

SIP25-001 Validating survey questions on prostate cancer screening including PSA testing and shared decision-making

Project Description

Several major professional societies including the United States Preventive Services Task Force (USPSTF) have issued prostate cancer screening recommendations which influence prostate cancer screening practices in clinical medicine (1-4). Survey-based questionnaires such as the National Health Interview Survey (NHIS) and the Behavioral Risk Factor Surveillance System (BRFSS) have been used to measure patient-reported receipt of prostate cancer screening (5-8). Although cognitive testing has been completed, the questions in these surveys have not been validated compared to a clinical gold standard (e.g. medical record review), such as if and when the patient received a prostate-specific antigen (PSA) test. For other cancer types, the concordance between self-report and electronic medical record verification varied widely depending on the cancer type (9). Therefore, it is difficult to determine the accuracy of survey results, such as the occurrence and timing of receiving a PSA test.

The primary purpose of this project is to provide a critical assessment of prostate cancer screening survey questions (e.g. questions asking about PSA-based screening) in NHIS and BRFSS and validate questions to most accurately assess if the US public is receiving prostate cancer screening services. For this primary purpose, the recipient will evaluate current survey questions on prostate cancer screening in NHIS and BRFSS, and (if these current questions are not sufficiently valid) modify existing questions or develop new questions, and then validate the modified or new questions. As part of this process, the recipient may need to identify a gold standard using real patient data, and use this standard to assess the validity and reliability of the current or proposed questions. The secondary purpose is to develop and validate questions related to shared decision-making (SDM) in the context of prostate cancer screening; this may include adopting and validating past survey questions related to SDM and prostate cancer screening. Because USPSTF and other professional organizations recommend SDM related to prostate cancer screening, assessing receipt of SDM is helpful in understanding if patients are receiving recommended cancer screening services. The recipient will then disseminate findings to make results available internally and to the public. Validated survey items can be used by CDC and the research community to better understand the prevalence of screening, impact of changing prostate cancer screening recommendations, occurrence of SDM, and disparities in screening. Validated survey items will help measure inequities in screening and inform efforts to improve disparities.

Project Objectives and Outcomes

Objectives: 1) To evaluate (validate) existing NHIS and BRFSS prostate cancer screening questions (such as receipt and timing of PSA-based testing). 2) If the current questions are not valid, propose and evaluate modified or new questions on prostate cancer screening. 3) Propose and evaluate survey questions assessing the receipt of SDM for prostate cancer screening; past survey questions assessing SDM may be utilized for this objective. Validating question should verify the accuracy of respondent understanding to questions and the accuracy of responses by using a clinical gold standard (e.g. electronic health record review).

Outcomes: A completed summary of findings from validation assessments of current and past BRFSS and NHIS prostate cancer screening survey items. A completed summary of new or modified BRFSS or NHIS validated measures for patient self-report prostate cancer screening survey items.

Healthy People 2030 Objectives
Reduce the prostate cancer death rate — C 08
Increase the proportion of adults who get recommended evidence-based preventive health care — AHS 08

Project Activities and Submission Requirements
Applications submitted in response to this SIP should present a **Research Plan** that addresses the following requirements listed below:

- Assess past research of peer-reviewed studies using NHIS and BRFSS prostate cancer screening questions (which would focus on studies evaluating the questions themselves but would also include studies using NHIS and BRFSS prostate cancer screening questions) and summarize current NHIS and BRFSS questions.
  Confirm or modify the wording of past questions and/or develop new questions for future survey-based questionnaires.
- Identify a clinical gold standard to validate prostate cancer screening questions.
- Perform cognitive (or related) testing on any substantially revised questions and on new proposed questions
- Validate patient responses to the new set of survey questions focusing on 1) PSA testing and 2) the occurrence of SDM for prostate cancer screening.
- Submit a report of findings.
- Propose recommendations for validated questions to include in future survey-based questionnaires. Identify 2-4 questions for each topic for surveys where only a small number of questions are possible.
- Disseminate results to CDC, NCI, and external audiences through various channels such as published reports or presentations

Study design and methods
Suggestions of methodology include evaluation of medical charts that would confirm patient receipt of a PSA test, review of electronic health records, review of electronic health record notes that detail the occurrence of SDM, observed interviews (might be more relevant to SDM), semi-structured interviews with patients or providers (might be more relevant to SDM), or another

validation standard chosen by the recipient (9-12).

Population of Focus
Population of focus includes individuals eligible for prostate cancer screening based on current recommendations. This includes individuals stated to be at high risk for prostate cancer (Black individuals and individuals with a family history of prostate cancer, according to the current USPSTF prostate cancer screening recommendations). By including Black individuals and individuals with a family history of prostate cancer, the project would be able to address populations at higher need of preventative health services related to prostate cancer (compared to an average risk population).

Collaboration/Partnerships
The recipient would need to partner with organizations who could help recruit subjects. This may include patients and health care organizations that can inform the study as well as help with recruitment.

Partnership with the CDC and National Cancer Institute (NCI) teams who manage the BRFSS and NHIS surveys is encouraged.

Recruitment Plan
The recruitment plan should describe sample size calculations, and how patients who are eligible for prostate cancer screening will be recruited.

Annual Action Plan
Provide a 12-month action plan using SMART goals and objectives to include a progressive timeline for completion of activities.

Evaluation Plan/Performance measurement
Applicants must provide an evaluation and performance measurement plan that demonstrates how the recipient will fulfill the requirements described. The evaluation plan must meet SMART goals and be consistent with the CDC evaluation framework (https://www.cdc.gov/evaluation/). A plan to evaluate data gathered as part of the research plan should be included.

Data Management Plan
If the applicant is collecting public health data, a standalone data management plan that addresses the 5 elements of AR-25 must be submitted the Other Plan(s) section of the application.
https://www.cdc.gov/grants/additional-requirements/ar-25.html

Dissemination & Translation Plan
Provide a dissemination plan that summarizes findings and provides recommendations of future directions of questions assessing prostate cancer screening. Dissemination in encouraged to include communication with CDC/NCI and publication of findings in peer-reviewed

publications. Audiences that should be reached include the public, patients, medical practitioners, policy makers, and public health researchers.

Public Health Impact
This project fills an evidence gap related to survey questions that address prostate cancer screening and SDM. Results will provide evidence of the strengths and limitations of currently available survey items on prostate cancer screening and SDM and guide future data collection on these topics. Having validated questions about prostate cancer screening can help surveys serve as important tools for monitoring impact of these changing recommendations on prostate screening trends. If new questions are proposed that replace recent questions, it will impact the ability of these surveys to monitor trends. However, if the project concludes that the older questions were not reliable, then new questions might be preferred. Alternatively, if the project concludes that these self-report questions are not valid or reliable for this purpose, then the impact of the study might be to deprioritize or discontinue these types of questions on the prostate cancer topics within NHIS and BRFSS.

Special Eligibility and Responsiveness
The following criteria specific to this SIP will be used to determine the institution's eligibility and responsiveness:

Special Eligibility Requirement: Access to the proposed study population(s); males of any age eligible for prostate cancer screening based on current recommendations.

Responsive Criteria:

The applicant must provide documentation, e.g., a letter of support or memorandum of agreement, demonstrating evidence of access to the study population and assuring access to the populations in which the study will be conducted.

Additional Review Criteria
In addition to the standard review criteria (Significance, Approach, Innovation, Investigators, and Environment) used to evaluate the scientific and technical merit of research applications, the following additional review criteria specific to this SIP will be considered in the determination of scientific merit and the priority score:

- Previous experience managing similar research projects, including validation of surveys, particularly cognitive testing.
- Evaluation if the proposed plan includes adequate sample size to achieve the study outcome.
- Evaluation if the proposed plan includes ability to include the population in focus (those eligible for prostate cancer screening, including high-risk groups).
- Previous experience conducting measurement validation studies, prostate cancer screening experience, and experience with conducting cognitive testing.

Funding Preferences
None

Research Plan Length and Supporting Material
The Research Strategy Section of the Research Plan is limited to a maximum of 12 pages. Supporting material included as appendices may not exceed 10 PDF (maximum of 30 pages) attachments. The appendices should include materials that show evidence of the applicant's ability to successfully conduct the proposed project and other evidence deemed necessary to support the contents of the proposal.
None

Availability of Funds
It is anticipated that approximately **$1,350,000** is available to fund **one** number of Prevention Research Center(s) for a **3-year** period of performance. The average award for each recipient is expected to be approximately **$450,000** for year one. The year one ceiling per recipient is **$450,000**. Funding may vary and is subject to change. Funding available includes direct and indirect costs.

Research Status
This project will be non-exempt research involving human subjects. It is anticipated that this project will require local IRB approval. Applicants should provide a federal- wide assurance number for each performance site.

OMB/PRA
OMB/PRA is not expected to apply

Award Administration
CDC staff will serve as consultants on this project, and will provide technical assistance, as requested, on project activities such as evaluation design, data collection and analysis, and data interpretation and dissemination of results. CDC staff may be co-authors on manuscripts. However, CDC staff will not have contact with human subjects or data collected from human subjects.

References

1. Screening for prostate cancer: U.S. Preventive Services Task Force recommendation statement. *Annals of internal medicine*. Aug 05 2008;149(3):185-91.
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SIP25-002 Prostate cancer active surveillance identification using electronic health records

Project Description.

A person can be categorized as a prostate cancer survivor when a prostate tissue biopsy confirms the presence of prostate cancer. Typically, low risk localized prostate cancer grows very slowly and, in many patients, may not progress to cause clinical symptoms or early mortality. Active surveillance (AS) is an ongoing regimen where the patient is closely monitored (e.g., with repeat prostate biopsy and PSA tests) to identify prostate cancer progression. Definitive treatment with intent to cure (i.e., radical prostatectomy or radiation therapy) is provided when progression is detected. Prostate cancer AS can help minimize complications or harms from unnecessary treatment with surgery or radiation therapy. Thus, men diagnosed with low risk, localized prostate cancer managed by AS can live longer, healthier lives. The American Urological Association (AUA) guidelines indicate clinicians should recommend AS as the preferred management option for prostate cancer survivors with low-risk, localized prostate cancer.[1] In the United States, community-based rates of AS have increased from 27% in 2014 to 60% in 2021, but with wide variation across practices and practitioners.[2] The use of AS is lower among African Americans and patients with lower incomes.[3-4].

For surveillance of trends, watchful waiting needs to be distinguished from prostate cancer AS. With watchful waiting, a prostate cancer case with limited life expectancy is followed with no definitive treatment and no repeat testing until the patient develops clinical symptoms. The health provider then provides palliative treatment for those symptoms with no intent to provide definitive treatment with intent to cure.[1]

It should be possible to examine prostate cancer cases managed with AS using electronic health record data. To do this, a case definition, or computable phenotype, that accurately described AS cases would need to be identified. A research challenge has been that a large amount of information in electronic health records is unstructured. The term unstructured refers to data in an electronic health record system that does not conform to a predefined data model or structure, making it difficult to categorize and analyze by computer. Common examples of unstructured information include clinical notes by providers, documents in PDF format, medical images, pathology reports, and patient correspondence. Natural Language Processing and machine learning models can be used to process and extract information from the unstructured data. Additional research is needed on how to improve and validate computable phenotypes to identify AS for prostate cancer surveillance based on the unstructured data contained in electronic health records.[5-10]

The primary purpose of this project is for the applicant to propose, develop, and evaluate improved computable phenotypes (case definitions) for use with electronic health records (EHRs) to identify whether a person with a biopsy-confirmed diagnosis of low-risk, localized prostate cancer is being managed by AS, especially phenotypes based at least in part on the unstructured data contained in electronic health records. Of special interest are valid estimates of prostate cancer AS for African American, Hispanic, non-Hispanic White, and low-income men.

Project Objectives and Outcomes

Project objectives are:

- Propose, develop, and evaluate improved computable phenotypes for use with electronic health record systems to identify whether a person with a biopsy-confirmed diagnosis of low-risk, localized prostate cancer is being managed by AS, especially phenotypes based at least in part on unstructured data contained in electronic health records. The phenotypes are expected to provide accurate and valid information about prostate cancer AS for African American, Hispanic, non-Hispanic White, and low-income men. The electronic health record system can be used at a single healthcare location or integrated across multiple sites. The applicant may propose one or several phenotypes to evaluate.
- Validate the proposed phenotypes by comparing the number and characteristics of cases (e.g., patient age, Prostate Specific Antigen level, Gleason Grade Group, clinical stage, histopathology, education, socioeconomic status, insurance coverage, and duration of management with active surveillance) identified by the proposed phenotypes with the number and characteristics of cases identified by medical chart review or by methods used by urological clinical registries (or equivalent) to extract information from electronic health records.[11-13]
- Evaluate the proposed phenotypes for any bias by the structures and processes of the health care systems providing the electronic health record data, and propose methods to mitigate bias.[14]

- Evaluate whether the proposed phenotypes can be used to predict future events such as prostate cancer progression that requires treatment with surgery or radiation.[15]

Outcomes: At the conclusion of this project, applicants are expected to provide a final report with details on the recommended phenotypes that accurately define a prostate cancer case managed with AS, a summary of any limitations (biases) of the study phenotypes, and any suggestions on how to best use Natural Language Processing and machine learning methods in future projects. In addition, applicants are expected to make available for open access (e.g., on GitHub) any final computer algorithms recommended by the project to use the recommended phenotypes or to facilitate processing of unstructured electronic health record data to identify prostate cancer active surveillance.

Healthy People 2030 Objectives
C-11: Increase the proportion of cancer survivors living 5 years or longer after diagnosis.
C-R01: Increase quality of life for cancer survivors**.**

NCCDPHP/DCPC Priority
Cancer survivors live longer, healthier lives.

Project Activities and Submission Requirements
Applications submitted in response to this SIP should present a **Research Plan** that addresses the following requirements listed below under study design and methods:

Study design and methods
The applicant will propose an appropriate study design to develop and evaluate phenotypes to identify prostate cancer cases managed with AS using data from electronic health records (EHRs), especially phenotypes based on the unstructured data electronic health records in electronic health records. The applicant will be expected to include a description of the electronic health record systems that will be analyzed, the number of cases with prostate cancer and years of data available, the structured data sources that will be included (e.g., a list of the ICD-9 and ICD-10, CPT, HCPCS, SNOMED, and LOINC codes that will be analyzed), and details on the unstructured data sources and variables that will be analyzed (e.g., clinical notes and laboratory, radiology, surgery, and laboratory PDF reports). The applicant will be expected to include details on the proposed sample size for African American, Hispanic, non-Hispanic White, and low-income men, and the methods that will be used to evaluate whether sample sizes are sufficient to answer the study questions. The applicant will be expected to include details on the methods that will be used to assess whether the proposed study phenotypes vary across education, socioeconomic status, and insurance coverage. The applicant also will be expected to include details on how Natural Language Processing and machine learning methods will be used, the characteristics of cases that will be evaluated, the methods for validation of prostate cancer active surveillance, and the methods to determine and mitigate bias by the structures and processes of the health care systems providing the electronic health record data.

Population of Focus

The study population will include male patients of any age who received their first prostate biopsy, and where the biopsy reported low-risk clinically localized prostate cancer. (The American Urological Association Guidelines define clinically localized low-risk prostate cancer as: Prostate-Specific Antigen <10 ng/mL AND Gleason Grade Group 1 AND clinical stage T1-T2a)[1]. To evaluate prostate cancer AS, men who meet the study definition will need to be followed over their lifetime from their first prostate cancer biopsy confirmed diagnosis until patient management with AS ends (e.g., the patient receives surgery or radiation therapy) or until the study observation period ends, whichever occurs first. Study populations are preferred that can provide valid estimates for Black or African American, Hispanic or Latino, non-Hispanic White, and low-income men.

Collaboration/Partnerships

Describe plans for collaboration/partnerships with data sources to develop and analyze phenotypes for active surveillance of prostate cancer and accomplish the study objectives. Examples might include state cancer registries (or equivalent), urological cancer registries (or equivalent), academic, medical practice-based sources, or other data sources. The plan should describe how partners will be engaged throughout the period of performance to inform the study.

Recruitment Plan

Applicants will be expected to obtain approvals from study health care locations to analyze and evaluate phenotypes using the electronic health record systems and data at those locations. If needed to validate the phenotypes, applicants also will be expected to obtain any additional approvals needed from patients, providers, or study locations.

Annual Action Plan

Provide a 12-month action plan using SMART goals and objectives to include a progressive timeline for completion of activities.

Evaluation Plan/Performance measurement

Applicants must provide an evaluation and performance measurement plan that demonstrates how the recipient will fulfill the requirements described. The evaluation plan must meet SMART goals and be consistent with the CDC evaluation framework (https://www.cdc.gov/evaluation/). A plan to evaluate data gathered as part of the research plan should be included.

Data Management Plan

If the applicant is collecting public health data, a standalone data management plan that addresses the 5 elements of AR-25 must be submitted in the Other Plan(s) section of the application.
https://www.cdc.gov/grants/additional-requirements/ar-25.html Applicants should use the NCCDPHP Data Management Plan template available at:
https://www.cdc.gov/nccdphp/dch/media/files/Data-Management-Plan-template.docx

Dissemination & Translation Plan

Provide details on anticipated strategies to disseminate and translate the findings of the research; for example, any anticipated peer-reviewed scientific articles, conferences, or other plans to

distribute project highlights to public health practitioners, non-governmental organizations, and healthcare decision makers. Applicants are expected to make available for open access (e.g., on GitHub) any final computer algorithms recommended by the project to use the recommended phenotypes or to facilitate processing of unstructured electronic health record data to identify prostate cancer AS.

Public Health Impact
The computable phenotypes for electronic health records potentially may lead to improved data to plan and make interventions to increase prostate cancer AS and to reduce disparities in the use of prostate cancer AS.[16-17] In addition, the project findings on methods to extract information from unstructured electronic health record data may be useful as part of other projects to modernize public health data and provide actionable insights for decision-making at all levels of public health and healthcare.

Special Eligibility and Responsiveness
The following criteria specific to this SIP will be used to determine the institution's eligibility and responsiveness:

Special Eligibility Requirements:

Access to the numbers of the subpopulations of interest needed to address the study questions.

Responsiveness Criteria:

The applicant must provide documentation (e.g., letters of support or memorandum of agreement) demonstrating evidence of access to the numbers of the subpopulations of interest needed to address the study questions.

Additional Review Criteria
In addition to the standard review criteria (Significance, Approach, Innovation, Investigators, and Environment) used to evaluate the scientific and technical merit of research applications, the following additional review criteria specific to this SIP will be considered in the determination of scientific merit and the priority score:

- Do the investigators show previous research expertise that have provided high quality outputs and contributed to improvements in public health practice?
- Does the applicant provide evidence of expertise of team members on AS of prostate cancer, clinical phenotypes based on electronic medical records, including Natural Language Processing, machine learning, and statistical modeling?
- Does the applicant describe experience creating translation and dissemination products for public health practitioners and non-governmental organizations?
- Does the proposed study design include details on the study sample size, especially for African American, Hispanic, non-Hispanic White, and low-income men?
- Does the applicant include details on the proposed methods to assess whether the results of the proposed phenotypes vary across education, socioeconomic status, and insurance coverage?

Funding Preferences

The following preferences specific to this SIP will be considered in the funding decision:

None

Research Plan Length and Supporting Material

The Research Strategy Section of the Research Plan is limited to a maximum of 12 pages. Supporting material included as appendices may not exceed 10 PDF (maximum of 30 pages) attachments. The applicant must provide documentation, e.g., letters of support or memorandum of agreement, demonstrating evidence of access or assuring that the applicant has access to the electronic health record data sets that the applicant has proposed to analyze to develop and evaluate phenotypes.

Availability of Funds

It is anticipated that approximately **$800,000** is available to fund 1 Prevention Research Center for a 2-**year** period of performance. The average award for each recipient is expected to be approximately **$400,000** for year one. The year one ceiling per recipient is **$400,000**. Funding may vary and is subject to change. Funding available includes direct and indirect costs.

Research Status

This project will be non-exempt research involving human subjects. It is anticipated that this project will require local IRB approval. Applicants should provide a federal- wide assurance number for each performance site.

OMB/PRA

OMB/PRA is not expected to apply

Award Administration

CDC staff will serve as consultants on this project, and will provide technical assistance, as requested, on project activities such as evaluation design, data collection and analysis, and data interpretation and dissemination of results. CDC staff may be co-authors on manuscripts. However, CDC staff will not have contact with human subjects and will not receive or analyze identifiable data.

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SIP25-003 Scaling What Works within the National Comprehensive Cancer Control Program

Project Description

CDC's National Comprehensive Cancer Control Program (NCCCP) has a 26-year history of working to enhance large scale efforts to reduce cancer risk, improve screening utilization, enhance

the quality of life of cancer survivors, and ameliorate health disparities in the community and within health systems to help achieve health equity among all populations covered (1). Over the years, NCCCP has piloted evidence-based interventions (EBIs) related to cancer survivorship (2), ovarian cancer (3, 4), and prevention of adult cancers during childhood (5) with small subsets of NCCCP recipients, although sustaining these practices and scaling these interventions and practices to additional NCCCP has proved challenging. Implementation science research has shown that practitioners implementing programs require additional support to build capacity around implementing new interventions, given the complexities and competing demands of their work environments (6).

To offer additional implementation support, in FY24, CDC's Division of Cancer Prevention and Control (DCPC) Comprehensive Cancer Control Branch (CCCB) launched Scaling What Works (SWW), a supplemental project through the CPCRN network (See Scaling What Works). SWW conducted a brief assessment of barriers to program implementation, provided opportunities for pilot site staff to mentor other NCCCP programs seeking to implement the successful interventions, developed a 3-day training and technical assistance (TA) symposium that included didactic content and structured breakout sessions for project development, and provided ongoing TA to NCCCP awardees through virtual learning collaboratives to help sites sustain or adopt these successful interventions. The symposium and learning collaboratives were based on an adaptation of the CPCRN Putting Public Health Evidence in Action (PPHEA) Training (found here: Training | CPCRN). The SWW project was highly successful. In one year, the SWW project engaged, through at least one these activities, 41 (of 66) geographically diverse NCCCP recipients to implement EBIs based on at least one NCCCP pilot projects (referenced above and described below).

CDC's Division of Cancer Prevention and Control (DCPC), Comprehensive Cancer Control Branch (CCCB) seeks applications to conduct implementation research that help seeks to understand how focused TA and training can help all 66 NCCCP sites either adopt or sustain EBIs already implemented in the NCCCP sites engaged in this work from the previous SWW project. CCCB staff will work with the SIP recipient to reach and engage NCCCP recipients. This work will not only benefit the NCCCP recipients, it will also provide insights that will contribute to the implementation science literature. Research activities will include, but not be limited to, assessing barriers to implementation (particularly for programs not reached in the previous SWW project), exploring the effectiveness of the adaptation of the PPHEA curriculum for NCCCP programmatic use, developing and implementing a TA and training plan for EBI implementation across NCCCP sites, assessing how programs have adapted the interventions to meet the needs of their populations and jurisdictional contexts, and evaluating the reach of the TA and training provided by the SIP recipient. The translational goal for this research is for the SIP recipient to help scale and sustain several successful demonstration projects piloted within NCCCP sites: 1) Using Project ECHO (Extension for Community Healthcare Outcomes) and Patient Navigation to Improve the Health and Wellness of Cancer Survivors in Rural Communities, 2) Increasing Receipt of Ovarian Cancer Care from a Gynecologic Oncologist, 3) Addressing Risk Factors for Adult Cancers during Childhood, and 4) Health System Changes to Address Risk Factors in Cancer. The overall purpose of this research is to: 1) examine barriers and facilitators to scaling up the EBIs used in the 4 pilot projects to all NCCCP sites, 2) identify barriers and facilitators to adoption of these EBIs within NCCCP sites, 3) provide TA and training to NCCCP sites to help them increase the adoption and

of sustainable strategies and EBIs that aim to decrease the burden of cancer and achieve more health equity among US populations and 4) examine the reach and effectiveness of the TA and training services employed by the SIP recipient. NCCCP recipients are continually funded under an ongoing, separate, non-research cooperative agreement to implement specific activities including these four projects; however, it is expected that the SIP recipient will use their research funds to engage NCCCP recipients in a manner that accelerates uptake of the four projects. This engagement could include surveys and key informant interviews to determine barriers to uptake, meetings and symposia where TA and training would be provided, and targeted dissemination of information through manuscripts, success stories and other documents for public health practitioner and research audiences.

Project Objectives and Outcomes

The objective of this project is to integrate a framework, such as the evidence-based system for innovation support (EBSIS) (6), to support a TA and training model to support adoption and implementation of EBIs within a major public health program (NCCCP). Specific EBIs to be supported within NCCCP are: 1) Using Project ECHO and Patient Navigation to Improve the Health and Wellness of Cancer Survivors in Rural Communities, 2) Increasing Receipt of Ovarian Cancer Care from a Gynecologic Oncologist, 3) Addressing Risk Factors for Adult Cancers during Childhood, and 4) Health System Changes to Address Risk Factors in Cancer. Applicants are expected to provide technical assistance (TA) and training to NCCCP recipients as well as to evaluate the reach and efficacy of the TA and training provided. Specific objectives are to: 1) assess facilitators and barriers to implementation, 2) explore how can we best engage TA and training recipients, i.e., NCCCP staff/sites, 3) determine how to best build trust among TA and training providers and TA and training recipients, especially across a diverse range of NCCCP sites, and 4) identify which methods are most effective in providing TA and training for public health programs across diverse jurisdictions.

1) provide TA and training for NCCCP recipients that are already implementing these interventions and strategies to improve and sustain interventions; 2) provide TA and training to NCCCP recipients who have not adopted or implemented these interventions and strategies to adopt and implement and then sustain, and 3) provide TA and training for all recipients to evaluate these interventions and strategies. Applicants are expected to use an evidence-based support system or planning approach, such as PPHEA, to support NCCCP sites in adoption, adaption, evaluation, and sustaining EBIs.

Outcomes: At the conclusion of the funding period, all 66 NCCCP sites should be adopting, evaluating, and sustaining at least one of these four projects in their programmatic work to decrease cancer risk factors, ensure those diagnosed with ovarian cancer receive proper care, and increase the health and wellness of cancer survivors. Applicants will be expected to provide dissemination products at the end of the period of performance, including an evaluation of the reach of their TA and training activities to all 66 NCCCP sites and a summary of lessons learned, especially related to how to support adaptation in special populations, such as US-affiliated Pacific Islands, US territories, tribal jurisdictions, and rural communities.

Healthy People 2030 Objectives

Goal: Reduce new cases of cancer and cancer-related illness, disability, and death.

Objectives:

- Increase quality of life for cancer survivors (C-R01)
- Increase the proportion of people who discuss interventions to prevent cancer with their providers (C-R02)
- Reduce the proportion of students in grades 9 through 12 who report sunburn (C-10)
- Reduce infections of HPV types prevented by the vaccine in young adults (IID-07)

Project Activities and Submission Requirements

Applications submitted in response to this SIP should present a Research Plan that addresses the following expectations listed below:

1. Assess barriers and facilitators to EBI implementation within NCCCP. A theoretical framework, such as (EBSIS) (6) should be used as a basis for the assessment.

2. The SIP recipient is expected to participate in the CPCRN network to work with staff within the 66 NCCCP recipients to assist them with completing the following activities to implement and scale up the 4 pilot projects that have evidence of working in this setting:

a. Identify priority populations (i.e., populations that are affected by cancer) that would benefit most from project implementation (e.g., race-, ethnic-, geographic-, age-specific data analyses of cancer incidence, mortality or survival; hospital use or care-seeking behavior analyses; cancer risk factor analyses).
b. Identify local partners within the NCCCP recipient's community to help with implementation of EBIs (e.g., pediatricians, and ovarian cancer practitioners, hospital systems and networks, patient navigator and community health work organizations).
c. Develop new and tailor existing materials from CDC and other relevant evidence-based sources and methods to reflect specific population experiencing disparities in cancer related to these projects. For example, appropriately adapt materials and methods to the specific racial, ethnic, geographic, or age-specific population and support methods for implementation that suit the population, particularly those who experience cancer and other health disparities.
d. Convene and support community of practice of NCCCP recipients engaged in these projects to foster collaboration, further expertise, encourage information sharing, and promote sustained conduct of implementation projects. This may include CDC staff members as appropriate. The community of practice should ideally meet regularly and be formed as an ongoing and sustainable effort.
e. Assist NCCCP recipients with collecting data and evaluating activities reached for each project. The SIP recipient can work with NCCCP recipients to develop appropriate data collection methods and instruments (e.g., surveys/pre-post-tests) to assess reach and success of implementation activities. Data collection instruments and methods should be designed with the population in mind. Data collection during implementation can also be used for evaluation purposes.
f. Help NCCCP recipients develop plans for ongoing sustainability of EBIs.

3. Measure the reach of TA and training provided (how many NCCCP sites were reached and which EBIs they implemented). Evaluate how TA and training helped NCCCP implement the EBIs selected. Evaluate which TA and training methods (including which PPHEA modules) were most useful/successful. Identify lessons learned on how to successfully provide tailored TA across a variety of diverse jurisdictions, with special focus on US-affiliated Pacific Island Jurisdictions, US territories, tribal jurisdictions, and rural populations.
4. Disseminate TA and training methods, evaluation results, successful, and lessons learned (described in #3 above). A variety of dissemination products should be considered including slide sets, one-page project descriptions, one-page success stories, podcasts, and scientific publications. Dissemination products should ideally be made publicly available to ensure access by public health practitioners and researchers beyond those involved in NCCCP. These products can also be used as an additional measure of success of these efforts.

Study design and methods

The study design and methods should be consistent with best practices for community-level public health program engagement and intervention. The types of implementation activities and evaluations performed by the NCCCP, NCCCP priorities, actions and success stories can be found on the CDC website to assist with this (1). It is crucial that the awarded PRC has a good understanding of the NCCCP, and how they engage with their communities and populations to prevent and control cancer.

Population of Focus

Applicants have the option of identifying populations of focus within NCCCP jurisdictions that would benefit most from project implementation. Applicant should focus on factors such as, race, ethnicity, geography (including tribal communities, U.S.-affiliated Pacific Island Jurisdictions, and territories), socioeconomic status, and health literacy.

Collaboration/Partnerships

Collaborations with CDC staff, including NCCCP project officers and researchers who designed and performed the 4 pilot projects, is essential to accomplish the project outcomes. The NCCCP maintains a wide variety of partners at the federal level (such as American Cancer Society, National Association of Chronic Disease Directors, etc.), as well as local partners in each program. Collaborations with these partnering organizations may be extremely useful in scaling these 4 pilot projects. Local level partners include cancer coalition leaders and members. Additionally, collaboration with program staff in each of the NCCCP recipients is critical to this project. CDC staff will facilitate access to these program staff. Additionally, the SIP recipient is expected to participate in the CPCRN network.

Recruitment Plan

Participants in this project should be recruited via NCCCP community channels, including listservs, meetings, and via CDC staff, who will assist with accessing the NCCCP recipients.

Annual Action Plan

Provide a 12-month action plan using SMART goals and objectives to include a progressive timeline for completion of activities.

Evaluation Plan/Performance measurement
Applicants must provide an evaluation and performance measurement plan that demonstrates how the recipient will fulfill the requirements described. The evaluation plan must meet SMART goals and be consistent with the CDC evaluation framework (https://www.cdc.gov/evaluation/). A plan to evaluate data, such as reach and effectiveness of the TA and training provided by the SIP recipient, gathered as part of the research plan should be included.

Data Management Plan
If the applicant is collecting public health data, a standalone data management plan that addresses the 5 elements of AR-25 must be submitted the Other Plan(s) section of the application.
https://www.cdc.gov/grants/additional-requirements/ar-25.html

Dissemination & Translation Plan
A variety of dissemination products should be considered including slide sets, one-page project descriptions, one-page success stories, podcasts, and scientific publications. Because this project is about scaling up evidence-based pilot projects in the larger NCCCP setting, it is critical that dissemination products are made with a view toward sharing widely and broadly with public health audiences. These products can be used as a measure of success.

Public Health Impact
Given the national reach of the NCCCP (66 programs, including all 50 states and DC, 8 U.S. territories and U.S.-Affiliated Pacific Island Jurisdictions, and 7 tribes/tribal organizations), this project has the potential to have a tremendous public health impact. In the U.S., ovarian, skin, liver/intrahepatic bile duct, and HPV-related cancers account for approximately 148,197 new cancer diagnoses each year (7). Importantly, this project also has the potential to improve the quality of life of the estimated 18.1 million cancer survivors currently living in the U.S. (8).

Special Eligibility
The following criteria specific to this SIP will be used to determine the institution's eligibility and responsiveness:
None

Responsiveness
The recipient should demonstrate previous experience through letters of support from NCCCP recipients they have previously worked with.

Additional Review Criteria
In addition to the standard review criteria (Significance, Approach, Innovation, Investigators, and Environment) used to evaluate the scientific and technical merit of research applications, the following additional review criteria specific to this SIP will be considered in the determination of scientific merit and the priority score:

Collaborations/Partnerships

- Given it is essential that the applicant work within the NCCCP setting, does the applicant have experience in working with NCCCP?
- Does the applicant demonstrate successful experience working with federal, state, or local public health and other social service agencies?
- Does the applicant have knowledge and expertise in cancer?

Evaluation

- Does the applicant demonstrate successful experience evaluating the impact of public health interventions?
- Does the applicant demonstrate an understanding of all aspects of the evaluation (i.e., evaluating implementation, costs, effectiveness, scalability)?

Dissemination and Translation

- Does the applicant demonstrate creating translation and dissemination products targeting public health practitioners, non-governmental organizations, and/or decision makers?
- Does the applicant demonstrate ability to adapt complex and/or technical content to suit the needs of diverse audiences?

Capacity Building and Technical Assistance
- Does the applicant demonstrate the ability to provide comprehensive and responsive technical assistance (TA) to stakeholders throughout the lifecycle of a project?
- Does the applicant demonstrate a plan for delivering TA, including training, ongoing support, and troubleshooting, to ensure the successful implementation and scaling of interventions?
- Does the applicant demonstrate strategies that emphasize maximizing organizational capacity and context in achieving project goals?

Funding Preferences

The following preferences specific to this SIP will be considered in the funding decision:
None

Research Plan Length and Supporting Material

The Research Strategy Section of the Research Plan is limited to a maximum of 12 pages. Supporting material included as appendices may not exceed 10 PDF (maximum of 30 pages) attachments. The appendices should include materials that show evidence of the applicant's ability to successfully conduct the proposed project and other evidence deemed necessary to support the contents of the SIP.
Appendices should include materials that could be used by NCCCP programs to work on implementation and evaluation plans and other previously published/produced dissemination and implementation materials relevant to the NCCCP, such as TA/Training meeting or agendas and learning collaborative timelines/schedules. Appendices may include feedback forms for assessing the various TA and training initiatives.

Availability of Funds
It is anticipated that approximately **$2,208,000** is available to fund **1** Prevention Research Center(s) for a **4-year** period of performance. The average award for each recipient is expected to be approximately **$552,000** for year one. The year one ceiling per recipient is **$552,000**. Funding may vary and is subject to change. Funding available includes direct and indirect costs.

Research Status
This project will not involve human subjects research; therefore, it will not require local or CDC IRB approval.

OMB/PRA
OMB/PRA is expected to apply.

Award Administration
CDC staff will serve as consultants on this project, and will provide technical assistance, as requested, on project activities such as evaluation design, data collection and analysis, and data interpretation and dissemination of results. CDC staff may be co-authors on manuscripts. However, CDC staff will not have contact with human subjects or data collected from human subjects.

References

1. National Comprehensive Cancer Control Program | NCCCP | CDC
2. Rohan, E., Kuiper, N., Bowen, S.A., Mast, D.K., House, M., French, C., Tharpe, F.S., Henley, S.J., Wanliss, E. and Puckett, M., 2022. Pairing Project ECHO and patient navigation as an innovative approach to improving the health and wellness of cancer survivors in rural settings. *The Journal of Rural Health*, *38*(4), pp.855-864.
3. Rim SH, Moore AR, Stewart SL. Collaborating with the Centers for Disease Control and Prevention's National Comprehensive Cancer Control Program to Increase Receipt of Ovarian Cancer Care from a Gynecologic Oncologist. J Womens Health (Larchmt). 2022 Nov;31(11):1519-1525. doi: 10.1089/jwh.2022.0372. PMID: 36356183; PMCID: PMC10990150.
4. Stewart SL, Mezzo JL, Nielsen D, Rim SH, Moore AR, Bhalakia A, House M. Potential Strategies to Increase Gynecologic Oncologist Treatment for Ovarian Cancer. J Womens Health (Larchmt). 2021 Jun;30(6):769-781. doi: 10.1089/jwh.2021.0178. PMID: 34128688; PMCID: PMC10120807.
5. Tai E, Chovnick G, Momin B, Townsend JS, Holman DM, Siegel D, House M. Reducing Cancer Risk Through Primary Prevention Activities Among Children: A Demonstration Project. J Public Health Manag Pract. 2024 Mar-Apr 01;30(2):E54-E64. doi: 10.1097/PHH.0000000000001838. Epub 2023 Nov 30. PMID: 38032233; PMCID: PMC11274665.
6. Wandersman, A., & Scheier, L. M. (2024). Strengthening the science and practice of implementation support: Evaluating the effectiveness of training and technical assistance centers. *Evaluation & the Health Professions*, *47*(2), 143-153.
7. USCS Data Visualizations - CDC

8. Statistics and Graphs | Division of Cancer Control and Population Sciences (DCCPS)

SIP25-004 Lifestyle Change Implementation Research Network

Project Description

Increasing physical activity and improving nutrition are well-established risk-reduction strategies for the prevention and management of multiple chronic conditions including obesity, diabetes, heart disease, hypertension, and cancer. There are many evidence-based and evidence-informed lifestyle change interventions (LCIs) that help individuals and families create healthier habits around nutrition and physical activity (i.e., National Diabetes Prevention Program (National DPP), The Smart Moves Program, Diabetes Self-Management Education and Support (DSMES), YMCA's Blood Pressure Self Measurement (BPSM) Program, YMCA's Livestrong Program, etc.). However, social, structural, political, economic, programmatic, and psychological barriers may disproportionately affect the ability of some populations of focus to enroll and complete an LCI (1-33). Additionally, organizations that serve populations of focus often face significant issues with making their intervention sustainable because their revenues (outside of grants) are insufficient to cover the full cost of the intervention (2, 12,14, 27, 34, 35).

In response to these implementation challenges, the Lifestyle Change Implementation Research Network (LCIRN) was formed in 2023 with support from the Centers for Disease Control and Prevention's (CDC's) Division of Diabetes Translation (DDT), Division for Nutrition, Physical Activity, and Obesity (DNPAO), and Division for Heart Disease and Stroke Prevention (DHDSP). LCIRN was formed to convene a diverse network of experts in lifestyle change programs to share lessons learned and provide insight into how to best serve populations of focus.

In 2024, the LCIRN held a hybrid in-person/virtual workshop to review a synthesis of research findings (including a literature review, environmental scan, focus group discussions, and previous information gathering efforts with LCIRN) related to barriers, facilitators, strategies, and adaptations for LCIs. LCIRN members discussed remaining gaps and opportunities and identified priorities for an open implementation science agenda. LCIRN agendas are not platforms to give consensus advice to CDC, but instead a way to share information and maximize resources towards scaling LCIs with a health equity lens. The LCIRN agenda informs (but does not direct) the work of LCIRN and the research that CDC funds through this SIP. LCIRN identified two goals with 8 specific aims for an open LCIRN Open Implementation Science Agenda to Scale LCIs using a Health Equity and Sustainability Lens.

Goal 1. Improve Enrollment and Retention of Participants from Populations of Focus in LCIs.

Aim 1.1 Improve actual and perceived feasibility of LCI timing, duration, and frequency by various populations of focus

Aim 1.2 Improve motivation and self-efficacy to enroll and complete LCIs for various populations of focus

Aim 1.3 Increase awareness of LCIs by various populations of focus

Aim 1.4 Increase health care provider referrals and improve clinical-community linkages to LCIs for various populations of focus

Aim 1.5 Decrease out-of-pocket costs for participation in LCIs for various populations of focus

Goal 2. Increase adoption and improve sustainability of LCIs for implementers that serve populations of focus.

Aim 2.1 Improve financial sustainability for organizations that implement LCIs and serve populations of focus

Aim 2.2 Improve the knowledge, skills, and cultural sensitivity of LCI staff to implement LCIs as intended for populations of focus.

Aim 2.3 Improve alignment between the mission and vision of LCIs and implementing organizations that serve populations of focus. CDC's Division of Diabetes Translation seeks to continue to support and grow the work of LCIRN with this special interest project (SIP) thematic network. The LCIRN will consist of multiple collaborating centers recipients and one coordinating center recipient. Multiple collaborating centers may work together on research and translation activities. The Coordinating Center recipient will facilitate and support collaborative research activities among all LCIRN recipients, their partners, and affiliates; and help support the translation and dissemination of findings. LCIRN Collaborating Centers will complete activities listed in Component A below. The LCIRN Coordinating Center will complete activities included for both Component A and B listed below.

Project Objectives and Outcomes

Component A: LCIRN Collaborating Centers (Required)

Projects

To address the eight aims, we will fund four projects (some of which include multiple activities). Applicants may apply for only one project and we will fund only one applicant for each project.

Project 1

Activity 1.1. Conduct new retrospective analyses or update systematic reviews and meta-analyses on the dose response relationship between length of LCI exposure (meaning the length an individual stays in a program or number of sessions they attend) and…

a. long-term behavior changes related to "risk reduction" activities, such as engaging in more physical activity or eating more fruits and vegetables and/or
b. long-term key cardiometabolic indicators (i.e., weight loss, A1C, blood pressure, etc.)
c. long-term chronic disease prevention for multiple chronic conditions

Activity 1.2. Conduct comprehensive studies of LCI implementation costs (including marketing, staff support, staff training, data reporting, insurance billing, etc.) and how these costs differ by factors such as delivery mode, type of organization (including clinical- and community-based), location of the program, etc.

Activity 1.3. Conduct new economic evaluations or update reviews on the cost effectiveness of LCIs for prevention of multiple chronic conditions rather than a single condition.

Project 2

Activity 2.1. Develop or identify novel approaches for marketing the frequency/length/duration of LCIs in a way that improves perception of the feasibility of LCIs for individuals and families who have competing demands on their time (e.g., rather than marketing as a 12-month program, market as a 3- or 6-month program with bonus support for a full year). Evaluate these approaches in diverse markets across the U.S. to identify those that are effective for moving an individual or family from awareness to enrollment.

Activity 2.2. Develop or identify customized marketing approaches for individuals and families with varying motivations for joining LCIs (e.g., prediabetes/chronic disease prevention or weight loss or overall wellness for themselves and their families or self-affirmation language that promotes feelings of self-efficacy). Evaluate these approaches in diverse markets across the U.S. to identify those that are effective for moving an individual or family from awareness to enrollment.

Activity 2.3. Conduct landscape analysis to identify innovative LCI approaches (could include non-traditional coaching models, 1:1 coaching, or asynchronous models, etc.) where content is client-centered and hyper-customized to the individual preferences of what they want to learn, the health outcomes they want to achieve, and the skills they want to achieve. Evaluate these approaches in diverse markets across the U.S. to identify those that are effective for improving enrollment and/or retention.

Project 3

Activity 3.1. Conduct formative research in diverse settings across the U.S. to understand the factors that influence healthcare provider decision-making related to whether (and when) to refer patients to an LCI when they prescribe medications used to treat obesity, diabetes and cardiovascular disease (e.g., GLP-1 agonists and GLP-1/GIP dual agonists). Evaluate whether these factors vary across different populations of focus.

Activity 3.2. Conduct formative research in diverse settings across the U.S. to understand the factors that influence patient self-efficacy, motivation, and decision-making related to enrolling in LCIs when their physician prescribes them medications used to treat obesity, diabetes and cardiovascular disease (e.g., GLP-1 agonists and GLP-1/GIP dual agonists). Evaluate whether these factors vary across different populations of focus.

Project 4

Activity 4.1. Study the effects of participation in various LCIs (i.e., behavior change programs that help individuals and families create healthier habits around nutrition and physical activity) among those taking medications used to treat obesity, diabetes, and cardiovascular disease (e.g., GLP-1 agonists and GLP-1/GIP dual agonists)

i. Potential outcomes of interest related to motivation and self-efficacy include (but are not limited to)

a. Self-efficacy related to healthy eating approaches and physical activity

b. Motivation to make improvements to nutrition and physical activity

ii. Potential behavior change outcomes of interest include (but are not limited to)

a. Intake of fruits and vegetables
b. Protein intake
c. Resistance training
d. Physical activity minutes and/or walking time
e. Regular eating patterns, meal timing

iii. Potential implementation and effectiveness outcomes of interest related to LCI participation include (but are not limited to)

a. Retention in LCI
b. % change in lean body mass
c. Risk of developing type 2 diabetes or other metabolic diseases

Project Outcomes

Outcome 1.a Strengthened science underlying the core components of evidence-based and evidence-informed LCIs to help implementers better understand the bounds of adaptations that can be made to tailor the timing, frequency, and duration of LCIs for populations of focus while still maintaining program fidelity

Outcome 1.b Improved knowledge base that underpins reimbursement and reimbursement models for implementers and ultimately contributes to sustainable and equitable implementation of LCIs

Outcome 2. Improved understanding of effective strategies to market LCIs and customize programmatic approaches for populations of focus

Outcome 3. Improved knowledge base that underpins how to tailor healthcare provider referral strategies in the future for individuals who are prescribed medications used to treat obesity, diabetes and cardiovascular disease (e.g., GLP-1 agonists and GLP-1/GIP dual agonists)

Outcome 4. Improved knowledge base that underpins how to tailor LCIs in the future for individuals who are prescribed medications used to treat obesity, diabetes and cardiovascular disease (e.g., GLP-1 agonists and GLP-1/GIP dual agonists)

Component B: Coordinating Center - Optional

In addition to project objectives from component A, the Coordinating Center will facilitate and support collaboration, communication, translation, and dissemination of research activities among collaborating centers, communities of practice, a LCIRN Leadership Council, CDC, and other affiliates of these partners that aim to advance implementation research of LCIs. The coordinating center will work to advance all 8 aims of the LCIRN open agenda through the development of communities of practice.

Project Activities

Activity 1. Support and maintain communication and collaboration across all of LCIRN, including collaborating centers, communities of practice, a LCIRN Leadership Council, CDC, and other affiliates of these partners that aim to advance implementation science of LCIs.

Activity 2. Develop, support, and maintain the network's communities of practice and a LCIRN Leadership Council (comprised of co-chairs from each community of practice). The purpose of the communities of practice is to provide a space where members can connect, share information, and organize efforts across organizations and disciplines to advance the larger list of the aims within the open agenda. The first communities of practices will be organized around the eight aims in the LCIRN open agenda, and they may develop sub-groups within these communities. Each community of practice can develop their own mission, goals, and agenda for how they would like to operate and what they would like to achieve.

Activity 3. Facilitate and coordinate translation and dissemination of research activities among collaborating centers, communities of practice, CDC, and other affiliates to advance implementation research of LCIs.

Activity 4. Facilitate opportunities for mentorship, technical assistance, and capacity building of implementers of LCIs.

Activity 5. Identify insurance reimbursement models that incentivize organizations to enroll and retain populations of focus (as opposed to outcome-based reimbursement which may disincentivize organizations from enrolling populations that historically do not achieve those outcomes as quickly or consistently) and create a synthesis of key elements.

Activity 6. Facilitate connections among network members and non-members such as national, state, and local partners, insurers, and federal agencies (i.e., HRSA, CMS, etc.) to advance efforts aligned with LCIRN's mission.

Activity 7. Conduct an evaluation of LCIRN activities and collaborations.

Activity 8. Facilitate the update of the open research agenda in 2029.

Project Outcomes

Strengthened supporting structures of implementation research and translation in the knowledge to action (K2A) framework through:

Outcome 1. Enhanced communication, coordination, and collaboration between LCIRN collaborating centers, members of LCIRN communities of practices, CDC, and other LCI stakeholders who are working to scale LCIs

Outcome 2. Coordinated translation and dissemination of LCI implementation research findings

Outcome 3. Coordination of evaluation of network activities and impact

Note: All applicants of this SIP are **REQUIRED** to apply for Component A (LCIRN Collaborating Centers).

Applicants MAY apply for Component B (LCIRN Coordinating Center).

Only 1 applicant will be funded for **BOTH** components A and B. Other applicants applying for both components will remain in consideration for funding for only Component A.

Healthy People 2030 Objectives

This SIP aligns with the topics of Nutrition and Healthy Eating; Physical Activity; Diabetes; Heart Disease and Stroke; Overweight and Obesity.
Select objectives that align with this project include-

- D-01: Increase the proportion of eligible people completing CDC-recognized type 2 diabetes prevention programs
- D-02: Reduce the proportion of adults who don't know they have prediabetes
- NWS-04: Reduce the proportion of children and adolescents with obesity
- NWS-03: Reduce the proportion of adults with obesity
- NWS-06: Increase fruit consumption by people aged 2 years and over
- NWS-07: Increase vegetable consumption by people aged 2 years and older
- NWS-10: Reduce consumption of added sugars by people aged 2 years and over
- NWS-12: Reduce consumption of sodium by people aged 2 years and over
- PA-01: Reduce the proportion of adults who do no physical activity in their free time
- PA-08: Increase the proportion of adolescents who do enough aerobic and muscle-strengthening activity
- PA-09 Increase the proportion of children who do enough aerobic physical activity
- HDS-01: Increase overall cardiovascular health in adults
- HDS-04: Reduce the proportion of adults with high blood pressure
- HDS-06: Reduce cholesterol in adults

Project Activities and Submission Requirements
Applications submitted in response to this SIP should present a **Research Plan** that addresses the following requirements for both components listed below:

Component A: LCIRN Collaborating Centers (Required)

- Describe previous experiences that support the proposed activities to address within the project that the applicant is applying for. Depending on the project the applicant applies for, this may include (but is not limited to):

  - Previous experience designing, conducting, and analyzing meta-analyses.
  - Previous related experience developing models/ simulations.
  - Previous experience designing, conducting, and analyzing representative national surveys, including experience designing surveys that measure self-reported behavior change.
  - Previous experience designing, conducting, and analyzing economic evaluations.
  - Previous experience designing, conducting, and analyzing qualitative studies around marketing messages/approaches.
  - Previous experience designing, conducting, and analyzing mixed methods research studies.
  - Previous experience designing, conducting, and analyzing observational research studies.
  - Previous experience designing, conducting, and analyzing quasi-experimental research studies.

- Previous experience deploying engagement strategies to engage difficult-to-reach populations of focus.
- Previous experience deploying buy-in and engagement strategies with stakeholders like insurance companies and healthcare providers.

- Describe the staffing plan for carrying out the research project.

- For each person, describe their demonstrated knowledge, experience, and ability in planning and conducting research that is like the types proposed here in complexity, scope and focus. If a position is yet to be filled, provide a position description in the appendix. Include the percentage of time each person will devote to project activities.
- Of the named staff, provide evidence of the interdisciplinary nature of the key center leadership and experiences in successfully conducting and being funded for the types of research activities the applicant is applying for.

- Discuss the potential for collaborations of your PRC with relevant stakeholders such as public health departments, community-based organizations, health systems, other federal agencies, insurance companies, etc.

- Recipients are expected to actively participate in the LCIRN network, including one or more LCIRN communities of practice. Funded collaborating centers will be expected to actively participate in cross-center research or translation projects developed and conducted in collaboration with other funded centers. One of the purposes of the network is to foster multi-center collaborations, by leveraging the expertise, partnerships, and resources of participating centers. It is expected that a minimum of 25% of resources, which could include funded staff time, budget, etc., will be used to support cross-center LCIRN projects.

Component B: LCIRN Coordinating Center - Optional

Applicants of component B should submit a plan to coordinate, facilitate, support, and disseminate activities of LCIRN with the following requirements:

1. Describe leadership strategies, resources, and processes that the applicant will use to support and maintain communication and collaboration across the entire LCIRN and detail a plan for each of the following activities:

a. Identify priorities and support collaborative research or translation opportunities among network members, their partners, and affiliates
b. Facilitate monthly LCIRN leadership council meetings
c. Support innovative and creative translation efforts of network members through writing assistance and or technical assistance on the development of specific resources that go beyond traditional implementation toolkits
d. Coordinate and facilitate quarterly virtual meetings with the entire network
e. Develop quarterly newsletters

f. Enhance, update, and manage LCIRN's web presence, including a LCIRN website for easy access and sharing of products for LCIRN members (including each community of practice) and practitioners

2. Describe leadership strategies, resources and processes that the applicant will use to support and maintain the LCIRN communities of practice and detail a plan for each of the following activities:

a. Recruit new members and co-chairs
b. Organize and host an in-person annual strategic planning workshop for co-chairs at the beginning of each year
c. Provide ongoing mentorship and structured strategic planning support to co-chairs
d. Provide a platform (for example, Zoom), and IT logistics for communities of practice meetings

3. Describe leadership strategies, resources, and processes that the applicant will use to build the capacity of implementers and detail a plan for each of the following activities:

a. Host regular opportunities (i.e., webinars, recorded videos, trainings, etc.) for sharing of promising practices in the field or dissemination of tools and resources that may help improve enrollment and retention of populations of focus (i.e., "How to partner with a faith-based institution") or sustainability of implementers (i.e., "How to become a Medicaid supplier")
b. Host hybrid implementation workshops or learning expos for LCI implementers
c. Develop Technical Assistance (TA) or mentorship programs for implementers and coaches based on tailored needs and expertise
d. Disseminate network products and other tools and resources that may be useful for implementers

4. Describe leadership strategies, resources and processes that the applicant will use to facilitate connections among network members and non-members such as national, state, and local partners, insurers, federal agencies (i.e., HRSA and CMS, etc.) to advance efforts aligned with LCIRN's mission.
5. Describe the staffing plan for leading and coordinating LCIRN.
6. Provide relevant experience, a description of roles, and the proportion of time each person will spend on activities. Examples of these personnel may include an administrator, project manager, data manager, Webmaster and others.
7. Describe an evaluation plan of network activities and impact.
8. The 2024 LCIRN open agenda is based on comprehensive information gathering for 37 topic areas, including an environmental scan, literature review, and multiple information gathering activities with LCIRN members. Describe leadership strategies, resources, and processes that the applicant will use to update this knowledge base and facilitate the update of the LCIRN open agenda in 2029.

*Note that the CDC comprehensive reports for each of these topic areas are internal documents but can be provided to the applicants so that they better understand the comprehensive nature of this update. CDC can also share the report from the 2024 workshop where the 2024 open research agenda was prioritized.

Study design and methods
In addition to the requirements above, the applicant should include information on study design and methods in their plan for each objective for which they are applying that describes potential research question(s) and how applicants will use scientifically rigorous methods to address them. Applicants are strongly encouraged to think creatively and critically about design and methods they are proposing to ensure they are both feasible (the design and methods must be compatible with a 4-year period of performance) and appropriate for the research questions of interest. For relevant project objectives, the applicant shall include appropriate implementation outcome measures with established psychometrics (when available) and propose appropriate implementation science theories, models, and frameworks.

Population of Focus
Component A: LCIRN Collaborating Centers (Required)
DDT defines populations of focus based on Healthy People 2030 definition of health disparity: Those who have systematically experienced greater obstacles to health based on their racial or ethnic group; religion; socioeconomic status; gender; age; mental health; cognitive, sensory, or physical disability; sexual orientation or gender identity; geographic location; or other characteristics historically linked to discrimination or exclusion.

Applicants should identify study populations based on health disparities data and/or LCI data on disparities in enrollment and retention that fit the DDT definition for populations of focus.

Component B: LCIRN Coordinating Center - Optional
Component B applicants are encouraged to share plans for how they will grow the LCIRN network beyond it's current membership (described in the next section) and disseminate findings, specifically with LCI stakeholders who serve populations of focus. Populations of focus that LCI stakeholders work with should include American Indians, Alaskan Natives, Black/African Americans, Children, Hispanic/Latinos, Individuals with disabilities, Men, Native Hawaiian/Pacific Islanders, Older adults (age 65+), women, men, LGBTQIA+. LCIs tend to be more successful when they are tailored to specific populations, so many of our current LCIRN members work specifically with one population of focus, which adds to their expertise for how improve LCIs for a particular population. The applicant should discuss plans to identify this type of LCI stakeholder and engage them in the work.

Collaboration/Partnerships
Component A: LCIRN Collaborating Centers (Required)
All funded PRCs for this SIP will collaborate with a variety of external partners and organizations including members of the study population or organizations representing this population, that can help them achieve the goals of LCIRN.

Component B: LCIRN Coordinating Center - Optional (if funding more than 1 PRC)
The Coordinating Center is expected to foster existing relationships and grow the existing membership of LCIRN. The coordinating center is also expected to enhance and expand dissemination and translation efforts as appropriate to increase reach, impact, and speed of research into practice.
LCIRN members have significant experience working with populations of focus with a variety of different LCIs, and they also work for a variety of different organization types, including:

- Community based organizations
- For profit organizations
- Federally qualified health centers or community health centers
- Business coalitions
- Cooperative extension sites
- Health plans and insurers
- Hospitals/ healthcare systems, medical groups, physician practices
- Indian Health Service/Tribal/Urban Indian Health Systems
- Local or community YMCAs
- Pharmacies/Drug Stores/Compounding Pharmacies
- State/Local Health Departments
- Virtual-only programs
- Synchronous and asynchronous programs
- Programs supported by Community Health Workers (CHWs)
- Universities/Schools
- Worksites/Employee Wellness Programs

The founding members of the network include 47 individuals from across the U.S. with over 465 years of collective experience in one or more of the following:

- Implementing lifestyle change interventions that are geared, at a minimum, toward improving both nutrition and physical activity
- Supporting these implementing organizations that are working with populations of focus (e.g., provide support or training related to LCIs)
- Studying implementation improvement strategies for populations of focus
- Adapting lifestyle change interventions for populations of focus for national or multi-state/site organizations

Recruitment Plan
The applicant should describe plans to recruit and work with populations of focus or with implementers who serve populations of focus, where applicable. The applicant may include (but should not limit their plan to) coordination with founding LCIRN members as a part of their recruitment plan.

Annual Action Plan
Provide a 12-month action plan using SMART goals and objectives to include a progressive timeline for completion of activities.

Evaluation Plan/Performance measurement
Applicants must provide an evaluation and performance measurement plan that demonstrates how the recipient will fulfill the requirements described. The evaluation plan must meet SMART goals and be consistent with the CDC evaluation framework (https://www.cdc.gov/evaluation/). A plan to evaluate data gathered as part of the research plan should be included.

Data Management Plan
If the applicant is collecting public health data, a standalone data management plan that addresses the 5 elements of AR-25 must be submitted in the Other Plan(s) section of the application.
https://www.cdc.gov/grants/additional-requirements/ar-25.html

Dissemination & Translation Plan

Component A: LCIRN Collaborating Centers (Required)
The applicant should propose specific dissemination and translation products or strategies for each research activity within the project the applicant is applying for. Products and strategies may include but are not limited to:

1. National marketing campaigns
2. Implementation toolkits
3. 'Promising practices' or 'Best practices' guides
4. Policy or practitioner briefs
5. Manuscripts
6. Webinars
7. Presentations

Component B: LCIRN Coordinating Center - Optional (if funding more than 1 PRC)
In addition to the dissemination and translation that is described as a part of the section "Project Activities and Submission Requirements for component B", applicants should also describe

- A process for collecting and distributing products and resources developed by LCIRN members
- Plans to support translation efforts across collaborating centers, including but not limited to development of toolkits or publication of peer-reviewed articles.
- Plans to develop and distribute the evaluation report of the network activities and collaborations
- Plans to develop and disseminate the 2029 open LCIRN agenda

Public Health Impact

Improved adoption and sustainability of LCIs that serve populations of focus
Increased enrollment and retention of populations of focus in LCIs
Increased engagement in risk reduction strategies for populations of focus (e.g., increased

physical activity and improved nutrition)
Increased health equity in chronic disease prevention and management

Special Eligibility and Responsiveness
None.

Additional Review Criteria
In addition to the standard review criteria (Significance, Approach, Innovation, Investigators, and Environment) used to evaluate the scientific and technical merit of research applications, the following additional review criteria specific to this SIP will be considered in the determination of scientific merit and the priority score:

Component A: LCIRN Collaborating Centers (Required)
Study Methods and Design

- Does the applicant propose a rigorous study design and identify appropriate potential data sources to accomplish the required objectives?
- (Where applicable) Does the proposed plan include adequate sample size to achieve the study outcomes? Does the applicant describe an approach to optimize data collection, validation, and quality control?

Study Populations

- Does the applicant demonstrate evidence of successful experience with recruitment and retention of hard-to-reach populations and/or LCI stakeholders such as insurance companies?

Project Team

- Does the research team include staff with the skills and expertise needed to develop the dissemination and translation products proposed?
- (Where applicable) Does the applicant demonstrate experience with (or demonstrate a commitment from a subcontractor who has experience with) marketing of prevention programs to different populations of focus with varying motivations?

Collaborations/Partnerships

- Does the applicant demonstrate successful experience working with federal, state, or local public health and other social service agencies?
- Does the applicant demonstrate experience working with LCIs and LCI stakeholders?

Dissemination and Translation

- Does the applicant describe experience creating translation and dissemination products targeting public health practitioners, stakeholders of LCIs, decision makers?
- Does the applicant describe how the results from the research findings will be translated, disseminated, and ultimately scaled?

Component B: LCIRN Coordinating Center -

In addition to the review criteria in component A above, the following additional review criteria for Component B applications specific to this SIP will be considered in the determination of scientific merit and the priority score:

Collaborations/Partnerships

- Does the applicant provide evidence of successful experience fostering growth and development of networks or large-scale collaborations?
- Does the applicant include staff in their plan that have significant experience leading large networks or collaborations?
- Does the applicant provide evidence of working with multiple stakeholders to develop research priorities or research agendas?

Evaluation

- Does the applicant demonstrate experience successfully evaluating networks and collaborations?
- Does the applicant propose a sufficient evaluation plan for the network?

Funding Preferences

Selection to ensure that only one applicant is funded for each of the four projects of the Collaborating Centers of Component A.

Research Plan Length and Supporting Material

The Research Strategy Section of the Research Plan is limited to a maximum of 12 pages. Supporting material included as appendices may not exceed 10 PDF (maximum of 30 pages) attachments. The appendices should include materials that show evidence of the applicant's ability to successfully conduct the proposed project and other evidence deemed necessary to support the contents of the SIP.

Availability of Funds

It is anticipated that approximately **$10,000,000** is available to fund up to **4** Prevention Research Center(s) for a 4-year period of performance. Funding may vary and is subject to change. Funding available includes direct and indirect costs.

Component A: LCIRN Collaborating Centers

Period of Performance: 4-year period of performance. 09/30/2025-09/29/2029
Estimated total funding (direct and indirect costs) per year: $1,500,000
Estimating total funding (direct and indirect) per recipient per year: $500,000.

Year-1 ceiling: $500,000

Estimated number of awards: 3

Component A and B: LCIRN Collaborating and Coordinating Center

Period of Performance: 4-year period of performance. 09/30/2025-09/29/2029.
Estimated total funding (direct and indirect costs) per recipient per year: $1,000,000

Estimated funding (direct and indirect costs) per year: $1,000,000
Year-1 ceiling: $1,000,000
Estimated number of awards: 1

Research Status
This project will not involve human subjects research; therefore, it will not require local or CDC IRB approval.

OMB/PRA
OMB/PRA is not expected to apply

Award Administration
CDC staff will serve as consultants on this project, and will provide technical assistance, as requested, on project activities such as evaluation design, data collection and analysis, and data interpretation and dissemination of results. CDC staff may be co-authors on manuscripts. However, CDC staff will not have contact with human subjects or data collected from human subjects.

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SIP25-005 Understanding the potential of early childcare and education (ECE) centers in promoting childhood vaccines and RSV prevention products

Project Description

ECE centers (i.e., daycare facilities) for infants, toddlers, and preschool aged children can serve as trusted sources of information for parents and guardians of young children. Although ECE centers play a clear role in ensuring young children receive vaccines mandated by law, there is potential for them to play an additional role in promoting other ACIP-recommended vaccines for young children, such as influenza and COVID-19 vaccines, as well as nirsevimab for infants and maternal respiratory syncytial virus (RSV) vaccine for pregnant parents. While many young

children do receive recommended vaccines according to the ACIP immunization schedule, efforts are needed to ensure that children who have missed vaccination are caught up on all routinely recommended vaccines to prevent disease outbreaks (1) and to ensure that as many children as possible are up-to-date for kindergarten entry with all required vaccines (2) Staff at ECE centers can serve as “trusted messengers” to build vaccine confidence among families of preschool aged children. ECE centers communicate directly with parents through multiple means, such as by sending emails and text messages, through school newsletters and social media posts, by sending printed information home with children or at events that include parents. While studies have looked at risk perceptions and health-seeking behaviors among parents of children attending ECE centers (3), and while educational materials on the importance of pediatric vaccinations have been created for ECE centers (4), there is little information about whether and to what extent ECE-originating communications and other simple interventions offering education and encouraging vaccinations beyond those mandated by law, or directing families to vaccination services, can motivate parent behavior. **The purpose of this project is to assess the potential of ECE-originating vaccination-related education, communications, and/or other simple interventions to impact parent attitudes toward uptake of non-mandated childhood vaccines (e.g., COVID- 19, influenza), maternal RSV vaccine, and nirsevimab.** Additionally, the purpose of this project is to identify effective ECE-originating interventions that influence parental/caregiver attitudes toward childhood vaccination, by analyzing how (if at all) parental attitude and intention to vaccinate has changed pre- and post-ECE intervention.

Project Objectives and Outcomes

The primary objective will be to assess the potential of ECE-originating vaccination-related education, communications, and/or other outreach strategies to impact parental knowledge, attitudes, and beliefs towards receiving routinely recommended childhood vaccines, maternal RSV vaccine (if applicable), and nirsevimab (if applicable). The applicant will develop at least one novel ECE-originating vaccination-related education/communication intervention and test that intervention(s) among parents and caregivers of children attending the ECE center. A secondary objective will focus on acceptability of intervention(s) conducted at ECE centers among parents and caregivers. Another secondary objective will focus on assessing the acceptability of various ECE-originating intervention(s) among parents across multiple ECE centers from a variety of socio-demographic backgrounds. Given that there are multiple unique demographic subpopulations with children who are unvaccinated or under-vaccinated, this project should include ECE centers from multiple sociodemographic backgrounds (e.g., high income vs. low income; highly educated parents vs. less educated parents; urban vs. rural) to assess impact of ECE-originating vaccination-related education/messaging among parents from different subpopulations.

The primary outcome will be to develop a report summarizing the novel intervention(s) that was developed and implemented at ECE centers. Additionally, this report should highlight the novel intervention(s) that proved to be particularly effective at improving parental knowledge, attitudes, and beliefs towards childhood immunizations pre- and post- intervention. This report may also highlight how (if at all) the effectiveness of each implemented intervention varied based on ECE sociodemographic factors. A secondary outcome will be to develop a report that summarizes the acceptability of each implemented ECE-originating intervention among parents

and caregivers.

This project meets ISD's and NCIRD's mission to protect individuals and communities from vaccine-preventable diseases (5). Findings from this project will allow for data-informed decision making and development of public health interventions to improve vaccine uptake among young children.

Healthy People 2030 Objectives *(Mandatory)*
This project contributes to multiple Healthy People 2030 goals to increase uptake of routinely recommended vaccines among infants, toddlers, and young children (IID-02, IID-03, IID-04, IID-06, IID-09, IID-D03).

Project Activities and Submission Requirements
Applications submitted in response to this SIP should present a **Research Plan** that addresses the following requirements listed below:

Study design and methods
Applicants should describe plans to design, conduct, and analyze a study of parents and caregivers that participate in ECE centers that incorporate various parent/caregiver-focused communications and policy interventions aimed at increasing uptake of routine vaccinations among young children. The applicant should consider employing a rigorous study design (e.g., RCT) that will have adequate power to demonstrate primary outcomes.
Applicants should describe how ECE centers and participants will be recruited. Applicants should select ECE centers that span a range of teaching styles (Montessori vs. traditional), business models (for profit vs. non-profit vs. faith based), size (large vs. small), business locations (residential vs. non-residential), and Head Start programs.
The applicant may consider randomizing ECE centers to an intervention arm(s) or a control arm in which ECE centers continue with standard practices. Specific intervention(s) will be designed by the awardee and will be informed by initial formative research with parents of young children and ECE administration and health officials. Interventions will include at least one arm which includes vaccine-related, parent-focused messaging only. Primary outcome will be to assess the effectiveness of the intervention at improving the knowledge, attitudes, and beliefs among parents and caregivers towards receiving routinely recommended childhood vaccines, maternal RSV vaccine (if applicable), and nirsevimab (if applicable). Secondary outcomes will focus on acceptability of the intervention(s) conducted at ECE centers among parents and caregivers.

Applicants are expected to propose a study that includes the following activities:

1. Applicants should include a plan to solicit participation of ECE centers representing parental sociodemographic diversity, as described above.
2. Applicants should include a plan to conduct formative research to inform an intervention trial. As part of this process, awardee will assess if ECE staff currently serve as "trusted messengers" of health-related information (or how much parents engage ECE staff with questions about pediatric health issues, including vaccination). Awardee will use this formative research to guide and design the appropriate intervention(s).

3. Focus groups of parents of children, ECE administrators, and health officials will be held for message-testing and to explore acceptability and feasibility of the proposed intervention(s).
4. Awardee will develop and propose at least one parent-focused intervention. The intervention(s) may involve a multi-pronged approach and/or require stakeholder buy-in (consider trusted messenger training and vaccine education of ECE staff, etc.).
5. ECE centers will be recruited for the study and then randomized to study arms.
6. A sample of parents from each study arm will be surveyed prior to and following the intervention to assess vaccination-related knowledge, attitudes and other health behaviors (e.g., adherence to well-child visit schedule), trusted sources of health information, personal and child vaccination status, etc. Additionally, parental intent to vaccinate their children will be assessed pre- and post- intervention.
7. Intervention(s) will be implemented.
8. Analysis will be carried out.
9. Awardee will assess the effectiveness, feasibility, acceptability, and cost of the intervention(s).
10. Final report highlighting findings will be developed and disseminated.

Applicants should provide a translation and dissemination plan for their intervention, should it be found to be effective. The material(s), the audience(s), and the setting(s) for the intervention should be described. Additionally, any partner(s) who would be helpful in effectively implementing or disseminating information about the developed intervention(s) should be noted.

Population of Focus

There are multiple unique demographic sub-populations with children who are un-vaccinated or under-vaccinated, so it is important to recruit ECE centers from multiple backgrounds to assess variability in the impact of ECE-originating messaging for parents from different sub-populations. This includes ensuring that there is parental socio-demographic diversity, income diversity, parental educational diversity, urban vs. rural, etc. Additionally, the selected ECE centers should also span a range of teaching styles as much as is practical (Montessori vs. traditional), business models (for profit vs. non-profit vs. faith based), size (large vs. small), business locations (residential vs. non-residential), and Head Start programs.

Collaboration/Partnerships

Community partnerships and engagements are crucial to improving childhood vaccination uptake. The following collaborations and partnerships are expected and the applicant should describe partners, their roles, and how they will be engaged/collaborate throughout the period of performance to accomplish the proposed SIP activities including any partnership groups or advisory boards. The applicant should describe any collaboration with ECEs, healthcare providers, local and state public health, as well as faith-based and non-governmental organizations.

In addition, the applicant should describe partnerships among representatives from the population of focus (e.g., parents and caregivers), such as describing the process of recruiting

parents/caregivers to help inform the development of survey tools and to potentially serve as vaccine champions in their local community.

Recruitment Plan
The applicant should describe their plans to recruit ECE centers to participate in the study. Besides representing diverse socioeconomic backgrounds, the selected ECE centers should also span a range of teaching styles (Montessori vs. traditional), business models (for profit vs. non-profit vs. faith based), size (large vs. small), business locations (residential vs. non-residential), and Head Start programs.

Annual Action Plan

1. Provide a 12-month action plan using SMART goals and objectives to include a progressive timeline for completion of activities.
2. Within a 12-month period, establish collaborations and partnerships to recruit ECE centers that serve diverse populations of children from various socioeconomic backgrounds and span a range of size, geographic locations, teaching styles, and business models.
3. Within a 12-month period, develop parameters to assess how ECE-originating vaccination-related education, communications, and other simple interventions impacts parental attitudes toward uptake of non-mandated childhood vaccines (e.g., COVID- 19, influenza), maternal RSV vaccine, and nirsevimab.

Evaluation Plan/Performance measurement
Applicants must provide an evaluation and performance measurement plan that demonstrates how the recipient will fulfill the requirements described. The evaluation plan must meet SMART goals and be consistent with the CDC evaluation framework (https://www.cdc.gov/evaluation/). A plan to evaluate data gathered as part of the research plan should be included.

Data Management Plan
If the applicant is collecting public health data, a standalone data management plan that addresses the 5 elements of AR-25 must be submitted the Other Plan(s) section of the application.
https://www.cdc.gov/grants/additional-requirements/ar-25.html

Dissemination & Translation Plan
A final report highlighting findings from this project will be developed and disseminated, as described above.In addition, job aids and/or fact sheets may be developed and may be used in conjunction with ongoing campaigns or initiatives (e.g., Let's RISE School Toolkit). Such materials will be targeted to education professionals working at ECE centers, and/or public health personnel working at jurisdictional health departments.

Public Health Impact
The goal of this project is to assess the potential of ECE-originating vaccination-related education, communications, and/or other simple interventions to impact parental attitudes toward

uptake of: 1) non-mandated childhood vaccines (e.g., COVID-19, influenza), 2) maternal RSV vaccine, and 3) nirsevimab so that children are up-to-date on vaccinations by kindergarten.

Special Eligibility and Responsiveness
The following criteria specific to this SIP will be used to determine the institution's eligibility and responsiveness:
None

Additional Review Criteria
In addition to the standard review criteria (Significance, Approach, Innovation, Investigators, and Environment) used to evaluate the scientific and technical merit of research applications, the following additional review criteria specific to this SIP will be considered in the determination of scientific merit and the priority score:
Prior experience working with ECE centers or conducting ECE intervention research is preferred, but not required. Prior experience with quantitative/qualitative survey research methods (especially among parents/caregivers) is preferred, but not required.

Funding Preferences
The following preferences specific to this SIP will be considered in the funding decision:
None

Research Plan Length and Supporting Material
The Research Strategy Section of the Research Plan is limited to a maximum of 12 pages. Supporting material included as appendices may not exceed 10 PDF (maximum of 30 pages) attachments. The appendices should include materials that show evidence of the applicant's ability to successfully conduct the proposed project and other evidence deemed necessary to support the contents of the SIP.
N/A

Availability of Funds
It is anticipated that approximately **$1,500,000** is available to fund **1** Prevention Research Center(s) for a **3-year** period of performance. The average award for each recipient is expected to be approximately **$500,000** for year one. The year one ceiling per recipient is **$500,000**. Funding may vary and is subject to change. Funding available includes direct and indirect costs.

Research Status
This project will be non-exempt research involving human subjects. It is anticipated that this project will require local IRB approval. Applicants should provide a federal wide assurance number for each performance site.

OMB/PRA
OMB/PRA is not expected to apply

Award Administration

CDC staff will serve as consultants on this project, and will provide technical assistance, as requested, on project activities such as evaluation design, data collection and analysis, and data interpretation and dissemination of results. CDC staff may be co-authors on manuscripts. However, CDC staff will not have contact with human subjects or data collected from human subjects.

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SIP25-006 Overdose Prevention and Treatment Research Network (OPTRN)

Project Description

In 2023, more than 100,000 overdose deaths were reported in the United States; most (>80,000) involved opioids (1). It is unknown which of the recommended prevention strategies to prevent overdoses and overdose deaths should be scaled nationally. As one important example, medications for opioid use disorder (OUD) substantially reduce overdose-related and overall mortality (2) and are strongly recommended by CDC and others (3) but are markedly underused. In 2022, an estimated 9.4 million Americans needed OUD treatment, but only one quarter (25.1%) received medications for OUD (4). From mid-2023 to mid-2024, 224,068 nonfatal overdoses presenting in Emergency Departments (EDs) were recorded in CDC's Drug Overdose Surveillance and Epidemiology (DOSE) system (CDC data). Previous opioid overdose is associated with substantially increased risk for future nonfatal or fatal opioid overdose (5). ED visits and hospitalizations for OUD-related problems, including overdose, represent opportunities for initiation of medications for OUD. Initiation of medications for OUD within 7 days of ED visit or hospitalization has been associated with reduced risk for fatal or nonfatal overdose at 6 months (6). However, at a national level, few patients seen at EDs for OUD or overdose receive medications for OUD (7,8). Clinician-reported barriers to initiating medications for OUD include too little experience treating OUD (9) and uncertainty about where the patient can receive follow-up care to continue receiving medications for OUD. Between 2019 and 2023,

the California (CA) Bridge Program used a combination of support for hospitals for a local clinical champion and a patient navigator along with training and technical assistance to increase initiation of medication (buprenorphine) for OUD in the ED (10). From the first month of implementation to the final month of data reporting, hospitals funded by CA Bridge reported increases in encounters where buprenorphine was administered or prescribed ($P < .001$) from a median of 1 (IQR 0–5; range 0–80) to 5 (IQR 1–15; range 0–167). However, there was wide variation between higher- and lower-performing sites in the CA Bridge initiative (10).

It is unknown whether increases in buprenorphine administration would be sustained without continued external support for patient navigators, whether other innovative approaches (e.g., refinement of existing protocols/resources (11) and implementation of locally-adapted protocols for post-overdose and OUD care, including identification of treatment resources available in the community for continued OUD treatment and establishment of a network of referral options; training and technical assistance for primary care clinicians in the community to continue treatment for patients initiated on buprenorphine in the ED); or other initiatives such as quality performance incentives could improve buprenorphine initiation rates.

CDC's Division of Overdose Prevention seeks to establish the Overdose Prevention and Treatment Research Network (OPTRN) with this special interest project (SIP). The OPTRN will consist of multiple collaborating center recipients and one coordinating center recipient. All recipients of this SIP will identify, implement, and evaluate innovative, feasible, and sustainable strategies to increase effective care for people who use drugs and prevent overdoses, such as ED initiation of buprenorphine for OUD and retention in treatment with medications for OUD after ED encounters. Multiple collaborating centers may work together to facilitate testing of different strategic components as well as sharing of expertise across centers, given existing variation in extent of experience with interventions to increase initiation of and retention in evidence-based care for OUD. The Coordinating Center recipient will facilitate and support collaborative research activities among all OPTRN recipients, their partners, and affiliates; and help support the translation and dissemination of findings. OPTRN Collaborating Centers will complete activities listed in Component A below. This SIP is expected to have the greatest impact for patients presenting to EDs where initiation of buprenorphine for OUD is not yet routine; however, the presence of at least one local clinician initiating buprenorphine for OUD in the ED who can serve as a local champion is likely to increase the success of the SIP. Therefore, applications from potential Collaborating Centers with participating EDs where, at baseline, buprenorphine for OUD is initiated for some (>0%) but not most (<40%) patients presenting with overdose or signs of OUD will be prioritized. The OPTRN Coordinating Center will complete activities included for both Component A and B listed below.

Project Objectives and Outcomes

Component A: Research Project (Required)
Objectives:

1. Identify and evaluate effectiveness and sustainability of at least two promising strategies (strategies with a strong rationale or inclusion of characteristics of effective strategies or best practices and limited evidence of and/or sustainability) to increase initiation of

evidence-based care (i.e., medications for OUD) for patients with OUD in the ED and linkage to ongoing evidence-based treatment. Strategies can be implemented and tested in combination in one or more clinical sites, or for Collaborating Centers with more than one participating clinical sites, different strategies can be implemented in different clinical sites. Sustainability might be assessed by evaluating outcomes such as buprenorphine initiation for OUD several months to a year after completing initiation of a new strategy as well as before and immediately after initiation of a new strategy. Estimation of ongoing costs for maintaining a strategy might also contribute to evaluation of sustainability. Promising strategies might include the following:

a. Development and implementation of practice-specific protocols for post-overdose and OUD care that describe elements such as how patients will receive buprenorphine until outpatient treatment is established (e.g., hospital dispensing of a limited supply of buprenorphine), identification of treatment resources available in the community (e.g., local or virtual primary care, addiction medicine, addiction psychiatry, or Opioid Treatment Programs) for continued OUD treatment, and establishment of a network of referral options spanning the levels of care that patients might need to enable rapid collaboration and referral
b. Building capacity of ED clinicians to identify and effectively treat patients with OUD presenting to the ED. Strategies can be tailored to the needs of local clinicians (e.g., mentoring or consultation available in real time while clinicians are managing patients in the ED, and/or webinars available asynchronously on demand) to develop practice-based evidence on effectiveness.
c. Training and technical assistance for primary care clinicians in the community to continue treatment for patients initiated on buprenorphine in the ED.
d. Support for patient navigator(s)
e. Quality performance initiatives (12) (e.g., developing measures and providing feedback to clinicians on numbers or percentages of patients with opioid-related problems who are screened for OUD, initiated on medication for OUD, and linked to outpatient treatment for OUD)
f. For one of their strategies, sites can propose to implement and test another innovative approach with a strong rationale for but unknown effectiveness, or a strategy with evidence of effectiveness but unknown sustainability.

Outcomes:

1. Identify a set of effective and sustainable strategies for increasing buprenorphine treatment for ED patients.
2. Improve knowledge for a set of strategies to build capacity of ED clinicians to identify and effectively treat patients with OUD presenting to the ED.

Component B: Coordinating Center - Optional

Objectives:

1. Facilitate and support collaborative research activities among network members, their partners, and affiliates.

2. Lead and facilitate network discussions related to strategic planning, and the development of research expertise in the application of proven overdose prevention and OUD treatment initiation and linkage strategies in community and clinical settings.
3. Facilitate collaborative research across collaborating centers, network planning and discussions regarding the development and completion of research activities related to implementation of evidence-based overdose prevention and OUD treatment initiation and linkage strategies.
4. Facilitate connections among collaborating centers and non-members such as national, state, and local partners to advance efforts aligned with OPTN's mission.
5. Coordinate the evaluation of network activities and impact.
6. Lead and facilitate network discussions related on identification and evaluation of effectiveness and sustainability of promising strategies to increase initiation of evidence-based care (i.e., medications for OUD) for patients with OUD in the ED and linkage to ongoing evidence-based treatment.
7. Lead and facilitate network discussions related to important measures to consider when implementing initiation of evidence based treatment in ED (e.g., number and percent of individuals entering the ED with a nonfatal opioid-related drug overdose or with other opioid-related problems who are identified as having OUD; who receive buprenorphine in the ED; leave with a prescription for buprenorphine, are referred to ongoing treatment outside of the ED; who receive at least one dose of buprenorphine outside of the E
8. Support translation of findings across the network.
9. Coordinate broad dissemination of findings Nationally (e.g., webinars, technical resources, peer-reviewed publications).

Outcomes:

1. Increase numbers of network-associated ED clinicians who initiate medications (e.g., buprenorphine) for patients with OUD in the ED

2. Increase across the network, for patients presenting to the ED with overdose and other opioid-related problems:

a. ED identification of patients with OUD
b. Initiation of evidence-based treatment (i.e., medications for OUD)
c. Linkage to continued evidence-based treatment (i.e., medications for OUD)

3. Broadly available (beyond the network) resources for EDs, health systems, and clinicians to consult to facilitate initiation of medications for OUD in the ED and linkage to ongoing treatment.

Healthy People 2030 Objectives
Reduce the proportion of people who had opioid use disorder in the past year — SU-18
Increase the rate of persons with an opioid use disorder receiving medications for addiction treatment (developmental objective)

Project Activities and Submission Requirements
Applications submitted in response to this SIP should present a **Research Plan** that addresses the following requirements for both components listed below:

Component A: Research Project (Required)
The Research Plan for the Collaborating Centers should contain the following sections: (a) Previous experience delivering and testing effectiveness of capacity building approaches to improve clinical practice or previous experience testing effectiveness and sustainability of ED interventions. (b) Research questions, (c) Data sources and data collection, (d) Data Management Plan, (e) Outcomes, and (f) Dissemination of results.

Applications should present a Research Plan that addresses the following content:

1. Demonstrate existing infrastructure and track record to successfully implement this project
2. Baseline frequency of buprenorphine initiation for patients with overdose or signs of OUD
3. Established data collection protocols/systems to enable the applicant to begin collecting data quickly
4. Strategies for sharing insights and promising practices across OPTRN

Component B: Coordinating Center - Optional
The Research Plan for the Coordinating Center should contain the following sections: (a) Previous experience coordinating improvement efforts across clinical practices or EDs (b) Research questions, (c) Approach to supporting the Network members, (d) Data sources and data collection, (e) Data Management Plan, (f) Outcomes, and (g) Dissemination of results.
Applications should present a Research Plan that addresses the following content:

1. Engage and manage a geographically diverse network through facilitated monthly meetings and other communication strategies
2. Facilitate experiential learning by coordinating and/or providing interactive peer-learning education for the network;
3. Provide subject matter expertise and leadership to the network in initiating buprenorphine in the ED and in linkage to ongoing treatment (see Project Objectives and Outcomes section). depth of expertise in building clinician capacity to initiate evidence-based OUD treatment for socioeconomically diverse populations.
4. Provide technical assistance to Component A sites in geographically diverse settings with variable local capacity for linkage to continuing OUD treatment.

Study design and methods
Applications should present a rigorous research study approach/design examining effectiveness and sustainability that is appropriate to capture necessary data components to answer the research questions.

Population of Focus

Component A: Research Project (Required)

Applicants should propose projects that focus on increasing evidence-based care for socioeconomically diverse patients with OUD presenting to EDs. Including disproportionately affected populations (e.g., American Indian/Alaska Native and Black persons, who have high rates of fatal overdose (13); younger and older adults, who are less likely to receive medications when treated for OUD (4), and individuals living in underserved areas, including rural and other counties without Opioid Treatment Programs (14) is desirable and may be factored into scoring). The SIP is expected to have the greatest impact for patients presenting to EDs where initiation of buprenorphine for OUD is not yet routine; however, the presence of at least one local clinician initiating buprenorphine for OUD in the ED who can serve as a local champion is likely to increase the success of the SIP. Therefore, applications for Component A from centers with participating EDs where, at baseline, buprenorphine for OUD is initiated for some (>0%) but not most (<40%) patients presenting with overdose or signs of OUD will be prioritized.

Component B: Coordinating Center - Optional

Applicants should describe how they will provide technical assistance to Component A sites in building clinician capacity to initiate evidence-based OUD treatment for socioeconomically diverse populations in geographically diverse settings with variable local capacity for linkage to continuing OUD treatment.

Collaboration/Partnerships

Component A: Research Project (Required)

Collaborating center recipients will collaborate with EDs as clinical sites for the project and with clinicians in the EDs to increase initiation of and linkage to ongoing treatment for OUD. To develop and evaluate strategies to increase local capacity to accept patients for continuing treatment for OUD, PRCs should engage local programs and outpatient clinicians (e.g., primary care clinicians, psychiatrists) through health systems or other organizations. PRCs may collaborate with partners to deliver technical assistance or training to clinicians or patient navigators. Component A sites will collaborate with the Coordinating Center in building clinician treatment capacity and expertise and in evaluating outcomes across the network.
If collaborating center recipients are located in cities, counties, or states funded by CDC's Division of Overdose Prevention Overdose Data to Action (OD2A) cooperative agreement (which seeks to reduce drug overdoses and the impact of related harms), collaborating center recipients are encouraged to explore partnerships. Among multiple other strategies, funded OD2A jurisdictions work to engage clinicians/health systems, enhance IT/PDMP and increase community-based linkage to care.

Component B: Coordinating Center - Optional (if funding more than 1 PRC)

The Coordinating Center will work with the collaborating center (Component A) recipients to build clinician treatment capacity and expertise and in evaluating outcomes across the OPTRN. Collaborations will include professional clinical organizations such as the American College of Emergency Physicians, the American Society of Addiction Medicine, and the American Hospital Association to facilitate dissemination of results and to promote successful strategies. The Coordinating Center is encouraged to collaborate with CDC's OD2A program and may collaborate with national partners who support at-risk populations. Funded OD2A jurisdictions

work to engage clinicians/health systems, enhance IT/PDMP and increase community-based linkage to care. Collaboration with the PRC's state and/or local jurisdiction(s)' health department is also encouraged.

Recruitment Plan
Applicants for Component A should include a description of the proposed approach for identifying, engaging, and working with one or more EDs with sufficient clinician staff and visit volume to allow for meaningful increases in ED clinician expertise and treatment capacity, and in treatment initiation for individual patients with OUD. Applicants for Component A should describe how clinical sites can contribute diversity (e.g., geographic, socioeconomic) to the overall study population across the network. Applicants for Component A should describe plans to recruit sites that serve the population of focus.

Annual Action Plan
Provide a 12-month action plan using SMART goals and objectives to include a progressive timeline for completion of activities.

Evaluation Plan/Performance measurement
Applicants must provide an evaluation and performance measurement plan that demonstrates how the recipient will fulfill the requirements described. The evaluation plan must meet SMART goals and be consistent with the CDC evaluation framework (https://www.cdc.gov/evaluation/). A plan to evaluate data gathered as part of the research plan should be included.

Data Management Plan
If the applicant is collecting public health data, a standalone data management plan that addresses the 5 elements of AR-25 must be submitted in the Other Plan(s) section of the application.

https://www.cdc.gov/grants/additional-requirements/ar-25.html

Dissemination & Translation Plan

Component A: Research Project (Required)
The applicant should incorporate translation of findings and lessons learned into locally appropriate clinical protocols and disseminate protocols or lessons learned to clinicians and trainees, using methods such as trainings, talks/webinars, and practice tools (e.g., flow charts, EHR prompts). Dissemination of results to the PRC's state and/or local jurisdiction(s)' health department is encouraged. All dissemination and translation efforts are intended to help other EDs adopt and incorporate successful approaches to support ED initiation of buprenorphine for OUD and retention in treatment with medications for OUD after ED encounters.

Component B: Coordinating Center - Optional
The applicant should coordinate broad dissemination of findings beyond the OPTRN (e.g., webinars, technical resources, peer-reviewed publications) and to coordinate production of broadly available (beyond the network) resources (e.g., technical resources, peer-reviewed publications) for EDs, health systems, and clinicians to consult to facilitate initiation of

medications for OUD in the ED and linkage to ongoing treatment. The Coordinating Center is encouraged to collaborate and/or disseminate results to CDC's OD2A program. All dissemination efforts are intended to help other EDs adopt and incorporate successful approaches to support ED initiation of buprenorphine for OUD and retention in treatment with medications for OUD after ED encounters.

Public Health Impact
Medications for OUD substantially reduce overall and overdose-related mortality and are strongly recommended by CDC and others but are markedly underused. ED visits for nonfatal overdose (estimated at 224,068 for the year ending in June 2024 in CDC's DOSE system) represent opportunities for initiation of medications for OUD. Initiation of medications for OUD within 7 days of an ED visit or hospitalization has been associated with reduced risk for fatal or nonfatal overdose at 6 months, yet few patients seen at EDs with OUD or overdose receive medications for OUD. While there have been successful local and regional initiatives to increase ED initiation of and linkage to ongoing evidence-based treatment for OUD, there is a need to understand how to increase initiation and linkage to care more broadly in geographically diverse sites and to understand which components are necessary to be successful and sustainable. This project will inform CDC Division of Overdose Prevention programmatic efforts for jurisdictions funded for CDC's OD2A cooperative agreement, including linkage to care surveillance in OD2A-Local and health system initiatives in OD2A-State.

Special Eligibility and Responsiveness
The following criteria specific to this SIP will be used to determine the institution's eligibility and responsiveness:

Component A: Research Project (Required)
Special Eligibility Requirement: Access to the proposed study population. Specifically, the PRC must demonstrate previous or current relationships/collaboration with at least one ED where patients present with nonfatal overdose and/or other opioid-related problems.

Responsiveness Criteria: The applicant must provide documentation (e.g., a letter of support or memorandum of agreement), demonstrating evidence of access to the study population and assuring access to the populations in which the study will be conducted in Appendix 1.
Special Eligibility Requirement: The PRC's team must include experts in ED initiation of medications for OUD.

Responsiveness Criteria: The PRC's team includes one or more researcher with expertise in initiation of medications for OUD. Evidence of expertise of team members should be shown in the Research & Related Senior/Key Person Section of the SF424 (R&R).

Component B: Coordinating Center - Optional
Special Eligibility Requirement: The Coordinating Center must include experts in building clinician capacity for initiation of medications for OUD in acute settings. The Coordinating Center must have experience in facilitating and supporting collaboration across a network of organizations.

Responsiveness Criteria: Team includes one or more researcher with expertise in building clinician capacity for initiation of medications for OUD in acute settings. Evidence of expertise of team members should be shown in the Research & Related Senior/Key Person Section of the SF424 (R&R).

Additional Review Criteria

In addition to the standard review criteria (Significance, Approach, Innovation, Investigators, and Environment) used to evaluate the scientific and technical merit of research applications, the following additional review criteria specific to this SIP will be considered in the determination of scientific merit and the priority score:

Component A: Research Project (Required)

- Does the applicant have a proposed plan that includes adequate sample size to achieve the study outcomes?
- Does the applicant demonstrate that collaborating EDs at baseline are initiating buprenorphine for OUD in a range including some (>0% but <40%) patients presenting with overdose or signs of OUD?
- Does the applicant's proposed research team demonstrate experience in and commitment to initiating buprenorphine in the ED?
- Does the applicant demonstrate successful experience evaluating the impact of public health interventions?
- Does the applicant demonstrate an understanding of all aspects of the evaluation (i.e., evaluating implementation, costs, effectiveness, scalability)?

Component B: Coordinating Center - Optional (if funding more than 1 PRC)

- Does the applicant demonstrate evidence of successful experience working with partners, including a group of academic institutions around a common agenda?
- Does the applicant demonstrate depth of expertise in building clinician capacity to initiate evidence-based OUD treatment for socioeconomically diverse populations?
- Does the applicant demonstrate that they are equipped to provide technical assistance to Component A sites in geographically diverse settings with variable local capacity for linkage to continuing OUD treatment?
- Does the applicant describe experience creating translation and dissemination products targeting public clinicians and/or health care system decision makers?
- Does the applicant describe how the results from the research findings will be translated, disseminated, and ultimately scaled to be used by clinicians and/or ED, hospital or health system leadership?
- Does the applicant demonstrate a successful collaboration and coordination track record (i.e., both capacity and experience) by executing a project of similar scope and complexity.

Funding Preferences

The following preferences specific to this SIP will be considered in the funding decision:

Component A: Research Project (Required)

1. Relevance of the proposed project to program priorities.
2. ED settings where OUD is initiated but for less than 40% of patients.
3. Geographic diversity and/or patient population diversity of study sites
4. Diversity across study sites in intervention components to be studied. In the event that all highest scored applicants study the same strategies, study sites with different objectives might be prioritized for funding to increase diversity of strategies tested.

Research Plan Length and Supporting Material (Components A and B)

All applicants of SIP 25-00X are REQUIRED to apply for Component A (Collaborating Center) and will serve as a member of the OPTRN.

Applicants that wish to serve as the OPTRN Coordinating Center in addition to a collaborating center MAY also apply for Component B.

Only 1 recipient will be funded for BOTH components A and B

- Applicants should indicate at the beginning of the Specific Aims, the respective Component(s) under which the application should be considered (A, or A and B).
- Components A (Collaborating center) and B (Coordinating Center) applicants must follow the Research Strategy page length provided below.

Research Strategy Length	
Components	**Maximum Number of Pages**
A	12
A & B	18

Supporting material included as appendices may not exceed 10 PDF (maximum of 30 pages) attachments. The appendices should include materials that show evidence of the applicant's ability to successfully conduct the proposed project and other evidence deemed necessary to support the contents of the SIP.

Availability of Funds

The estimated total funding (direct and indirect) for the 4-year period of performance is $6,000,000 to support up to 4 awards (as described below). Awards issued under this NOFO are contingent upon availability of funds and enough meritorious applications.

Component A: OPTRN Collaborating Centers

Period of performance: 4 years, 09/30/2025-09/29/2029

Estimated total funding (direct and indirect costs) per year: $1,050,000

Estimated funding (direct and indirect costs) per recipient per year: $350,000

Year 1 Ceiling: $350,000
Estimated number of awards: 3

Component A & B: OPTRN Network Collaborating and Coordinating Center
Period of performance: 4 years, 09/30/2025-09/29/2029
Estimated total funding (direct and indirect costs) per year: $450,000
Year 1 Ceiling: $450,000
Estimated number of awards: 1

Research Status
This project will be non-exempt research involving human subjects. It is anticipated that this project will require local IRB approval. Applicants should provide a federal- wide assurance number for each performance site.

OMB/PRA
OMB/PRA is not expected to apply.

Award Administration
CDC staff will serve as consultants on this project, and will provide technical assistance, as requested, on project activities such as evaluation design, data collection and analysis, and data interpretation and dissemination of results. CDC staff may be co-authors on manuscripts when appropriate. However, CDC staff will not have contact with human subjects or data collected from human subjects.

References

1. https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm
2. https://www.bmj.com/content/357/bmj.j1550
3. https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm#recommendations
4. https://www.cdc.gov/mmwr/volumes/73/wr/mm7325a1.htm
5. https://www.acpjournals.org/doi/10.7326/M15-0038
6. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2821275
7. https://www.sciencedirect.com/science/article/pii/S0735675724002468?via%3Dihub
8. https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2820177
9. https://www.sciencedirect.com/science/article/pii/S0376871621003069?via%3Dihub
10. https://ajph.aphapublications.org/doi/pdf/10.2105%2FAJPH.2024.307710
11. Illustrative examples of existing protocols/resources, note this is not a comprehensive list, the applicant may propose to refine something else: https://www.naccho.org/uploads/downloadable-resources/ED-based-substance-use-response-toolkit.pdf; https://nida.nih.gov/nidamed-medical-health-professionals/discipline-specific-resources/emergency-physicians-first-responders/initiating-buprenorphine-treatment-in-emergency-department/motivating-patients#case-1-opioid-overdose-ed-initiated-buprenorphine
12. https://www.sciencedirect.com/science/article/pii/S0196064418312083?via%3Dihub
13. https://www.cdc.gov/nchs/data/databriefs/db491-tables.pdf

14. https://www.everycrsreport.com/files/20190624_R45782_ed39091fadf888655ebd69729c3180c3f7e550f6.pdf