

Centers for Disease Control and Prevention

NATIONAL CENTER FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION

Health Promotion and Disease Prevention Research Centers: 2024 Special Interest Project Competitive Supplements (SIPS)

RFA-DP-24-062

03/04/2024

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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: 2024 Special Interest Project Competitive Supplements (SIPS)

Activity Code

U48

Notice of Funding Opportunity Type

New

Agency Notice of Funding Opportunity Number

RFA-DP-24-062

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 (SIP) 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-24-062, 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:
02/02/2024
Publication Date:

12/15/2023

Letter of Intent Due Date:

02/05/2024

Application Due Date:
03/04/2024
Application Due Date:

03/04/2024

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:
04/25/2024
Secondary Review:

06/24/2024

Estimated Start Date:
09/30/2024

Expiration Date:
03/05/2024

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.

Note: The Research Strategy component of the Research Plan is limited to 18 pages.

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

For this specific NOFO, the Research Strategy component of the Research Plan narrative is limited to 12 pages, except for applications to both Component A AND B of a thematic network, which are limited to 18 pages for the Research Strategy.

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.

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 $36,075,000. It is anticipated that up to 28 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 Project Period.** The estimated total funding (direct and indirect) for the first 12-month budget period, 9/30/2024 - 9/29/2025, is $8,775,000. See **Section VIII. Other Information - Special Interests Project Descriptions** for the funding amount and project period 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 2024. 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 2024 SIP research activities align with following the Healthy People 2030 topic areas: Arthritis, Cancer, Environmental Health, Epilepsy, Health Care, Health Communications, Maternal Infant Child Health, Mental Health and Mental Disorders, Nutrition, Physical Activity, People with Disabilities, and Vaccination/Immunizations.

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

Arthritis:

- Arthritis Management and Well-being Research Network: (A-01, A-02, A-03, A-04)

People with Disabilities (includes Epilepsy)

- Managing Epilepsy Well Network (MEW) (MHMD, HC)

Cancer:

- Understanding the needs of Ovarian Cancer Survivors (C-11, C-R01)
- Survivorship care plans and mortality among adult cancer survivors (C-11, C-R01)
- Cancer Prevention and Control Research Network (C1-C11))
- Gauging men’s reaction to relabeling of GG1 prostate cancer and understanding of pathology reports (C-08, C-R01)
- Understanding the impact of reducing social isolation and loneliness on health indices among cancer survivors (C-R01)

Health Communications:

- Mental Health and Chronic Disease Prevention Network (HIT-04)

Nutrition:

- Nutrition Obesity Policy Research and Evaluation Network (NWS-01, NWS-04, NWS-06, NWS-08, NWS-09, NWS-10, MICH15-16)

Physical Activity:

- Physical Activity Policy and Evaluation Research Network (PA01, PA-02, PA-06, PA-10, PA-11, EH02 and EVP06)

Immunizations:

- Advancing Research in Immunization Services Network (IID-02-11, IID-D01-IID-D03)

Vaccinations:

- Assessment of perceptions and effectiveness of interventions to increase MMR vaccination among children in close-knit communities with longstanding vaccine hesitancy (IID-02, IID-03, IID-04)
- Understanding the potential of schools in promoting non-mandated childhood vaccinations (IID-07, IID-08, IID-09)

Additional information on specific HP2030 and other National Strategic Priorities are described for each Special Interest Project in **Section VIII. Other Information, Special Interests Project Descriptions.**

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 expective objectives and outcomes during the reporting/funding period as described in **Section VIII. Other Information - Special Interest Project Descriptions.**

Target Population
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:

$36,075,000

Estimated BY Funding:

$8,775,000 (direct and indirect costs) for the first budget year.

Estimated Total Funding:

$36,075,000 (direct and indirect costs) for the entire period of performance.

Anticipated Number of Awards:

28

It is anticipated that 28 awards will be funded under this NOFO in the first year of funding.

Estimated BY Funding:

$8,775,000 (direct and indirect costs) for the first budget year.

Estimated Total Funding:

$36,075,000 (direct and indirect costs) for the entire period of performance.

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

Award Ceiling:

$675,000

Per Budget Period

Award Floor:

$0

Per Budget Period

Total Period of Performance Length:
60-month project period with five 12-month budget periods. 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 not 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.

Competition is limited to the 20 institutions approved for funding under CDC RFA-DP-24-004 as CDC Prevention Research Centers (PRCs). The institutions currently approved for funding 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

Competition is limited to recipients funded under RFA-DP-24-004 because they are uniquely positioned to perform, oversee, and coordinate applied public health promotion and chronic disease prevention research due to their established relationships with community partners.

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.
- 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, it will be deemed non-responsive and will not enter into the peer review process.

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

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Project Director/Principal Investigator (PD/PI) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for HHS/CDC support.

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.

Applicants may apply to more than one SIP listed in **Section VIII: Other Information - Special Interest 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 IX. Special Interest Project Descriptions.

The SIP PI/PD may be anyone that meets the qualifications from within the selected recipient PRC institution (RFA-DP-24-004 Core Award). 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-PI/PD.

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

Applicants must use FORMS-G application packages for due dates on or before January 24, 2023 and must use FORMS-H application packages for due dates on or after January 25, 2023.

Application guides for FORMS-G and 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.

Please use the form and instructions for SF 424 (R&R) **FORMS-H** for applications due on or after January 25, 2023.

3. Letter of Intent

Due Date for Letter Of Intent 02/02/2024

02/02/2024
Due Date for Letter Of Intent (LOI) 02/02/2024

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-24-0062: Health Promotion and Disease Prevention Research Centers -2024 Special Interest Projects (SIPS) Competitive Supplements

The LOI should be emailed to the CDC Scientific Program Official with subject line "NOFO RFA-DP-24-062" and the SIP proposal number which applicant will apply (i.e., SIP 24-001).

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 time line.
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. **Authentication of Key Biological and/or Chemical Resources**
12. **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 Resource Sharing Plan 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, or limitations to, 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);
- 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).

CDC OMB approved templates may be used (e.g. NCCDPHP template https://www.cdc.gov/chronicdisease/pdf/nofo/DMP-Template-508.docx)

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

Applicants must use FORMS-G application packages for due dates on or before January 24, 2023 and must use FORMS-H application packages for due dates on or after January 25, 2023.

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

Consortium/Contractual Arrangements: Subcontracts may not exceed 50% of the total award.

Please use the form and instructions for SF424 (R&R) **FORM-H** for applications due on or after January 25, 2023.

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.

Applicants must use FORMS-G application packages for due date on or before January 24, 2023 and must use FORMS-H application packages for due dates on or after January 25, 2023.

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

Please use the form and instructions for SF424 (R&R) **FORMS-H** for applications due on or after January 25, 2023.

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/web/grants/support.html
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 03/04/2024

03/04/2024
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 Resource Sharing Plan(s) section of the PHS398 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, privacy and confidentiality considerations, embargo issues).

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. Other Submission Requirements and Information

Risk Assessment Questionnaire Requirement

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

CDC requires all applicants to complete the Risk Questionnaire, OMB Control Number 0920-1132 annually. This questionnaire, which is located at

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

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

Duplication of Efforts

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

Report Submission: The applicant must upload the report 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/organization/mission.htm), 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 clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

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?

- Do the investigators have a successful track record in public health research?
- Is there evidence of past collaborations with the proposed research team?
- Have previous research results provided high-quality outputs and contributed to improvements in public health practice and population health?

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

If the project involves clinical research, are there plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

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?

Review Criteria for each SIP:

- See **Section VIII. Other Information - Special Interest Project Descriptions** for additional review criteria that will be used in the review of applications submitted in response to this NOFO.
- As applicable for the project proposed, reviewers will evaluate the additional items while determining scientific and technical merit, and in providing an overall impact/priority score.

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).

If your proposed research involves the use of human data and/or biological specimens, you must provide a justification for your claim that no human subjects are involved in the Protection of Human Subjects section of the Research Plan.

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/maso/Policy/policy496.pdf).

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

New additional requirement: CDC requires recipients for projects and programs that involve data collection or generation of data with federal funds to develop and submit a Data Management Plan (DMP) for each collection of public health data.

Investigators responding to this Notice of Funding Opportunity should include a detailed DMP in the Resource Sharing Plan(s) section of the PHS 398 Research Plan Component of the

application. The AR-25 outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.

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

The DMP should include, at a minimum, a description of the following:

- 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, or limitations to, 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);
- 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 de-identified data).

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.

CDC OMB approved templates may be used (e.g. NCCDPHP template https://www.cdc.gov/chronicdisease/pdf/nofo/DMP-Template-508.docx

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

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 (currently the Federal Recipient Performance and Integrity Information System (FAPIIS)) prior to making a Federal award where the Federal share is expected to exceed the simplified acquisition threshold, defined in 41 U.S.C. 134, over the period of performance. At a minimum, the information in the system for a prior Federal award recipient must demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics. CDC may make a Federal award to a recipient who does not fully

meet these standards if it is determined that the information is not relevant to the current Federal award under consideration or there are specific conditions that can appropriately mitigate the effects of the non-Federal entity's risk in accordance with 45 CFR §75.207.

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

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

(1) Financial stability;
(2) Quality of management systems and ability to meet the management standards prescribed in this part;
(3) History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;
(4) Reports and findings from audits performed under 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.

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 grantee'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

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.

The following are additional policy requirements relevant to this NOFO:

Should you successfully compete for an award, recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy).This includes taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.

- For information on your specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and taking appropriate steps to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.

- HHS-funded health and education programs must be administered in an environment free of sexual harassment, see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html.

- For guidance on administering your project in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-

discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

3. 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. Pursuant to applicable grant regulations and CDC's Public Access Policy, Recipient agrees to submit into the National Institutes of Health (NIH) Manuscript Submission (NIHMS) system an electronic version of the final, peer-reviewed manuscript of any such work developed under this award upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. Also at the time of submission, Recipient and/or the Recipient's submitting author must specify the date the final manuscript will be publicly accessible through PubMed Central (PMC). Recipient and/or Recipient's submitting author must also post the manuscript through PMC within twelve (12) months of the publisher's official date of final publication; however, the author is strongly encouraged to make the subject manuscript available

as soon as possible. The recipient must obtain prior approval from the CDC for any exception to this provision.

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

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. Grantees (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 new 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 Project Scientist/Scientific Collaborator will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards. 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:

1. **Yearly Non-Competing Grant Progress Report** is due 90 to 120 days before the end of the current budget period. 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.

2. **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.**
3. **A final progress report**, invention statement, equipment/inventory report, and the final FFR are required **90 days after the end of the period of performance.**

B. Content of Reports

1. Yearly Non-Competing Grant Progress Report: The grantee's continuation application/progress 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:

Specific to this NOFO, the following instructions clarify the reporting requirement detailed in Section VI, 5. Reporting, B. Content of Reports.

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 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, final progress report, and Final Invention Statement and Certification within 90 days 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 grantee'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
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
Email: commons@od.nih.gov
Hours: Monday - Friday, 7am - 8pm U.S. Eastern Time

Note: Include NOFO number (**RFA-DP24-062**) 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).

1. Special Interests Project Descriptions

The section includes the description and requirements for each Special Interest Project included in this NOFO.

SIP-24-001: Understanding the needs of ovarian cancer survivors

Project Description

Ovarian cancer is the fifth leading cause of cancer death in the United States. Ovarian cancer incident cases and death cases are expected to increase in the next 15 years, due largely to the growth of the aging population. (1) Given the lack of evidence-based methods for prevention and early detection, most public health efforts in ovarian cancer focus on survivorship.

Survivors of ovarian cancer face a multitude of unique challenges. Most ovarian cancer survivors receive active treatment until the end of life, and often report poor physical and mental health. Those who complete active treatment deal with the risk of recurrence or secondary primary cancers and late and long-term side effects. The toll on survivors and their families is significant. (2) The National Academies of Sciences, Engineering, and Medicine (NASEM) recommended that supportive care needs of ovarian cancer survivors be specifically studied with the goal of improving physical and psychosocial outcomes.

The goal of this project is to better understand the needs of ovarian cancer survivors, including the following areas:

1. Physical and mental health conditions ovarian cancer survivors experience including those that impact quality of life,
2. Pharmacologic and non-pharmacologic interventions ovarian cancer survivors utilize to manage their conditions,
3. Barriers ovarian cancer survivors have in accessing and receiving appropriate care, and
4. Unmet needs ovarian cancer survivors have. Addressing these areas will further the development of a strong knowledge base of ovarian cancer survivor needs for public health programs.

Project Objectives and Outcomes

The project objectives include development, recruitment for, and implementation of a research plan to assess the needs of ovarian cancer survivors. An ovarian cancer survivor is anyone who

has had ovarian cancer, which includes anyone diagnosed with ovarian cancer after the point of diagnosis. This research plan could include a comprehensive survey of ovarian cancer survivors, or another appropriate method of collecting similar data. In the second year, the PRC is expected to complete plan implementation, data analysis, and evaluation of the survey findings. Milestones for the project will include research plan development, recruitment plan development, completion of data collection, and final data analysis and reporting.

Outcomes of this project will include completed data analysis that provides a better understanding of ovarian cancer survivor needs as identified by the research project. These results will contribute to the knowledge of the unmet needs of ovarian cancer survivors and will provide insight into areas that can be incorporated into future programmatic work.

Public Health Priorities

Healthy People 2030 Objectives

C-11: Increase the proportion of cancer survivors who are living 5 years or longer after diagnosis: This project will lead to a better understanding of factors associated with good physical and mental health after an ovarian cancer diagnosis and reveal unmet needs in this population. Interventions developed based on this research may ultimately lead to improved survival.

C-RO1: Increase quality of life for cancer survivors: This project will lead to a better understanding of the medications, complementary and alternative medicines, and medical services used by ovarian cancer survivors that result in improved quality of life.

NCCDPHP Approach to Social Determinants of Health - SDOH Domains

Community-Clinical Linkages, which is defined as connections made between health care, public health, and community organizations to improve population health are called community-clinical linkages. These connections can reduce health disparities by bridging the gap between clinical care, community or self-care, and the public health infrastructure. More information can be found here: https://www.cdc.gov/chronicdisease/healthequity/sdoh-and-chronic-disease/nccdphp-and-social-determinants-of-health/community-clinical-linkages.htm

NCCDPHP Objectives: This project aligns with strategies in NCCDPHP/DCPC programs:

- The National Academies of Sciences, Engineering, and Medicine (NASEM): Supportive Care Needs of Ovarian Cancer Survivors
- DCPC: Improve Cancer Survivors' Quality of Life

Project Activities and Submission Requirements

Applications submitted in response to this SIP are expected to present a Research Plan that addresses the following requirements listed below:

The applicant is expected to describe a research plan to better understand the needs of ovarian cancer survivors. Specific focus areas could include: (1) physical and mental health conditions ovarian cancer survivors experience including those that impact quality of life, (2) pharmacologic and non-pharmacologic interventions ovarian cancer survivors utilize to manage their conditions, (3) barriers ovarian cancer survivors have in accessing and receiving appropriate care, and (4) unmet needs ovarian cancer survivors have. In all of these areas, a focus

on health equity/social determinants of health is also encouraged. Particularly, assessing aspects related to differences in unmet needs by race and ethnicity, socioeconomic status, geographic location, and sexual identity could be included. Addressing these areas will further the development of a strong knowledge base of ovarian cancer survivors' needs for public health programs.

Study Design and Methods

The applicant is expected to propose a research plan that will collect data directly from ovarian cancer survivors on their needs related to their diagnosis or their status as an ovarian cancer survivor. This project may require local institution IRB review but will not require CDC IRB review.

Target Population

The target population for this project are people living in the United States who have or have had ovarian cancer, which includes anyone diagnosed with ovarian cancer from the point of diagnosis with ovarian cancer through treatment and the rest of life. Survey is expected to attempt to capture the phase of care of survivors with survivors in various phases of treatment. Additionally, survey is expected to attempt to include participants with a variety of demographic characteristics including race, ethnicity, geography, and socioeconomic status so that health equity may be assessed.

Collaboration/Partnerships

The applicant will collaborate with CDC staff to refine topics to cover in the data collection. The applicant is expected to collaborate with national ovarian cancer survivor organizations and state cancer registries, as appropriate. CDC staff will not have contact with human subjects or data collected from human subjects, other than aggregate tables without identifiers provided as part of project progress reports and as part of scientific articles. CDC staff will serve as consultants on this project, and will provide technical assistance, as requested, on activities such as design and nature of research, co-authoring manuscripts, and dissemination of results.

Recruitment Plan

The applicant is expected to recruit people who are ovarian cancer survivors, as defined above. Recruitment plans are expected to aim to be sufficiently powered to assess differences in needs of minority populations.

Annual Action Plan

Provide a 24-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 Appendix A. https://www.cdc.gov/grants/additional-requirements/ar-25.html

Dissemination & Translation Plan

Provide a plan for disseminating the methodology and translating the results of this project to academic, health care practice, and community audiences. The dissemination and translation plan should include a purposeful and facilitated process of distributing and translating information and materials for community, practice, and academic audiences, organizations, and individuals who can use them to improve the lives of ovarian cancer survivors. This may include, but not limited to, white papers and peer-reviewed manuscripts, presentations to National Comprehensive Cancer Control Programs and their partners, talks to health care provider audiences at cancer control conferences, grand rounds at academic centers, and digital and social media outlets.

Public Health Impact

This project seeks to reduce and prevent morbidity and mortality among the more than 20,000 women diagnosed with ovarian cancer each year. It will yield valuable information and potential interventions, with the goal of improving the quality and duration of life among ovarian cancer survivors.

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:

- Existing relationships with or access to ovarian cancer survivor populations, particularly those including racial/ethnic minorities, varying age ranges, geographic variation, and sexual and gender minorities.
- Previous experience working in cancer survivor populations, including publishing on cancer survivors and/or 5+ years of experience working in the subject area.
- Previous experience of 5+ years managing research projects, including surveys with broad geographic reach.

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.

Availability of Funds

It is anticipated that approximately $500,000 is available to fund one Prevention Research Center(s) for a 2-year project period. The average award for each recipient is expected to be approximately $250,000 for year one. The year-one ceiling per recipient is $250,000. Funding may vary and is subject to change. **Funding available includes direct and indirect costs.**

Research Status

It is expected that 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 included in the project.

OMB/PRA

OMB/PRA is not expected to apply.

Award Administration

CDC Project Scientist/Scientific Collaborator will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards. 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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1. Weir, H.K., et al., The past, present, and future of cancer incidence in the United States: 1975 through 2020. Cancer, 2015. 121(11): p. 1827-37.
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SIP-24-002: Survivorship care plans and mortality among adult cancer survivors

Project Description

A priority of the Division of Cancer Prevention and Control (DCPC) is to improve the health and wellness of cancer survivors. Survivorship care plans provide a history of a patient's cancer and treatment, outline future need for follow-up tests, possible long-term effects of cancer treatment, and identify health care providers responsible for care. In 2006, the Institute of Medicine recommended that every cancer patient receive a survivorship care plan (1). Accrediting organizations, such as the Commission on Cancer, previously included the use of survivorship care plans as a mandatory requirement for hospital accreditation (2). As a result, the adoption and use of survivorship care plans has steadily grown.

While there has been increased use of survivorship care plans (2), there is limited evidence that the implementation of survivorship care plans decreases mortality among cancer survivors. Given the widespread use of survivorship care plans and the significant resources that support these efforts, it is important to understand the effectiveness of survivorship care plans. This project aims to evaluate if receipt of survivorship care plans decreases cancer mortality among adult cancer survivors. CDC plans to disseminate the results widely within DCPC's National Comprehensive Cancer Control Program and to public health partners outside of CDC to prioritize resources to improve the health of cancer survivors.

Project Objectives and Outcomes

Applicants are expected to design and conduct a research study to determine whether the receipt of survivorship care plans decreases cancer mortality among adult cancer survivors. The results of this study will provide evidence of the effectiveness of survivorship care plans in decreasing mortality. This will inform CDC-funded National Comprehensive Cancer Control Programs and other public health partners outside of CDC to prioritize resources to improve the health of cancer survivors. If this study finds that use of survivorship care plans decreases cancer mortality among cancer survivors, these results will provide an argument for the increased implementation of survivorship care plans. If this study finds that survivorship care plans do not decrease mortality, this will help public health practitioners consider other strategies to improve cancer survivorship.

Public Health Priorities

Healthy People 2030 Objectives

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

C-R01: Increase quality of life for cancer survivors

Chronic Disease Prevention and Health Promotion Domains

This project aligns with the Center priority of 'Health Care system interventions.'

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

Describe the design of the research study and analytic methodology:

- Explore the potential impact of survivorship care plans on reducing cancer mortality among adult survivors. Retrospective cohort analysis can be performed to compare mortality rates between two groups of adult cancer patients: those who received survivorship care plans and those who did not. Several clinical and socio-demographic characteristics, such as age, gender, race, ethnicity, income, employment status, health insurance status, type and stage of cancer, comorbidities, treatment methods, hospital factors, and year of treatment, can be considered in the analysis. By conducting a comprehensive examination, this study can provide meaningful insights into the effectiveness of survivorship care plans in reducing cancer mortality among adult survivors.
- Ensure data sources for vital records, medical records, and proof of cancer survivorship plans for adult cancer survivors are available. Obtain IRB approval and secure data sources within six months of project start.
- Use approved data sets: existing public use data or another dataset approved by the local IRB.

Target Population

Inclusion of adult cancer survivors (persons who have ever been diagnosed with cancer) from a variety of cancers as well as a diverse population with respect to age, sex, race, ethnicity, and socioeconomic status as well as other potential variables mentioned above (see Study design and methods) would maximize generalizability of the findings.

Collaboration/Partnerships

- The applicant is expected to partner with the CDC science collaborator associated with this SIP.
- The applicant is expected to consult with other experts in the field as needed to accomplish the project's aims and objectives.
- The applicant is expected to collaborate with appropriate organizations that represent the target population.

Recruitment Plan

N/A

Annual Action Plan

Provide a 24-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 Appendix A. https://www.cdc.gov/grants/additional-requirements/ar-25.html

Dissemination & Translation Plan

Provide a plan for disseminating the methodology and translating the results of this project to academic, health care practice, and community audiences. The dissemination and translation plan should include a purposeful and facilitated process of distributing and translating information and materials for community, practice, and academic audiences, organizations, and individuals who can use them to promote health and prevent disease. This may include, but not limited to, white papers and training sessions for CDC-funded Comprehensive Cancer Control programs, peer-reviewed manuscripts, talks to health care provider audiences at cancer control conferences, grand rounds at academic centers, and digital and social media outlets.

Public Health Impact

This project will help improve care for cancer survivors by determining the health impact of survivorship care plans. The benefit of this research is longer lives for cancer survivors. This project will also benefit health systems by providing evidence for the effectiveness of survivorship care plans, thus allowing public health practitioners to allocate limited resources to the most impactful evidence-based interventions for cancer survivors. This project may also have applicability to other persons with chronic diseases with long-term health effects such as diabetes. The effectiveness of survivorship care plans for cancer may inform how long-term sequelae from other chronic diseases are monitored, prevented, and treated. If this project finds that survivorship care plans are found to be effective, this may provide more evidence that survivorship care plans should be delivered more universally to all cancer survivors.

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:

- Does the applicant:
    - Demonstrate access to:
    - Data sources that include vital records,
    - Medical record data,
    - Appropriate sample size and power analysis,
    - Data sources that include receipt of cancer survivorship plans,
    - Data sources that include cancer survivors, and
    - Data containing clinical and socio-demographic elements noted above (Study Design and Methods)?
- Propose a study capable of comparing mortality differences among adult cancer survivors by receipt of survivorship care plan?
- Demonstrate ability to secure data and obtain IRB approval within 6 months of start of project?
- Demonstrate ability to conduct the study and perform all analysis within the two-year project period?
- Demonstrate experience with mortality analysis?

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.

Availability of Funds

It is anticipated that approximately $700,000 is available to fund one Prevention Research Center for a 2-year project period. The average award for each recipient is expected to be approximately $350,000 for year one. The year-one ceiling per recipient is $350,000. Funding may vary and is subject to change. Funding available includes direct and indirect costs.

Research Status

It is expected that 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 included in the project.

OMB/PRA

OMB/PRA is not expected to apply.

Award Administration

CDC Project Scientist/Scientific Collaborator will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards. 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. Hewitt M, Greenfield S, Stovall E. *From Cancer Patient to Cancer Survivor: Lost in Transition.* Washington DC: National Academies Press; 2006.
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SIP-24-003 Cancer Prevention and Control Research Network (CPCRN)

Project Description

Research over the past several decades has identified interventions that are effective in promoting recommended cancer screening use and addressing cancer-related risk factors, such as tobacco use, obesity, and inadequate physical activity [1], as well as social determinants of health, such as community clinical linkages, food and nutrition security, social connectedness, tobacco-free policy and built environment [2]. These efforts can address risk factors at one or more levels, such as community, workplace, health system, healthcare provider and individual levels. The implementation of these and other promising interventions can help drive progress towards national Healthy People 2030 cancer-control objectives (Healthy People 2030 | health.gov). The value of these interventions, however, lies in their ability to be adopted, implemented and sustained within a range of health care and community settings. A better understanding of the multilevel intervention implementation process is necessary to inform cancer control research and practice and accelerate adoption of evidence-based interventions. Implementation science can study how multilevel strategies to implement evidence-based cancer control interventions operate [3].

Initiated in 2002 with funding from the Centers for Disease Control and Prevention (CDC) and the National Cancer Institute (NCI), the Cancer Prevention and Control Research Network (CPCRN) is a national network of academic, public health, and community partners that work together to reduce the burden of cancer, especially among those disproportionately affected [3]. The purpose of the CPCRN is to work with partners to develop scientific knowledge to accelerate the implementation of evidence-based cancer prevention and control interventions in communities [4]. The CPCRN engages in enhancing large-scale efforts to reduce cancer risk, increase use of recommended cancer screening services, improve the health and well-being of cancer survivors, and reduce cancer-related disparities in communities and within health systems that serve the medically underserved [5.6]. The CPCRN conducts community-based, participatory research related to cancer prevention and control across its network centers [7]. Through multicenter collaboration, CPCRN leverages the expertise, partnerships, and resources of participating centers. The broad geographic reach, diverse study populations, and strong relationships among CPCRN investigators allow the network to achieve greater collective impact than individual centers could achieve on their own. The mission, vision, and logic model of the CPCRN have been described on the network website [8]

CDC's Division of Cancer Prevention and Control seeks to continue to support the CPCRN with this special interest project (SIP). The CPCRN consists of multiple collaborating center recipients and one coordinating center recipient. All recipients of this SIP will conduct implementation research to study factors affecting the implementation of behavioral interventions as well as environmental, policy or systems-wide solutions and strategies that address cancer prevention and control in underserved, minority, rural and other populations. The Coordinating Center recipient will facilitate and support collaborative research activities among network members, their partners, and affiliates; and help support the translation and dissemination of findings.

CPCRN Collaborating Center recipients will complete activities listed in Component A below. The CPCRN Coordinating Center will complete activities included for both Component A and B listed below

Project Objectives and Outcomes

Component A: CPCRN Collaborating Centers (Required)

Project Objectives

- Conduct an implementation research project to study factors affecting the implementation of behavioral interventions as well as environmental, policy or systems-wide solutions and strategies that address cancer control in underserved, minority and other at-risk populations.
- Engage in enhancing large-scale efforts to reduce cancer risk, increase use of recommended cancer screening services, improve the health and well-being of cancer survivors, and reduce cancer-related disparities in communities and within health systems that serve the medically underserved.
- Carry out research, training, and technical assistance based on implementation science theories and models and using established organizational infrastructure, strong community relationships, and cross-center projects.
- Engage community and partners in prevention strategies and implementation and research activities.
- Develop measures and outcomes for evidence-based cancer prevention and control activities and establish partnerships with health care systems and other sectors

Project Outcomes

- Accelerate the use of evidence-based cancer prevention and control strategies in communities and strengthen multi-center efforts to reach populations disproportionately affected by cancer to 1) reduce the incidence of preventable cancers; 2) increase the impact of cancer screening; and 3) improve the health of cancer survivors.
- Strengthen the science underlying the implementation of effective, community-based interventions for cancer prevention and control and facilitate the translation of evidence into practice through collaborative activities.
- Expand understanding of the factors that drive the achievement of these goals equitably
- Enhance workforce capacity to equitably disseminate and implement effective cancer prevention and control strategies.

- Increase partner knowledge and capacity around cancer evidence-based intervention implementation and translation.

Component B: CPCRN Coordinating Center

Project Objectives

- Facilitate and support collaborative research activities among network members, their partners, and affiliates.
- Lead and facilitate network discussions related to strategic planning, and the development of research expertise in the application of proven cancer prevention and control interventions in community and clinical settings and implementation science.
- Facilitate collaborative research across member sites, network planning and discussions regarding the development and completion of research activities related to implementation of evidence-based cancer prevention and control interventions.
- Facilitate connections among network members and non-members such as national, state, and local partners to advance efforts aligned with CPCRN's mission.
- Coordinate the evaluation of network activities and impact.
- Disseminate network products

Project Outcomes

- Collaborative research activities across network centers and their partners.
- Connections among network members and partners to work on network activities.
- Communications across network centers
- Coordination of evaluation of network activities and impact

Note: All SIP 24-003 applicants MUST apply for Component A (Collaborating Center) and will serve as a member of the CPCRN.

Applicants that wish to serve as the CPCRN coordinating center, in addition to a collaborating center, MAY also apply for Component B.

Only one recipient will be funded for BOTH components A and B.

Public Health Priorities

Healthy People 2030 Objectives

Healthy People 2030 includes cancer-related objectives that focus on increasing cancer screening use based on the most recent guidelines, reducing cancer mortality, and increasing cancer survival.

C1: Reduce the overall cancer death rate

C2: Reduce the lung cancer death rate

C3: Increase the proportion of adults who get screened for lung cancer

C4: Reduce the female breast cancer death rate

C5: Increase the proportion of females who get screened for breast cancer

C6: Reduce the colorectal cancer death rate

C7: Increase the proportion of adults who get screened for colorectal cancer

C8: Reduce the prostate cancer death rate

C9: Increase the proportion of females who get screened for cervical cancer

C11: Increase the proportion of cancer survivors who are living 5 years or longer after diagnosis

Additional objectives relate to potential cancer prevention factors (e.g., sun safety, HPV vaccination, tobacco use).

Additional information about cancer-related objectives, including research and developmental objectives, can be found at https://health.gov/healthypeople/objectives-and-data/browse-objectives/cance

NCCDPHP Approach to Social Determinants of Health - SDOH Domains

Community-Clinical Linkages: Connections made between health care, public health, and community organizations to improve population health [9]. This project aligns with the NCCDPHP priority to incorporate health system strategies to improve the delivery and use of clinical and other preventive services and community-clinical linkages to ensure that people have access to resources to prevent or manage diseases.

Cancer Moonshot

This project aligns with the recommendations from the Blue Ribbon Panel to expand development and implementation of evidence-based interventions to reduce cancer risk and cancer-related disparities, as well as Cancer Moonshot goals related to reducing the cancer death rate and cancer survivorship [10,11]

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: CPCRN Collaborating Centers (Required)

- Propose a research project for studying the implementation of cancer prevention and control interventions directed at one or more levels (community, health care system, health care provider, individuals), and the effects of the intervention on the study population.
    - Include a description of the change process and the metrics to be used to measure implementation at any given level.
    - Describe how the project will address cancer disparities and inequities in the study population.
- Describe previous experiences that support proposed activities.
    - Provide a description of prior research, practice, and evaluation experiences in intervention and implementation science in the community.

- Describe experiences with community-based participatory research, specifically with regard to addressing health disparities through partnerships with community-based organizations.
- Describe experiences related to cancer detection, prevention and control, particularly for screen-detectable cancers, within existing health systems, the community and/or rural settings.
- Describe experiences with other academic and community partners in a multi-site project, and how your center distributes resources and support to large-scale network projects.
- Describe links to other cancer control research and practice centers. Include examples of your achievements in the appendices, such as peer-reviewed articles and grants received.

- Describe 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 behavioral interventions, implementation science, and environmental, or systems-wide strategies that address cancer control in underserved, minority and other populations.

- Describe experience related to strengthening or expanding the capacity of public health programs.Discuss the potential for collaborations of your center with public health departments, community-based organizations, health systems and foundations.
- Recipients are expected to actively participate in the CPCRN network as a collaborating center with recipients of Component A and B. Funded centers will be expected to actively participate in cross-center work group research projects developed and conducted in collaboration with other funded CPCRN centers. The purpose 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 50% of resources, which could include funded staff time, budget, etc., will be used to support cross-center network work group projects.
  - Discuss how dissemination and implementation efforts of established or pending resources in areas relevant to public health, implementation science and community-based cancer prevention and control could be enhanced through the CPCRN to improve cancer prevention and control outcomes.

Study Design and Methods

- In addition to the requirements above, the Research Plan should describe how applicants will use scientifically rigorous methods to address their research questions.

Component B: CPCRN Coordinating Center (Optional)

- Propose a plan to coordinate, facilitate, support, and disseminate activities of the CPCRN, a national network of academic, public health, and community partners that work together to conduct community-based participatory research, with the ultimate goal of reducing the burden of cancer, especially among those disproportionately affected.
- Describe how the coordinating center will support the CPCRN infrastructure, including but not limited to the following items:
    - Describe the resources and processes that will facilitate linkages and activities of the CPCRN, such as convening of network members, coordination of conference calls, distribution of network information, and dissemination of research findings and products. Include resources that will support non-funded affiliate members on work groups.
    - Describe the processes through which network projects would be identified, selected, facilitated, and monitored across CPCRN centers or workgroups. Describe the process of how non-funded affiliate members would be invited and selected to work on network projects.
    - Describe the process for collecting and distributing products and results from CPCRN members to Prevention Research Centers, and other audiences.
    - Describe the methods for transitioning current resources (evaluation databases, websites, etc.) to insure smooth transition and maintenance of historical documents.
    - Describe the plan to monitor and evaluate the network's progress in achieving key deliverables and major accomplishments including a description of expectations of workgroups and how impact will be evaluated.
    - Describe communication plans, including but not limited to publication of peer-reviewed articles and reports.

- Describe leadership strategies to foster and expand the reach of the network.
    - Indicate how this will be assessed and monitored during the project period.
    - Describe strategies to identify and involve additional partners to participate in CPCRN, and how recipient will foster participation of non-funded affiliate members.
    - Describe the activities the Coordinating Center would undertake to ensure collaboration occurs among the CPCRN, federal, state, and local partners.

- Describe staffing plan for leading and coordinating CPCRN.
    - Provide relevant experience, a description of roles, and the proportion of time each will spend on activities. Examples of these personnel may include an administrator, project manager, data manager, Webmaster and others.

Target Population

Component A

The CPCRN is focused on those who are disproportionately affected by cancer (e.g., medically underserved, racial/ethnic minorities). The applicant should describe the study population and how the population is consistent with the CPCRN focus, including describing cancer disparities for this population of focus.

Collaboration/Partnerships

Component A and B

The following collaborations/partnerships are expected and should be considered in the development of the proposal for Component and A and B.

- Recipients will conduct community-engaged research by collaborating with external partners and organizations (e.g., organizations, individuals, community members, governmental, non-governmental and/or private sector partners), including members of the study population or organizations representing this population, that can help them achieve the goals of CPCRN.
- Members of populations or communities experiencing disparities in cancer prevention, screening, or survivorship, as appropriate to the proposed project, should be involved in every stage of the research process.
- Partners may include health systems (e.g., federally qualified health centers), community partners and organizations, and non-traditional partners that may allow them to address social determinants of health (e.g., housing, transportation)
- Recipients of Component A and B are expected to collaborate to enhance and expand dissemination and translation efforts as appropriate to increase reach, impact and speed of research into practice.

Recruitment Plan

Component A: Collaborating Centers

The applicant should describe their plans to recruit research participants in their study population(s) for Component A as described above, including describing the recruitment of populations disproportionately affected by cancer or cancer risk factors (e.g., medically underserved, racial/ethnic minorities).

Annual Action Plan (Components A and B)

The applicant should provide a 12-month action plan using SMART goals and objectives that includes 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 Appendix A. https://www.cdc.gov/grants/additional-requirements/ar-25.html

Dissemination & Translation Plan

Component A: CPCRN Collaborating Centers (Required)

The recipient should develop a dissemination and translation plan that:

- Specifies dissemination audiences and describe the channels and strategies they will use to disseminate findings and products from their proposed research activities to relevant audiences.
- Describes how they will disseminate findings to key audiences beyond scientific and academic audiences, including how findings will be shared back with study participants, the community, and public health professionals. Dissemination activities can include, but should not be limited to, presentations and journal publications. This could include book chapters, public health practice tools, and other open access dissemination methods.
- Describes plans for developing translation tools and products for use by the cancer control community, potential audiences for these tools/products, and how partners would be engaged in developing translation products and translation and dissemination plans.

Component B: CPCRN Coordinating Center (Optional)

The recipient should develop a dissemination and translation plan that:

- Includes plans to support dissemination and translation of findings and products from CPCRN centers and cross-center activities.
- Describes strategies to ensure recipients of component A and B will collaborate to enhance and expand dissemination and translation efforts as appropriate to increase reach, impact, and speed of research into practice.

Public Health Impact

- Strengthen the science underlying the implementation of effective, community-based interventions for cancer prevention and control into practice.
- Expand understanding of the factors that accelerate the use of evidence-based cancer prevention and control strategies in communities and strengthen multi-center efforts to reach populations disproportionately affected by cancer.
- Increased and more rapid uptake of cancer control evidence-based interventions into practice and improved health equity.
- Workforce capable of disseminating and implementing effective cancer prevention and control strategies.

Special Eligibility and Responsiveness

Component A: None

Component B: 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: CPCRN Collaborating Centers

- Does the applicant demonstrate prior experience:
    - Conducting activities related to behavioral interventions, implementation science, environmental, policy or systems-wide solutions and strategies that address cancer control in underserved, minority, and other at-risk populations and that focus on innovative approaches and multi-level coordination?
    - Collaborating with proposed project partners in the form of publications or grants within the last five years?

- Does the applicant demonstrate the ability to:
    - Work with other academic-community partners in a multi-site effort where the partners have determined operating procedures, leadership structure, and priority projects?
    - Work with other academic and community partners in the successful completion of research projects, including multi-center projects?

- Is the applicant's proposed plan likely to have a substantial impact on reducing the incidence of preventable cancers, increasing cancer screening use, and/or improving the health and well-being of cancer survivors?

Component B: CPCRN Coordinating Center

- Does the applicant demonstrate the ability to :
    - Collaborate with academic and community partners in a multi-site effort where the partners as a whole have determined operating procedures, leadership structure, and priority projects?
    - Lead and manage multicenter collaborations?

- Does the applicant demonstrate interest or support from groups that may be involved or impacted by network activities?

Funding Preferences

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

Component A: CPCRN Collaborating Centers

- Geographic diversity of recipients
- Diversity of study populations disproportionately impacted by cancer (e.g., medically underserved, racial/ethnic minorities)

Component B: CPCRN Coordinating Center

- None

Research/Project Plan Length and Supporting Material

All applicants of SIP 24-003 MUST apply for Component A (Collaborating Center) and will serve as a member of the CPCRN. Applicants that wish to serve as the CPCRN 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).
- Component A (Collaborating Center) applicants must identify the research priority to be studied at the beginning of the Specific Aims
- 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 proposal. Applicants applying for both Components A and B must include a budget breakdown for each component in the appendix.

Availability of Funds: The estimated total funding (direct and indirect) for the 5-year period of performance is $13,875,000.00 to support up to 8 awards (as described below). Awards issued under this NOFO are contingent upon availability of funding through meritorious applications. Funding available includes direct and indirect costs.

Component A: Component A: CPCRN Collaborating Centers

Period of Performance: 5-year project period. 09/30/2024-09/29/2029
Estimated total funding (direct and indirect costs) per year: $2,100,000
Estimating total funding (direct and indirect) per recipient per year: $300,000
The year-1 ceiling is $300,000
Estimated number of awards: 7

Component A and B: CPCRN Collaborating and Coordinating Center

Period of Performance: 5-year project period. 09/30/2024-09/29/2029
Estimated total funding (direct and indirect costs) per recipient per year: $675,000
Estimated funding (direct and indirect costs) per year: $675,000
Year-1 ceiling: $675,000
Estimated number of awards: 1

Research Status

Component A: It is expected that this project will be non-exempt research. It is anticipated that this project will require local IRB approval. Applicants should provide a federal-wide assurance number for each performance site included in this project.

Component B: It is expected that Coordinating Center activities will not involve human subjects research; therefore, it is expected they will not require local or CDC IRB approval.

OMB/PRA: OMB/PRA is not expected to apply for either component.

Award Administration

The CDC Scientific Collaborators will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards. CDC staff will serve as consultants on this project and will provide technical assistance, as requested, on activities such as the design and implementation of the network as well as research and evaluation projects within the network. CDC staff may be co-authors on manuscripts but will not have contact with human subjects or data collected from human subjects.

References

1. Frieden TR. A framework for public health action: the health impact pyramid. Am J Public Health. 2010 Apr;100(4):590-5.
2. National Center for Chronic Disease Prevention and Health Promotion. NCCDPHP's Approach to Social Determinants of Health. https://www.cdc.gov/chronicdisease/healthequity/sdoh-and-chronic-disease/nccdphps-approach-to-social-determinants-of-health.html
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4. Khan S, Chambers D, Neta G. Revisiting time to translation: implementation of evidence-based practices (EBPs) in cancer control. Cancer Causes & Control 2021;32:221–230.
5. White A, Sabatino SA, Vinson C, Chambers D, White MC. The Cancer Prevention and Control Research Network (CPCRN): Advancing public health and implementation science. Prev Med. 2019 Dec;129S:105824.
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7. Ribisl KM, Fernandez ME, Friedman DB, et al. Impact of the Cancer Prevention and Control Research Network: Accelerating the Translation of Research Into Practice. Am J Prev Med. 2017 Mar;52(3S3):S233-S240.
8. CPCRN. The Cancer Prevention and Control Research Network. https://www.cpcrn.org/
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10. National Cancer Institute. Cancer Moonshot Blue Ribbon Panel. https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/blue-ribbon-panel.
11. Centers for Disease Control and Prevention. Cancer. Support for the Cancer Moonshot. https://www.cdc.gov/cancer/dcpc/about/moonshot.htm

SIP-24-004: Gauging men's reaction to relabeling of GG1 prostate cancer and understanding of pathology reports

Project Description

Reclassifying cancer has precedent in the relabeling of bladder, cervical, and thyroid cancers (1-3). The relabeling of low-risk, Gleason Grade Group 1 (GG1), prostate cancer (PCa) as non-cancer continues to generate much debate (4). The Grade Group is the most common system doctors use to grade prostate cancer and, along with other pathology elements, determines how the cancer might behave, and what treatment(s) are appropriate. In GG1 (Gleason score ≤6 (Gleason pattern ≤3+3)), the least aggressive grade, tumor cells appear similar to normal prostate cells and are likely to grow very slowly, if at all. Prostate cancer can be treated with surgery, radiation, or active surveillance (AS) where the patient is monitored, but treatment is delayed until there is evidence of progression.

The relabeling discussion has been conducted primarily among providers of clinical services and care, urologists and pathologists. Reclassification of GG1 would lead to markedly fewer diagnoses of PCa; fewer men receiving initial treatment with surgery or radiation; fewer men experiencing treatment-related side effects; more men being monitored with AS and fewer men receiving immediate treatment with surgery or radiation; and substantial reductions in financial burden to individuals and the health care system (5).

A cancer diagnosis is often accompanied by patient cancer worry and anxiety (6). This anxiety is prevalent among men on AS where the tumor remains untreated (7). Roughly 50% of men on AS will opt for definitive treatment after 5-10 years (8, 9) due to fear of cancer progression and other factors.
To date, a single study has assessed where prostate cancer patients stand on relabeling GG1 as non-cancer (10). That study was based on a convenience sample of men on AS drawn from prostate cancer support groups. Respondents were mostly affluent, educated white men. In that study, only 5% of respondents reported they would cease surveillance if relabeling occurred.

The purpose of this project is to design, conduct, and analyze a study of patient perspectives on relabeling GG1 as non-cancer, where respondents are a random sample of men with low-risk, localized prostate cancer from a population-based source (e.g., state cancer registries or equivalent), where the study would include sufficient numbers of African American and Hispanic men to provide reliable estimates about those groups, and would support analysis by race-ethnicity, socio-economic status (SES), insurance status, and social determinants of health. The applicant will assess patient anxiety, degree of anxiety, and reasons why AS may have been discontinued among respondents. An additional purpose of this project is to design, conduct, and analyze a study of patient understanding of the wording about Gleason Grade Group 1 included on pathology reports, so that, if appropriate, the wording of pathology reports shared with patients (e.g., through patient portals) in the future can be improved to provide clinical context and be more patient-friendly. The results of this study will help inform the discussion about whether GG1 should be relabeled as non-cancer, and also may be useful in planning interventions to increase clinician use of active surveillance as the first choice of care for patients with GG1 prostate cancer.

Project Objectives and Outcomes

Project objectives include:

- Design, conduct, and analyze a study of patient perspectives on relabeling of Grade Group 1 (GG1) prostate disease from "cancer" to “non-cancer”, where respondents are a random sample of low-risk prostate cancer patients recruited from population-based source(s) (e.g., state cancer registries or equivalent), and where the sample includes sufficient numbers of African American and Hispanic men to provide reliable estimates about those groups.
- Design, conduct, and analyze a study using above sample to evaluate patient understanding of pathology report wording about GG1 prostate cancer, and to inform how to design pathology report wording in the future to provide clinical context and be more consumer-friendly.

Public Health Priorities

Healthy People 2030 Objectives

C-08: Reduce the prostate cancer death rate

CR-01: Increase quality of life for cancer survivors

NCCDPHP/DCPC Priority

Cancer survivors live longer, healthier lives (Cancer Survivors | CDC)

Project Activities and Submission Requirements

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

Study Design and Methods

Applicants should describe plans to design, conduct, and analyze a study to assess patient perspectives on relabeling of GG1 prostate cancer, including whether men on AS protocols would continue disease monitoring if their tumor were to be relabeled as non-cancer. It is expected that studies will include a sample of GG1 prostate cancer cases from population-based source(s) (e.g., state cancer registries or equivalent), and will oversample African American and Hispanic patients to provide reliable estimates for those groups. Studies may include prostate cancer patients that started AS but opted out by time of study, and where the study evaluates the reasons that those men discontinued disease monitoring.

Applicants also should describe plans to design, conduct, and analyze a study to assess patients’ understanding of information contained in standard pathology reports and alternate versions designed to be more consumer-friendly and provide clinical context using study sample accrued above.

Sample size should support analysis by race-ethnicity, socio-economic status (SES), and insurance status. The applicant will assess patient anxiety, degree of anxiety, and reasons why AS may have been discontinued among respondents.

Applicants are to propose a study design and methods to include these major project milestones:

- Literature review and environmental scan of tools to assess cancer worry and anxiety

- Determine population-based sources for GG1 prostate cancer cases (e.g., state cancer registries or equivalent), develop sampling plan, plans to recruit patients, and develop analysis plan
- Develop alternate wording for pathology reports
- Develop final study protocol for IRB and population-based sources for GG1 prostate cancers
- Prepare and submit study protocol to IRB and population-based sources for GG1 prostate cancer and obtain appropriate IRB and any other approvals
- Develop computer programming for study data collection
- Identify low-risk prostate cases from population-based sources (e.g., state cancer registries or equivalent)
- Conduct studies
- Data analysis
- Study writeup/manuscript submission

Target Population

The target population for this study are men with low-risk, GG1 prostate cancer, and who are drawn from a population-based source (e.g., state cancer registries or equivalent). Sample should include sufficient numbers of African American and Hispanic men to provide reliable estimates about those groups.

Collaboration/Partnerships

Describe plans for collaboration/partnerships with population sources for recruitment of patients with GG1 prostate cancer (e.g., state cancer registries or equivalent), academic, medical practice-based sources, or other data sources to support accomplishments of the study objectives.

Recruitment Plan

Describe plans or approaches to recruit men with GG1 prostate cancer for the study of patient perspectives on relabeling GG1 prostate cancer as non-cancer and of pathology report wording.

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 Appendix A. (https://www.cdc.gov/grants/additional-requirements/ar-25.html)

Dissemination & Translation Plan

Provide details on anticipated strategies to translate and disseminate the findings of the research; for example, any anticipated peer-reviewed scientific articles and any plans to distribute project highlights to academic and practice-based clinical audiences, specifically medical providers who treat PCa patients.

Public Health Impact

- The study results will contribute to clinical discussions of relabeling GG1 disease.
- The study will assess patient response to tumor relabeling from “cancer” to “non-cancer”, and thereby help support clinical decision-making about relabeling.
- The study will assess patient ability to understand path reports' information about GG1 disease, and thereby help develop future wording that is more patient-riendly.

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:

- Demonstrates the racial and ethnic diversity of pool from which respondents will be recruited
- Demonstrates geographic diversity in the recruitment pool
- Document ability to successfully recruit adequate sample size of population of interest
- Plans to engage population-based sources to identify GG1 prostate cancer cases (e.g., state cancer registries or equivalent)
- Documents access to sufficient numbers of PCa cases to provide reliable estimates (e.g., letters of support)
- Demonstrate past experience in studies of similar scope and complexity to the current project including relevant publications and a narrative description of past work performed including a discussion of any problems encountered/corrective actions taken and significant accomplishment.

Funding Preferences

Preference will be given to:

- Studies that over sample African American and Hispanic men, and vary across education, socioeconomic status, and insurance coverage.
- Studies that engage multiple population-based recruitment sources

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.

Availability of Funds

It is anticipated that approximately $1,050,000 is available to fund one Prevention Research Center for a 3-year project period. The average award for each recipient is expected to be approximately $350,000 for year-one. The year-one ceiling per recipient is $350,000. Funding may vary and is subject to change. **Funding available includes direct and indirect costs.**

Research Status

It is expected that 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 included in the project.

OMB/PRA

OMB/PRA is not expected to apply.

Award Administration

CDC Project Scientist/Scientific Collaborator will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards. CDC staff will serve as consultants on this project, and will provide technical assistance, as requested, on project activities such as survey 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

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2. Darragh TM, Colgan TJ, Cox JT, et al: The lower anogenital squamous terminology standardization project for HPV-associated lesions: Background and consensus recommendations from the College of American Pathologists and the American Society for Colposcopy and Cervical Pathology. J Low Genit Tract Dis 16:205-242, 2012.
3. Nikiforov YE, Seethala RR, Tallini G, et al: Nomenclature revision for encapsulated follicular variant of papillary thyroid carcinoma: A paradigm shift to reduce overtreatment of indolent tumors. JAMA Oncol 2:1023-1029, 2016.
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11. Wolinsky H et al. Where do patients stand on relabeling Gleason *6* lesions as non-cancer? Results of a survey of active surveillance patients. ASCO Genitourinary symposium, February, 2023, San Francisco, CA.

SIP-24-005: Understanding the impact of reducing social isolation and loneliness on health indices among cancer survivors

Project Description

The maintenance of physical and mental health is central to human well-being and is mediated through social relationships (1, 2). Social isolation and loneliness are prevalent among older adults where a quarter report being socially isolated and over one-third report feeling lonely in nationally representative surveys (3). Older adults and cancer survivors have a greater probability of experiencing social isolation and loneliness due to changes in health, mobility, and social connections including the loss of family, friends, and meaningful close-relationships and interactions with others (4, 5) with socially disadvantaged older adults being particularly vulnerable. Socially isolated or lonely adults also report worse physical health, greater health care utilization (greater hospital readmissions, etc.), and higher mortality (3, 6) are reported among adults who report social isolation or loneliness. Older adults utilize the health care system at higher volume and higher frequencies (6). Although we know that social isolation and loneliness are worse for the poorest and most socially disadvantaged older adults (6), the existing evidence base lacks details on how to tailor interventions for these socially disadvantaged older people.

Social isolation and loneliness have been linked to a variety of biological conditions. From Steptoe et al, 2013, “socially isolated individuals are at increased risk for the development of cardiovascular disease, infectious illness, cognitive deterioration, and mortality. Social isolation also has been associated with elevated blood pressure, C-reactive protein, and fibrinogen and with heightened inflammatory and metabolic responses to stress. Loneliness has been linked with increased risk of cardiovascular disease and mortality, elevated blood pressure and cortisol, heightened inflammatory responses to stress, and modifications in transcriptional pathways linked with glucocorticoid and inflammatory processes.”

The National Academies of Sciences, Engineering, and Medicine suggests that health care systems are positioned to identify patients at higher risk for social isolation and loneliness

because of social disadvantage and partner with others to apply and evaluate interventions designed to address these challenges. (Recommendation 7-2, NASEM)(6). This project seeks to determine how addressing social isolation and loneliness may impact the health of socially disadvantaged cancer survivors through improvements in selected non-cancer-specific clinical endpoints as well as mental health metrics.

This project goal is twofold: (1) Identify and compile existing evidence-based interventions (EBIs) and resources that can be used to reduce social isolation and loneliness among cancer survivors, particularly socially-disadvantaged and elderly cancer survivors. (2) Use, modify, or adapt identified EBIs (or components of known interventions/resources) into a tailored program(s) to meet the physical and mental health needs of enrolled cancer survivors.

This project seeks to 1) determine the efficacy of referral of cancer survivors to community programs and 2) evaluate the effectiveness of community program intervention on outcomes of improving physical health (non-cancer-specific health metrics) and mental health (e.g., reducing loneliness and social isolation). The project also seeks to assess the sustainability of such programs.

Project Objectives and Outcomes

Objectives

Applicants are expected to achieve the following:

- Determine appropriate non-cancer specific clinical endpoints to use in the study to serve as indices of improved health of participants. Assess social isolation, loneliness, and selected non-cancer specific health metrics upon participant enrollment (pre-intervention assessment). Selected study intervention(s) will likely require modification to address differences in age, race, socioeconomic status (SES), cancer status within the study sample.
- Determine viable program components that work together to meet client needs. Determine schedule for follow-up assessments to enable evaluation of enrollees and/or modify program components to better meet client needs. Monitor non-cancer specific clinical endpoints before, during, and after intervention to assess improvement. Determine factors important for program sustainability.

Outcomes

- Improving the health of cancer survivors through the reduction of social isolation and loneliness has potential to impact the physical and mental well-being of this group, particularly the elderly or those with social disadvantage.

Public Health Priorities

Healthy People 2030 Objectives

CR-R01: Increase quality of life for cancer survivors

HS-S01: Improve cardiovascular health in adults

OA-01: Increase the proportion of older adults with physical or cognitive health problems who get physical activity

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

NCCDPHP Approach to Social Determinants of Health - SDOH Domains

Social Connectedness: When people or groups have relationships that create a sense of belonging and being cared for, valued, and supported.

NCCDPHP/DCPC Priority

Cancer survivors live longer, healthier lives (Cancer Survivors | CDC)

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 to evaluate the physical and mental health impacts of activities to reduce social isolation and loneliness among cancer survivors with particular emphasis on those socially-disadvantaged. Applicant should use a randomized controlled trial design, quasi-experimental design, or mixed-method design that will be appropriately powered to demonstrate primary outcomes. The expectation is that the applicant will select existing interventions based on literature, promising evidence, and need to use the intervention(s) as is or modify or adapt for their specific population of socially disadvantaged cancer survivors and/or setting.

Applicants are to propose a study design and methods to include these major project milestones:

- Literature review and environmental scan of theoretical frameworks to guide study, assessment tools, intervention types, and relevant clinical endpoints and mental health indices
- Specify target participants
- Develop draft study instruments - enrollment screener, study baseline assessment, draft intervention plan, and draft post intervention assessment and health measures
- Prepare IRB package and acquire approval
- Pretest and finalize assessment tools
- Formalize relationships with community partners
- Recruit cancer survivors and non-cancer comparison group
- Conduct study with long-term follow-up, e.g., $\geq$ 9 months
- Data analysis
- Study write-up/manuscript submission

Target Population

Target participants are all survivors of adult-onset non-metastatic cancers (excluding skin cancer), who have completed active treatment and a comparison group (no personal cancer history, gender and age-matched to 5-year age group). Applicant should prioritize participants with lower SES and other indicators of social disadvantage in sampling scheme, for example those on public assistance, public health insurance or uninsured, limited English proficiency, etc.

Collaboration/Partnerships

The applicant is expected to collaborate with any of the following organizations to identify potential study participants: healthcare organizations, community-level partnerships/programs, advocacy organizations, mental health organizations, physical activity organizations, faith-based organizations, state- and local-government, state cancer control coalitions, the cancer support community, and non-profit groups. Some examples of these groups are the American Medical Association, American Geriatrics Society, American Association of Retired Persons, American Society on Aging, Gerontological Society of America, National Hispanic Council on Aging, and the American Cancer Society. Applicants should provide documentation of current or planned partnerships with organizations necessary to conduct the proposed project. Applicants should highlight if previous, current, or planned partnerships have prioritized recruitment or engagement with socially disadvantaged patients and cancer survivors.

Applicants may consider establishing an advisory board with representation from public health disciplines and members of the target population to support phases of the research and objectives. The advisory board may assist with public health message development, and dissemination and translation of findings.

Recruitment Plan

Describe plans and approaches to identify potential participants to support accomplishment of the study objectives. Recruitment can include a plan to identify socially-disadvantaged cancer survivors through screening of those experiencing social isolation and loneliness.

Annual Action Plan

The applicant is expected to 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 Appendix A. https://www.cdc.gov/grants/additional-requirements/ar-25.html

Dissemination & Translation Plan

Applicant, together with community partners, will develop a translation and dissemination plan that describes how the results from the research will be shared with academic, practice, and community-based audiences including public health and/or health system messages, as applicable and as appropriate. Applicant, along with partners, should develop a report on factors related to sustainability of the program. Applicant and partners may jointly undertake creation of public awareness and education materials that highlight the health and wellness impacts of the intervention on social isolation and loneliness in cancer survivors or other appropriate

communications. Recipient investigators will prepare at least one scientific article that describes the methodological approach or study outcomes and present at a national conference.

Public Health Impact

Successful completion of the project will contribute to the sparse literature on successful interventions for social isolation and loneliness among cancer survivors and add to the existing evidence base on how to tailor interventions for socially-disadvantaged, older people experiencing chronic social isolation and loneliness. Contributions to the literature may include the effect of multifactorial intervention on selected clinical endpoints, elucidation of the hidden impact that social isolation and loneliness can have on the health of socially- disadvantaged cancer survivors, and the changes in selected noncancer-specific clinical endpoints through reduction in social isolation and loneliness.

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:

- Access to a diverse pool from which to recruit survivors of adult-onset non-metastatic cancers (excluding skin cancer) experiencing social isolation and loneliness and an age-matched (5-yr groups) comparison group with an emphasis on socially disadvantaged or elderly cancer survivors. Sample may embody diversity across demographic variables such as age, race and ethnicity, SES, insurance coverage, or disability status.
- Ability to successfully recruit adequate sample size of population of interest sufficient to examine differences across groups.
- Past experience in behavioral intervention studies of similar scope and complexity to the current project including relevant publications and a narrative description of past work performed including a discussion of any problems encountered/corrective actions taken and significant accomplishments.
- Comprehensive approach to addressing social isolation and loneliness using multiple intervention strategies.

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.

Availability of Funds

It is anticipated that approximately $1,200,000 is available to fund one Prevention Research Center for a 3-year project period. The average award for each recipient is expected to be $400,000 per year. The year-one ceiling is $400,000. Funding may vary and is subject to change. **Funding amounts include direct and indirect costs.**

Research Status

It is expected that 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 included in the project.

OMB/PRA

OMB/PRA is not expected to apply.

Award Administration

CDC Project Scientist/Scientific Collaborator will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards. CDC staff will serve as collaborators and/or co-investigators on this project and will have joint responsibility for recruitment strategy, evaluation design, data collection and analysis, and data interpretation, co-authoring manuscripts, and dissemination of results. However, CDC staff will not have contact with human subjects or data collected from human subjects.

References

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SIP-24-006: Nutrition Obesity Policy Research and Evaluation Network (NOPREN)

Project Description

Poor nutrition impacts child growth and development and is a leading cause of illness and lost productivity in the United States (1). Many determinants influence an individual's diet quality,

including factors at the household, neighborhood, state/tribal/territorial, national, and societal levels (2). Because of the multi-level, complex nature of addressing poor nutrition, information on which factors facilitate intervention implementation in real world settings may help to improve population health.

Evidence informed policy, system, and environmental (PSE) interventions are part of NCCDPHP's funded public health programs (3). These interventions are inherently complex and require an understanding of *context* and *inter-relationships* (4) leading to successful implementation. Emerging theories/constructs of implementation science can help clarify what is needed to successfully implement these interventions in different populations or settings; in addition, understanding how equity is considered in policy implementation may support greater health impact (5, 6).

In 2009, in response to the burden of diet-attributable chronic disease CDC's Division of Nutrition, Physical Activity, and Obesity (DNPAO) created the Nutrition and Obesity Policy Research and Evaluation Network (NOPREN) through the PRC Program. From 2009 to 2023, NOPREN members have carried out cross-collaborative research to study PSE interventions, publish findings, and create tools to support use in real world settings. The NOPREN network model:

- Provides a platform for transdisciplinary PSE researchers and evaluators to collaborate and inform practice-based research and implementation tools guided by practitioner input, community voice, and lived experience.
- Accelerates methods for studying implementation of a variety of policies that increase supports for improved diet quality, including increasing produce, whole grains, and reducing added sugars.
- Leverages cross-sector expertise from federal agencies (i.e., CDC, USDA, NIH), multi-disciplinary academics, evaluators, non-governmental organizations, healthcare, and public health practitioners to facilitate assessment of policy as a strategy.
- Aligns its research and evaluation agenda with priority settings and interventions included in CDC's state and local public health practice funding announcements (i.e., State Physical Activity and Nutrition program-SPAN, High Obesity Program-HOP, and Racial and Ethnic Approaches for Community Health-REACH). State and Local Programs | DNPAO | CDC
- Supports topic-specific, voluntary workgroups that align with current division strategies.

The purpose of this SIP is to facilitate research that supports successful implementation of evidence-based PSE interventions for nutrition and obesity. The recipient will accomplish this by carrying out an implementation research project (Component A) AND lead and coordinate the NOPREN (Component B).

Project Objectives and Outcomes

Component A: Conduct a Nutrition Policy Implementation Research Project

Project Objectives

- Conduct an implementation research study on at least one of the following nutrition/obesity priority research PSE interventions, included in:
    - DNPAO's real-world public health program strategies:

    - Early Care and Education obesity prevention standards included in state licensing policies
    - Food Service and Nutrition Guidelines (e.g., Food banks/pantries, Park and recreation, Worksites, Institutes of Higher Education)
    - Fruit and Vegetable Programs: Produce Prescriptions and Voucher/incentive Programs
    - Family Healthy Weight/Lifestyle Programs
    - Breastfeeding Workplace Supports (e.g., paid leave, state and organizational workplace accommodation policies)

- Primary implementation research question of interest is: Which policy determinants (e.g., enforcement, monitoring, funding to implement, training supports, sustainability plans, evaluation) act as barriers or facilitate successful PSE implementation by practitioners?
- The research project should also evaluate factors related to equitable policy implementation. This could include how community engagement and co-creation contribute to more equitable and sustainable strategy implementation (7, 8).

Project Outcomes

- Improve the understanding of key implementation supports associated with uptake of one or more DNPAO PSE program strategies within the unique cultural, political, social, or economic context of the community or setting.

Component B: Lead and Coordinate NOPREN

Project Objectives

- Plan and coordinate a monthly state of the science webinar series focused on timely nutrition policy research topics and methodologies.
- Support and maintain the network's transdisciplinary, policy research workgroups by supporting co-chairs and providing a zoom platform and IT logistics for workgroup meetings.
- Host an annual strategic workshop to review accomplishments and goals of the network.
- Host and manage NOPREN's web presence, including a NOPREN website for easy access and sharing of scientific products that highlight NOPREN's policy research findings for network members and nutrition professionals in the field.

Project Outcomes

- Increased capacity for high-quality transdisciplinary policy research that accelerates uptake of DNPAO's PSE implementation strategies to improve nutrition and prevent or treat obesity.
- Enhanced coordination and engagement among public health practitioners, organizational implementers, and academic nutrition and obesity researchers to ensure real-world research approaches, translation products, and dissemination to key public health audiences.

Note: All applicants of SIP 24-006 are **REQUIRED** to apply for Component A and Component B.

Public Health Priorities

Healthy People 2030 Objectives

This project relates to the HP2030 topic area of Nutrition and Weight Status and the SDOH topic area in the Economic Stability Domain https://health.gov/healthypeople/objectives-and-data/browse-objectives/nutrition-and-healthy-eating

Objectives include:

- NWS-01:Reduce household food insecurity and hunger
- NWS-08: Increase consumption of dark green vegetables, red and orange vegetables, and beans and peas by people aged 2 years and over
- NWS-06: Increase fruit consumption by people aged 2 years and over
- NWS-09: Increase whole grain consumption by people aged 2 years and over
- NWS-10: Reduce consumption of added sugars by people aged 2 years and over
- NWS-04: Reduce the proportion of children and adolescents with obesity
- MICH-16: Increase the proportion of infants who are breastfed at 1 year
- MICH-15: Increase the proportion of infants who are breastfed exclusively through age 6 months

NCCDPHP Approach to Social Determinants of Health - SDOH Domains

Food and Nutrition Security: Having reliable access to enough high-quality food to avoid hunger and stay healthy.

Community-Clinical Linkages: Connections made between health care, public health, and community organizations to improve populations' health.

NCCDPHP/DNPAO Objectives

This project aligns with strategies in NCCDPHP/DNPAO programs: State Physical Activity and Nutrition program- SPAN; High Obesity Program- HOP; and Racial and Ethnic Approaches for Community Health- REACH-State and Local Programs | DNPAO | CDC

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: Conduct a Nutrition Policy Implementation Research Project

- Describe how existing implementation science theories, constructs, and measures are used to support the work including those in the Consolidated Framework for Implementation Research (9)
- Identify the intervention strategy to investigate from one of DNPAO's five PSE strategies listed above; identify the specific research question and the rationale for the question. The research question should:
    - Examine which policy determinants (e.g., enforcement, monitoring, funding/resources, evaluation) act as barriers or facilitate successful PSE intervention implementation by practitioners.

    - Examine factors affecting equitable implementation (5-8) of the selected PSE intervention; for example, implementation context (social, cultural, political, economic, physical environment or organizational norms); implementation supports (resources, leadership motivation, training); and implementation processes (key workflows, staff roles, monitoring).

- Describe methods for community or organizational engagement that includes the use of community-based participatory research and needs assessments.
- Identify a local or state public health department or public health program recipient supporting the PSE intervention's implementation, and describe the role the collaborative partner will have in Component B.
- Identify an appropriate research design methodology (e.g., mixed methods study, qualitative software) and justify why it is appropriate to answer the research question.
- Consider appropriate health-related outcomes and additional community benefits such as social connectedness, economic development and/or climate and community resilience.

Study Design and Methods

In addition to the requirements above, the Research Plan should describe how applicants will use scientifically rigorous methods to address their implementation study research questions.

Component B: Lead and Coordinate NOPREN

Applicant should describe how they will:

- coordinate and host a monthly, network-wide state-of the-science webinar series featuring timely nutrition and obesity policy research topics or methodologies.
- support NOPREN's workgroup co-chairs, fellows, and senior advisors, and maintain NOPREN's multi-disciplinary policy research workgroups, including a virtual meeting platform and IT support services.
- utilize the *Science Impact Framework* and *Knowledge to Action* model to ensure research activities and translation products are practitioner-informed and relevant to decision-makers.
- host an annual, in-person or hybrid strategic planning workshop for NOPREN leadership and network members.
- host and manage NOPREN's web presence, including a NOPREN website for easy access and sharing of scientific products that highlight NOPREN's policy research findings for network members and nutrition professionals in the field.

Target Population

Component A: Conduct a Nutrition Policy Implementation Research Project

DNPAO's interventions are population-based, occurring in common community settings. Therefore, for Component A, the applicant should determine who is part of the intervention (designer, implementer) and who is being served by the intervention (population, patient, citizen, client). The applicant can self-identify target implementers and/or populations that are potentially impacted by the nutrition-based PSE intervention selected, using associated health risk indicators or social determinants of health metrics.

Examples of potential populations of interest may include:

- Early care and education (ECE) program staff working in childcare facilities serving households with lower incomes, those living in rural areas, or receiving childcare subsidies.
- Workplace health and wellness staff that support equity-centered breastfeeding, including those that help to reduce racial/ethnic disparities in breastfeeding initiation and duration.
- Program administrators and/or participants of park and recreation programs serving youth from socially-disadvantaged groups.
- Procurement officials or program administrators responsible for purchasing, preparing, and/or serving healthy food to at-risk youth in detention facilities or community centers.
- Individuals or families living in food-insecure communities that participate in fruit and vegetable prescription and voucher programs.
- Program administrators of family healthy-weight programs that are part of federally qualified health centers or safety-net programs.

Component B: Lead and Coordinate NOPREN

- Researchers and evaluators, with a particular focus on first-generation college graduates and junior researchers and/or researchers from historically socially-disadvantaged groups.
- People working in government agencies, public health practitioners or public health grantees/recipients.
- People representing professional organizations and community organizations.

Collaboration/Partnerships:

The following collaborations/partnerships are expected for each component:

Component A: Conduct a Nutrition Policy Implementation Research Project

- Include perspectives and lived experiences from individuals or groups potentially affected by the intervention (e.g., implementers, clients, patients, citizens) to inform study design.
- Identify potential end-users of the research; for example, public health practitioners, to inform interpretation and dissemination of findings.
- Include study participants in planning for translation and dissemination products to ensure findings reach relevant community-based leaders, members, and implementers.

Component B: Lead and Coordinate NOPREN

- Engage with other CDC-funded PRCs and thematic networks working on chronic disease research and/or health equity-focused research and collaborate where applicable.
- Collaborate with CDC program staff to provide strategic direction to the applied research network and advise on policy research gaps that have relevance to the field of public health practice.
- Collaborate with state and/or local-level CDC-funded program grantees from the State Physical Activity and Nutrition program-SPAN, High Obesity Program-HOP, and Racial and Ethnic Approaches for Community Health-REACH to inform on gaps in policy research, evaluation, and implementation. This may include partnerships with state health

departments, local health departments, and relevant national NGOs or other public health practice partners.
- Collaborate with academic institutions that conduct nutrition and obesity policy research.
- Facilitate strategic partnerships to prioritize needed efforts in nutrition and obesity policy research and evaluation, e.g., facilitate partnerships with research networks such as the Physical Activity Policy Research and Evaluation Network (PAPREN), RWJF Healthy Eating Research (HER) Program, and National Collaborative on Childhood Obesity Research (NCCOR), or other national partners such as the Association of State Public Health Nutritionists (ASPHN) and Council on Black Health.

Recruitment Plan

The applicant should describe their plans to recruit participants for the proposed implementation research project described in Component A. Research participants may include key informants from sites or communities that have already implemented one of DNPAO's PSE interventions.

Annual Action Plan

Applicant should provide a 12-month action plan that includes SMART goals and objectives, including a progressive timeline of tasks that allow for the completion of the activities listed below for both Component A and Component B. Note, the plan should delineate how the applicant plans to coordinate and monitor progress in carrying out all project objectives/outcomes in the first year of the award.

Component A: Conduct a Nutrition Policy Implementation Research Project

- Conduct relevant updated literature review.
- Solidify the community partner(s), practitioners, implementers to be involved with the study and/or lived experience of clients (e.g., design, research participant).
- Identify implementation science theories to guide study design.
- Identify equitable implementation constructs for use in the study design.
- Obtain IRB and ensure human subjects protections if appropriate.

Component B: Lead and Coordinate NOPREN

- Define annual performance expectations and expected outcomes for NOPREN.
- Engage with workgroup members to determine gaps and needs.
- Create a plan for the monthly state of the science webinar series.
- Facilitate an annual in-person meeting of the NOPREN leadership group to conduct strategic planning and review of network accomplishments.
- Create a plan to disseminate NOPREN's findings and accomplishments.

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.

Applicants are encouraged to assess NOPREN's impact using CDC's Science Impact Framework (SIF) and its 5 domains of influence (disseminating science, creating awareness, catalyzing action, effecting change, shaping the future). Key indicators in each SIF domain should be used by the applicant to develop an evaluation plan to monitor, track, and communicate NOPREN's performance over the SIP cycle for Component A and Component B. The applicant should also utilize the Consolidated Framework for Collaboration Research (10) when developing their evaluation plan. Post-award, CDC will work collaboratively with recipient to use the existing scientific frameworks to modify the evaluation plan, if needed, and to guide evaluation of the network with annual reporting by the applicant.

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

Dissemination & Translation Plan

The recipient should develop one Dissemination and Translation plan that addresses both components A and B (as described below). The applicant should describe how the research project findings, as well as NOPREN network outputs, will be used to leverage health impact along the research to practice continuum. This should include what information products will be developed and why. Products might include translation tools, implementation resources, briefs/fact sheets, abstracts, presentations, white papers, manuscripts.

Component A: Conduct a Nutrition Policy Implementation Research Project

- The recipient should develop a dissemination and translation plan that:
- Includes dissemination strategies for science products (e.g., abstracts, publications).
- Considers how information and research findings are best packaged and communicated (online fact sheet, webinar, videos, checklists) for state and local public health practitioners.
- Determines the unique translation needs of key partners, including community decision makers, implementers, and relevant coalitions.
- Outlines how key findings and translation products (e.g., professional development module, training, checklist) will be shared with key audiences responsible for PSE implementation (e.g., ECE teachers, food service operators, healthcare providers, pantry staff, professionals).

Component B: Lead and Coordinate NOPREN

A main goal of the NOPREN coordinating center is to ensure the translation and dissemination of network research findings to enhance the impact of public health practice and policy in real world settings. As such, recipient should address the following in the dissemination and translation plan:

- Assesses key audiences for NOPREN products.
- Describes oral and written communication methods that will be used to disseminate findings from NOPREN's research or to provide information on implementing select PSE research strategies and why. These methods could include:

- Web material highlighting workgroup research findings through the existing website.
- Policy briefs, fact sheets, webinars, student spotlights, conference panels.

Public Health Impact

Public health's PSE interventions and dissemination strategies must consider historical and structural barriers and be adapted or tailored to ensure acceptability and optimal uptake in community settings. NOPREN's public health impact is focused on conducting transdisciplinary, applied policy research with the goal of identifying key determinants of implementation that support healthy food access and population health. The network's expected impact is to provide a framework and platform to communicate and disseminate research findings related to:

- Successful implementation of nutrition and obesity PSE changes.
- Evidence and tools to support the quality improvement of public health programs and practice.
- Shortening the time from science to service.

Findings from the network's work are expected to help DNPAO-funded program recipients more successfully implement recommended strategies.

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:

Does the proposed study focus on one of the DNPAO PSE strategies with a clear rationale for the research question proposed?

Does the applicant demonstrate prior experience:

- Designing and executing nutrition/obesity PSE implementation research studies.
- Coordinating and/or managing a multi-site, collaborative research or evaluation initiative that was successfully sustained over multiple years.
- Collaborating with non-traditional partners such as the charitable food system, agriculture experts, health economists, psychologists, child health specialists, or administrators on research studies.
- Creating translation and dissemination products that are adapted with the end-user of the research, e.g., public health practitioners, non-governmental organizations, and/or decision-makers.
- Publishing scientific papers as a lead author or co-author on the implementation and/or evaluation of nutrition and/or obesity policy.

Does the applicant provide a letter of support from a local or state public health department or public health program recipient that specifies the collaborative role the partner will have in the implementation research study.

Component B:

The extent to which the applicant describes their ability to:

- Facilitate and coordinate strategic partnerships (as defined in the partnerships and collaboration section above) on behalf of an applied policy research network.
- Host multi-site calls or events on policy research and evaluation methods.
- Provide a virtual IT platform to host webinars and teleconferences and action steps.
- Maintain a public-facing, online clearinghouse for member materials and products.
- Measure network performance, growth, diversity, impact, and outputs using Scientific Frameworks

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.

Availability of Funds

Approximately $1,500,000 is planned to fund one (1) Prevention Research Center for the five (5) year project period. It is anticipated that approximately $300,000 is available to fund one-Prevention Research Center(s) in year one. The year one ceiling per recipient is $300,000. Funding may vary and is subject to change. Funding available includes direct and indirect costs.

Research Status

It is expected that 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 included in the project.

OMB/PRA

OMB/PRA is not expected to apply.

Award Administration

CDC Project Scientist/Scientific Collaborator will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards. 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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SIP-24-007 Physical Activity Policy and Research Evaluation Network (PAPREN): Policy implementation research to advance health equity

Project Description

Physical activity has significant short- and long-term health benefits (1-3). The Division of Nutrition, Physical Activity, and Obesity's (DNPAO) Priority Strategy for Physical Activity is Increasing Physical Activity Through Community Design (https://www.cdc.gov/physicalactivity/community-strategies/activity-friendly-routes-to-everyday-destinations.html (DNPAO's Physical Activity Priority Strategy). It supports activity-friendly routes to everyday destinations that improve the safety and convenience of pedestrian, bicycle and/or public-transit networks and increase the proximity to everyday destinations like schools, parks and recreation facilities, workplaces, healthcare settings, shopping, business establishments, and faith-based venues through actions such as comprehensive or master plans and zoning reforms (4, 5). There is limited research on what policy implementation factors

increase physical activity through community design strategies while also addressing health equity (6).

For the past 20 years, DNPAO supported the Physical Activity Policy Research and Evaluation Network (PAPREN) as a Coordinating Center for physical activity researchers and practitioners to advance the field. PAPREN serves as a forum to: (a) exchange scientific and programmatic information; (b) conduct applied physical activity policy research; (c) support topical workgroups to further advance the field in specific areas; and (d) translate and disseminate the science to the field (7-9).

The purpose of this SIP is to conduct research and network activities to advance health equity related to DNPAO's Physical Activity Priority Strategy. The recipient will accomplish this by carrying out a health equity-centered physical activity policy implementation research project (Component A) AND lead and coordinate PAPREN and its topical workgroups to advance research, translation, and partnership activities (Component B).

Project Objectives and Outcomes

Component A: Conduct a Physical Activity Policy Implementation Research Project

Project Objectives

- Conducting a health equity-centered and community-engaged physical activity policy implementation research study with at least one of the two following priority populations: racial/ethnic minorities and/or communities with lower incomes. The research study must also be inclusive of people with disabilities.

Project Outcomes

- Increased number of evidence-based, health equity-centered policy implementation strategies to encourage the uptake and/or adaptation of DNPAO's Physical Activity Priority Strategy within priority communities.
- Increased number of evidence-based, health equity-centered policy implementation strategies to encourage the uptake and/or adaptation of DNPAO's Physical Activity Priority Strategy within PAPREN's Topical Workgroup areas of focus (e.g., rural communities).

Component B: Lead and Coordinate PAPREN

Project Objectives

- Supporting network activities to advance research, translation, dissemination, and partnership activities to address health equity in priority communities.

Project Outcomes

- Increased translation and dissemination strategies and opportunities to implement DNPAO's Physical Activity Priority Strategy in priority communities.
- Increased multi-sectoral and community-engaged collaborations and partnerships to promote the evidence-based implementation of DNPAO's Physical Activity Priority Strategy in a way that reduces health inequities.

Public Health Priorities

Healthy People 2030 Objectives

This project relates to the topic area of Physical Activity and the following objectives:

- PA-01: Reduce the proportion of adults who do no physical activity in their free time
- PA-02: Increase the proportion of adults who do enough aerobic physical activity for substantial health benefits
- PA-06: Increase the proportion of adolescents who do enough aerobic physical activity
- PA-10: Increase the proportion of adults who walk or bike to get places
- PA-11: Increase the proportion of adolescents who walk or bike to get places
- EH-02: Increase trips to work made by mass transit
- IVP-06: Reduce deaths from motor vehicle crashes

Active People, Healthy Nation

(12): Increase number of people who are physically active by 2027.

NCCDPHP Approach to Social Determinants of Health - SDOH Domains

Built Environment: Human-made surroundings that influence overall community health and people's behaviors that drive health.

Social Connectedness: When people or groups have relationships that create a sense of belonging and being cared for, valued, and supported.

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: Conduct a Physical Activity Policy Implementation Research Project

- Identify the implementation strategy being addressed and the specific research question and the rationale for the question. The research question should address one or both of the following policy implementation research questions:
    - What translation activities will increase the uptake of DNPAO's Physical Activity Priority Strategy within priority communities and address health inequities?
    - How can DNPAO's Physical Activity Priority Strategy be adapted to include policies, programs, and practices to prevent community violence (13), displacement (14), and/or other historic inequities (e.g., addressing community resilience)?
- Describe the outcomes measured and the rationale for selecting one or both policy implementation research questions noted above.
- Identify the priority population/community of focus, which must include one or both of the following: racial/ethnic minority communities or communities with lower incomes.
- Describe the research design and rationale.
- Describe the type of data collected (e.g., quantitative, and qualitative data)
- Describe methods for community engagement that describes how the community will be involved in the data collection plans and the interpretation of the results.

Study Design and Methods

- The applicant should propose methods to conduct the implementation research project that advances health equity within racial/ethnic minority and/or communities with lower incomes.
- The recipient is prohibited from direct activities related to changing federal, state, or local laws and must adhere to applicable anti-lobbying provisions.
- When possible and as appropriate, the applicant should propose to integrate a health equity lens in its proposed activities through strategies such as meaningful community engagement and a community participatory approach.

Component B: Lead and Coordinate PAPREN

- Maintain PAPREN's Topical Workgroups to conduct applied, health equity-centered physical activity policy implementation research projects that promote DNPAO's Physical Activity Priority Strategy. The applicant should describe:
    - The methods and rationale that they will use to coordinate PAPREN Topical Workgroups specific to their Workgroup's areas of focus.
    - How the Topical Workgroups will be leveraged to promote these projects.
- Lead and guide the PAPREN Topical Workgroups and Steering Committee (comprised of Coordinating Center leadership, Topical Workgroup leadership, and CDC collaborators).
- Manage a system of monthly network calls on cross-cutting workgroup topics related to advancing DNPAO's Physical Activity Priority Strategy to advance health equity with priority communities.
- Plans to develop, host, and manage a website for the PAPREN network.
- Support workgroup administrative and organizational functions (e.g., small stipends, fellow support, publication fees).

Target Population

Component A: Conduct a Physical Activity Policy Implementation Research Project

- The applicant can self-identify their priority population/community of focus and provide demographic characteristics of their proposed priority population(s) with respect to race/ethnicity, income, and disabilities.

Component B: Lead and Coordinate PAPREN

- The applicant should describe ways that they will include their priority populations/community of focus in their network of researchers, practitioners, fellows, and Topical Workgroups.

Collaboration/Partnerships

Component A: Conduct a Physical Activity Policy Implementation Research Project

- Describe the partners the applicant will work with to support the Research Project and why. The applicant should consider potential partnerships with:
    - Priority communities.

- Other PRCs and other academic research centers such as USDOT's University Transportation Centers (https://www.transportation.gov/content/university-transportation-centers) who can serve as multisectoral research partners;
- Government or academic groups who conduct physical activity research;
- State and local health departments, and subject matters experts in health equity; and;
- SMEs in health equity with specific expertise in community-based participatory research and community engagement on research questions and design.

Component B: Lead and Coordinate PAPREN

- Describe how the applicant will broaden participation in PAPREN. The applicant should consider potential partnerships with:
  - Academic and other researchers;
  - Priority communities;
  - State and/or local-level CDC-funded DNPAO-funded recipients (15);
  - Active People, Healthy Nation (16,17,18) National Network (https://storybook.link/activepeoplenetwork/); and;
  - Nutrition and Obesity Policy Research and Evaluation Network (NOPREN).

Recruitment Plan

The applicant should describe the methods they will use/or have used previously to identify/select the population/community for the proposed implementation research project described in Component A. If individual-level data collection is proposed for the implementation research project, the applicant should describe the methods they will use to recruit individuals within the population/community.

Annual Action Plan

The applicant should provide a 12-month annual action plan that includes SMART goals and objectives, including a progressive timeline of all tasks and milestones for both Component A and Component B. Note that the plan should delineate how the applicant plans to coordinate and monitor progress in carrying out all project objectives/outcomes for the entire 5-year project period.

Evaluation Plan /Performance Measurement

Applicants must provide an evaluation and performance measurement plan that demonstrates how the recipient will fulfill the requirements described. The plan must have two subsections that provide separate and specific details on the evaluation and performance measurement plans for Component A and Component B. The evaluation plan must meet SMART goals and be consistent with the CDC's Science Impact Framework and its five domains. https://www.cdc.gov/os/impact/framework.html. Each subsection of the evaluation plan should at a minimum include, but not be limited to:

- The level of public health impact for the applicant's activities.
- The extent to which the applicant addresses the priority population/community.
- The extent to which all Research (Component A) and PAPREN (Component B)activities are inclusive of people with disabilities.

- The extent to which the applicant uses community-engagement, community-based participatory research, and needs assessment techniques to advance health equity (e.g., in partnership with DNPAO's funded recipients).
- A listing and description of possible translation resources created and provided to the intended audience(s) that include state and local public health practitioners, scientists, decision makers, and priority communities.
- The resources and costs involved in implementing Component A and Component B.

Post-award, CDC will work collaboratively with recipient to modify the evaluation framework as appropriate.

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

Dissemination & Translation Plan

The recipient should develop one Dissemination and Translation plan that addresses both components A and B (as described below). The applicant's translation and dissemination plan should describe:

- An evidence-based approach to translate research activities conducted by the Coordinating Center and Topical Workgroups.
- Strategies and approaches to engage priority communities to inform translation and dissemination.
- Strategies to reach priority audiences including priority communities, DNPAO-funded recipients, Active People, Healthy Nation partners, and other key sectors that influence community design for physical activity (e.g., transportation/land use; housing; parks; community-based organizations).
- An approach for disseminating translation products to priority audiences.

Public Health Impact

The applicant should describe how its Implementation Research Project and PAPREN activities can provide a framework and platform to communicate and disseminate findings related to physical activity that can shorten the time from science to practice for communities that have unequal opportunities to safe and healthy conditions for physical activity.

Special Eligibility and Responsiveness

- The following criteria specific to this SIP will be used to determine the institution's eligibility: The applicant must provide evidence that its PI and/or co-PI have expertise (in the bio sketch) within the field of physical activity policy research, as demonstrated by at least 3 peer-reviewed publications since 2016.
    - Publications can be accepted but not yet published.
    - The PI may also be the senior author on publications.

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: Conduct a Physical Activity Policy Implementation Research Project

Does the applicant demonstrate experience in:

- Designing, collecting information, and analyzing data on community design for physical activity (see definition in the Project Description (https://www.cdc.gov/physicalactivity/community-strategies/activity-friendly-routes-to-everyday-destinations.html).
- Policy implementation or outcomes as demonstrated by peer-reviewed publications and/or funded research.
- Addressing equity and cultural sensitivities for the proposed priority community/communities of focus.
- Does the applicant include an MOU with a community-based organization with lived experience with the priority population/communities?

Component B: Lead and Coordinate PAPREN

To what extent does the applicant demonstrate the ability to:

- Identify key staff who will be devoted to the PAPREN by describing their demonstrated knowledge, experience, and ability in planning and conducting research and network activities.
- Coordinate and manage multi-site, collaborative research, and evaluation activities.
- Work with state and local health departments and other sectors important to DNPAO's Priority Strategy through an MOU from these partners (e.g., transportation/land use; housing; parks; community-based organizations).
- Facilitate and coordinate strategic partnerships on behalf of the PAPREN
- Host multi-site calls or events on health equity-centered policy research and evaluation methods related to DNPAO's Priority Strategy.
- Translate and disseminate different products for different audiences (e.g., public health practitioners and/or decision makers) with considerations for evidence-based translation, outreach, and dissemination to the priority communities.
- Maintain a public-facing resource for community and member materials.
- Maintain a platform to document monthly calls and workgroup action steps.
- Does the applicant include an MOU with a community-based organization with lived experience with the priority population/communities.

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.

Applicants should provide at least one Letter(s) of Support and/or Memorandums of Understanding for Component A and Component B from any of the following: community-based organizations, state and local health departments, planning departments, departments of transportation, public safety, or housing, or economic development offices, or elected officials, in an Appendix.

Availability of Funds

Approximately $1,500,000 is planned to fund one (1) Prevention Research Center for the five (5) year project period.

It is anticipated that approximately $300,000 is available to fund one Prevention Research Center(s) in year-one.

The year-one ceiling per recipient is $300,000.

Funding may vary and is subject to change. Funding available includes direct and indirect costs.

Research Status

It is expected that the research project will be non-exempt research involving human subjects and will require local IRB approval. Applicants should provide a federal-wide assurance number for each performance site included in the project.

OMB/PRA

OMB/PRA is not expected to apply.

Award Administration

CDC Project Scientist/Scientific Collaborator will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards. 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.

CDC's role in the implementation of the project will include:

- Providing technical assistance as requested for Component A and B
- Co-authoring scientific manuscripts when appropriate
- Providing technical assistance on translation products based on PAPREN research activities
- Collaborating on dissemination activities for Active People, Healthy Nation and DNPAO's funded recipients.

References

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SIP-24-008 Managing Epilepsy Well (MEW) Network

Project Description

The CDC Epilepsy Program created the Managing Epilepsy Well (MEW) Network in 2007 to advance epilepsy self-management research and implement collaborative activities with community partners to translate findings into practice to improve epilepsy outcomes. The Mew Network programs have improved a range of clinical and psychosocial outcomes (e.g., reduced seizure frequency, depression, improved quality of life) with program effectiveness seen in diverse epilepsy subgroups (e.g., Hispanic Americans, rural adults) (1-7). Feasibility of MEW Network program implementation in diverse settings has also demonstrated promising results (1). There have been no economic evaluations of the MEW Network evidence-based programs and no systematic determination of program implementation costs. Economic evaluations of chronic disease self-management programs generally include cost-effectiveness, cost-utility, or cost-benefit approaches (8). In cost-effectiveness studies, measures of effectiveness vary by the disease under study and the health outcome of interest. Cost-utility studies generally assess cost per quality-adjusted life-year (QALY) (9). In cost-benefit analysis, there are two commonly used methods for assigning monetary values to health benefits—willingness to pay (WTP) and cost of illness (COI) (10). Findings from such evaluations will help CDC quantify costs and any economic benefits of these programs to facilitate opportunities for public and private payer program adoption and reimbursement.

The Division of Population Health, National Center for Chronic Disease Prevention and Health Promotion seeks to support the Managing Epilepsy Well (MEW) Network. The purpose of the MEW Network is to advance epilepsy self-management research, translate research into action and disseminate findings in collaboration with network members and non-members such as national, state, and local partners. The MEW Network consists of multiple Collaborating Centers and one Coordinating Center recipient. All recipients will conduct research activities that will focus on economic evaluation of evidence-based MEW Network programs to address research gaps. The MEW Network Coordinating Center will lead and guide the network through a collaborative model that engages key partners and fosters coordination and collaboration with MEW Network Collaborating Centers. The MEW Network Collaborating Center recipients will complete activities listed in Component A below. The MEW Network Coordinating Center recipient will complete activities listed for both Component A and B listed below.

Project Objectives and Outcomes

Component A: MEW Network Collaborating Centers (Required)

Project Objectives

- Assess program implementation costs of at least one evidence-based MEW Network Program in both a community-based setting (e.g., local epilepsy social service agency) and in a healthcare setting (e.g., epilepsy clinic) that accounts for the range of health professionals serving as program facilitators as relevant by program (e.g., licensed social worker; community health worker; nurse; clinical psychologist).
- Conduct an economic evaluation study of at least one evidence-based MEW Network epilepsy self-management program.
- Collaborate with other MEW Network members to share best practices, lessons learned, and innovations through conference calls, emails, on-line meetings, webinars, and other channels to share knowledge, best practices, and other resources.
- Contribute to an annual evaluation report of site-specific activities and network-wide collaboration.

Project Outcomes

- Enhanced knowledge regarding MEW Network program implementation costs by implementation setting.
- Enhanced knowledge regarding MEW Network programs' cost-effectiveness
- Research study products, including but not limited to, evidence-based tools, strategies or programs, peer-reviewed manuscripts, presentations at national and international meetings/conferences, other resources such as briefs, research summaries, electronic communications and/or other applicable translation products that will benefit payers and epilepsy partners.

Component B: MEW Network Coordinating Center (Optional)

Project Objectives

- Establish and facilitate an epilepsy self-management research network engaged in economic assessments of program costs and cost-effectiveness, translation and dissemination of findings, and annual evaluation of MEW Network activities.
- Establish a communication infrastructure to facilitate network collaboration (e.g., capacity for, and use of virtual meeting platforms; coordination and facilitation of monthly meetings; hosting the MEW Network website).
- Support collaborative research activities with network members, their partners, and affiliates.
- Develop an annual priority action plan.
- Lead an annual evaluation report of network-wide activities and outcomes.

Project Outcomes

- Development of a research network for epilepsy self-management comprised of funded Collaborating Centers including a Coordinating Center.
- Enhanced coordination and collaboration among epilepsy health and social service providers, public health practitioners, and other epilepsy partners focused on epilepsy self-management.

- Dissemination of research findings on the economic evaluation of epilepsy self-management programs that inform collaboration partners and payers.
- Translation and dissemination of MEW Network findings to include evidence-based tools, presentations at professional and community conferences/meetings, peer-reviewed manuscripts, and other resources such as briefs, research summaries, electronic communications, and
- Documented plans for MEW Network sustainability and growth.

Note: All SIP24-008 applicants MUST apply for Component A (Collaborating Center) and will serve as a member of the MEW Network.

Applicants that wish to serve as the MEW Network 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.

Public Health Priorities

Healthy People 2030 Goals

This special interest project addresses multiple Healthy People 2030 target areas:

- **People with Disabilities:** Improve health and well-being in people with disabilities.
- **Mental Health and Mental Disorders:** Improve mental health.
- **Health Care:** Increase access to comprehensive, high-quality health care services

NCCDPHP Approach to Social Determinants of Health - SDOH Domains

Community-Clinical Linkages, ensuring that all people have equitable access to resources to prevent or manage disease.

Project Activities and Submission Requirements:

Component A: **MEW Network Collaborating Center (Required)**

- Applicants must conduct an economic evaluation of evidence-based MEW Network Program(s) and determine program implementation costs.
- The applicant will determine the MEW Network program(s) to be evaluated subject to proposed study design and available resources.
- Study perspectives for economic evaluation include, but are not limited to, payer (e.g., public, private) and individual (i.e., study participant) perspectives.
- Both prospective and retrospective studies of cost-benefit, cost-utility, or cost-effectiveness will be considered.
- Retrospective studies based on data from previous MEW Network SIP efficacy and evaluation studies (e.g., 2014-2019 or 2019-2024 SIPs) are permitted.
- Retrospective studies using data from non-research cooperative agreements DP 21-2101 or DP23-007 activities are not permitted to avoid conflation of non-research program evaluation data with research data. Prospective studies may include randomized assignment of intervention.
- Any prospective study cannot include participants identified through any MEW Network community-based program implementation activities funded under Epilepsy Program

non-research cooperative agreements DP 21-2101 or DP23-007 to avoid conflation of non-research program evaluation data with research data.

- Applicants are expected to describe how they will:
    - Assess MEW Network program(s) implementation costs.
    - Conduct economic evaluation research and provide a rationale for the proposed study perspective(s)
    - Define key evaluation questions.
    - Identify potential data sources and/or data-collection tools with which to evaluate program implementation costs and for economic evaluation stud(ies).
    - Collaborate with other members of the MEW Network to share knowledge, best practices, and other resources to enhance study implementation, effectiveness, evaluation, and impact.
    - Partner with relevant federal (e.g., VA, federally qualified community-based health centers), state or county agencies (e.g., public health, mental health, transportation, Area Agency on Aging), and social service agencies (e.g., local Epilepsy Foundation) to implement study objectives, as relevant.
    - Support dissemination activities
    - Translate findings into tools for decision-makers and/or epilepsy partners.
- The applicant should describe the Target Population relative to use of a retrospective or prospective study design.

Study Design and Methods

- In addition to the requirements above, the Research Plan should describe how applicants will use scientifically rigorous methods to address their research questions.
    - Quasi-experimental evaluation design can be used if a comparison group can be clearly defined and justified, and participants do not overlap with non-research cooperative-agreements DP 21-2101 or DP23-007.

Component B: MEW Network Coordinating Center (Optional)

Applicants are expected to describe how they will establish the MEW Network infrastructure and how coordination/implementation of the network will be achieved. Specifically, applicants are expected to describe how they will:

- Create a plan that addresses logistics as well as organization, structure, and how coordination will be achieved.
- Identify relevant community stakeholders that will participate in the network.
- Develop and incorporate a timetable for the continuation of a fully functioning network.
- Develop and support the communication infrastructure, including a MEW Network website.
- Coordinate and lead annual evaluation of MEW Network collaboration processes and outcomes.
- Disseminate and provide technical assistance to translate MEW Network study findings and resources to professional and lay groups.
- Identify the proposed staff who will work on Coordinating Center activities. Provide their relevant experience, a description of their roles, and the proportion of time each will

spend on coordinating center activities. Examples of these personnel may include an administrator, project manager, data manager, Web designer and others.

Target Population

Component A: Collaborating Centers (Required)

- Adults with doctor-diagnosed epilepsy who have completed participation in a MEW Network Program or will complete a MEW Network program, if part of a proposed prospective study.
- Applicants must consider the spectrum of adults who have epilepsy by socio-demographic characteristics and/or comorbidity status and focus on those who are most vulnerable (e.g., uninsured/underinsured adults or Medicaid beneficiaries; adults with lower incomes) and at greatest risk when developing their specific programmatic activities.

Collaboration/Partnerships

Components A and B

The following collaborations/partnerships are expected and should be considered in the development of the proposal for the MEW Network Research Project:

- Local epilepsy health and social service providers (e.g., local Epilepsy Foundation), relevant federal (e.g., VA, federally qualified community-based health centers), state or county agencies (e.g., public health, mental health), local health care public or private payer entities to inform approaches.
- Other members of the MEW Network
- CDC Epilepsy Program staff

Recruitment Plan

Component A: MEW Network Collaborating Center

The recruitment plan will vary depending on the study design.

- For retrospective studies, the applicant needs to clearly identify the data source, describe the study sample characteristics, how they will access data for both the treatment and control arms and provide a justification for choosing the proposed control group.
- For prospective studies, the applicant must provide a plan to identify and recruit adults with epilepsy who will be recruited to participate in the proposed epilepsy self-management program(s) (e.g., by socio-demographic characteristics, comorbidity status, etc.), for both the treatment arm and the control arm and the proposed duration of the study.

Annual Action Plan (Components A and B)

The applicant should 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 for Component A and/or B 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.

Component A: MEW Network Collaborating Center

- Describe a plan to assess initial and ongoing activities that includes evaluation questions, milestones, and measurable outcomes.

Component B: MEW Network Coordinating Center

- Describe a plan to monitor and evaluate network progress in achieving key milestones and major accomplishments including a description of performance expectations and how impact will be evaluated. A resource regarding evaluation can be found at: https://www.cdc.gov/eval/index.htm.

Data Management Plan (Components A and B)

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

Dissemination & Translation Plan

Component A: MEW Network Collaborating Centers

MEW Network Collaborating Centers recipients are expected to create a plan to disseminate science and translate research findings for public health practice. This may include, but is not limited to, the dissemination of key outputs including translation and implementation tools and resources, policy briefs and fact sheets, abstracts, presentations at national and international meetings/conferences, webinars, white papers, peer-reviewed manuscripts and/or continuing education opportunities. Translation and dissemination strategies proposed by the applicant should address the following:

- Describe the key outputs expected for translation (e.g., number of manuscripts per year published in peer-reviewed journals, number of tools/resources developed, number of presentations, etc.) based on the selected research priority.
- How the applicant will translate study outcomes into tools that can be utilized by various public health audiences.
- How the applicant will share results with partners, public health practitioners, study participants and broader epilepsy partners.

Component B: MEW Network Coordinating Center

The MEW Network Coordinating Center is expected to develop a plan to maximize efforts to translate and disseminate research findings across the network into public health practice. Translation and dissemination strategies proposed by the applicant should address the following:

- How the coordinating center will work collaboratively with CDC scientific and programmatic staff and partners (described in the Collaboration/Partnerships section) to determine translation needs of public health audiences and epilepsy partners.
- How the applicant will facilitate technical assistance to network members, as needed, regarding translation approaches to translate study outcomes into useful tools that can be utilized by various public health audiences.
- How the applicant will disseminate network findings and resources with partners, public health practitioners, study participants and epilepsy partners.

Public Health Impact

Seminal reports from consensus conferences on public health and epilepsy recognize that a collection of high-quality, validated epilepsy self-management programs are necessary to address the spectrum of epilepsy and to maximize effectiveness and reach [11]. The MEW Network is intended to address applied research needs in priority areas identified by epilepsy stakeholders that advance the development and dissemination of evidence-based epilepsy self-management programs [2,11]. The proposed MEW Network will supplement previous behavioral science and implementation research by examining economic evaluation of epilepsy self-management evidence-based programs [1,2]. Findings from such evaluations will help CDC quantify any economic benefits of these programs to facilitate opportunities for public and private payer program adoption and reimbursement. Because several of these programs are delivered by phone, they have the potential to improve reach, reduce barriers to care, and reduce substantial health disparities reported in this population.

Special Eligibility and Responsiveness

Component A: MEW Network Collaborating Center

The following criteria specific to this SIP will be used to determine the institution's eligibility:

- Applicants must provide a letter of support demonstrating evidence of access to data from a study population from a completed MEW Network Program (i.e., for a retrospective study) or approval from MEW Network program principal investigator(s) for implementation of any prospective study to ensure use of the appropriate program protocol and to maintain program fidelity. Documentation should be placed in the appendices of the application.

Component B: MEW Network Coordinating Center

- Applicants must apply for Component A. Only applicants funded under Component A will be considered for funding under Component B.

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: MEW Network Collaborating Center

- Does the institution provide evidence that the project team will include experts in epilepsy, health services research, program evaluation, and implementation science as evidenced in the Research & Related Senior/Key Person Section of the SF424 (R&R)?
- Does the applicant have a research team that has evidence of prior experience (e.g., publications) in conducting epilepsy self-management research?
- Does the research team include health economists with evidence of expertise and prior experience (e.g., publications) conducting economic evaluations (i.e., implementation costs, cost-effectiveness, cost-utility, and/or cost-benefit analysis)?
- Does the applicant provide a letter of support from relevant MEW Network program investigators to obtain the epilepsy self-management program material and protocol for program implementation?
- Does the applicant provide a letter of support from one or more existing epilepsy partners (as mentioned above in the Collaborations/Partnerships sections) demonstrating partnership that specifies the collaborative role that the partner will have for the project?
- Does the applicant propose to assess program costs for more than one MEW Network program?
- Does the applicant propose to conduct economic evaluation of more than one MEW Network program?
- Does the applicant propose more than one methodological approach for Component A? For example,
    - Assessment of more than one endpoint is preferred, e.g., cost per quality-adjusted life-year (QALY) from cost-utility study, cost of illness (COI) and/or willingness to pay (WTP) from cost-benefit analysis;
    - Economic evaluation from more than one study perspective is preferred, e.g., individual, payer and/or societal perspectives.
- Does the applicant identify any anticipated barriers to conducting the study and how these will be addressed?

Component B: MEW Network Coordinating Center

- Does the applicant demonstrate prior experience:
    - Leading and evaluating academic and community-based partner networks and complex relationships between organizations (e.g., between health systems and community organizations).
    - Coordinating and/or managing a multi-site, collaborative research or evaluation initiative that was successfully sustained over multiple years.
    - Coordinating and/or managing a multi-site, collaborative research or evaluation initiative focused on epilepsy that was successfully sustained over multiple years.
    - Evaluating the impact of public health interventions or programs.
    - Translating and disseminating products that target various audiences (e.g., public health practitioners, community-based organizations, decision-makers, etc.).

Funding Preferences

Component A: MEW Network Collaborating Center

Diversity of MEW Network evidence-based programs.

Component B: **MEW Network Coordinating Center**

None.

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

All applicants of SIP 24-008 are REQUIRED to apply for Component A (Collaborating Center) and will serve as a member of the MEW Network.

Applicants that wish to serve as the MEW Network 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

Component A: MEW Network Collaborating Center

- Identify the selected MEW Network program(s) to be examined.
- Describe the type(s) of economic evaluation study proposed.
- Describe the proposed study cohort (e.g., prospective, retrospective).
- Describe the proposed study population (e.g., geographic location, epilepsy comorbidity, age, sex, race/ethnicity).
- If a prospective study is proposed, identify the MEW Program to be implemented, describe participant recruitment, their follow-up, and data collection frequency over the funding period.
- Describe the variables, e.g., health and economic evaluation outcomes to be collected and how they will be/were measured.
- Describe the proposed analytic or statistical methods for all study objectives. Describe the statistical tests and software to be used.

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.

Availability of Funds

The estimated total funding (direct and indirect) for the 3-year period of performance is $2,850,000 to support up to 3 awards (as described below). Awards issued under this NOFO are contingent upon availability of funds and enough meritorious applications.

Component A: MEW Network Collaborating Centers

Period of performance: 3 years, 09/30/2024-09/29/2027

Estimated total funding (direct and indirect costs) per year: $600,000

Estimated funding (direct and indirect costs) per recipient per year: $300,000

Year 1 Ceiling: $300,000

Estimated number of awards: 2

Component A & B: MEW Network Collaborating and Coordinating Center

Period of performance: 3 years, 09/30/2024-09/29/2027

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

Year 1 Ceiling: $350,000

Estimated number of awards: 1

R**esearch Status**

It is expected that this project will be non-exempt research. It is anticipated that this project will require local IRB approval. Applicants should provide a federal-wide assurance number for each performance site included in the project.

OMB/PRA

OMB/PRA is not expected to apply.

Award Administration

CDC Project Scientist/Scientific Collaborator will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards. 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

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SIP-24-009 Arthritis Management and Wellbeing Research Network (AMWRN)

Project Description

Arthritis is an often overlooked, leading contributor to chronic disease burden and a top cause of morbidity, work limitations, and reduced quality of life. More than 58 million adults in the United States have arthritis, half of whom are working-aged; and 78 million are projected to have it by 2040 *(1-2*). In 2013, the total national arthritis-attributable medical care costs and earnings losses among adults with arthritis were $303.5 billion *(3*). Arthritis poses a huge societal burden not only because of its high prevalence and large economic impact, but also because of the pain and limitations it causes in both physical and social functioning. Many adults with arthritis have moderate or severe joint pain and approximately 44% of adults with arthritis report limitations, which can include trouble doing daily activities attributable to arthritis (*1*).

Research has shown that engaging in regular physical activity can improve arthritis-related pain, physical function, and quality of life *(4-6*). Self-management education interventions can also help adults with arthritis improve self-efficacy and skills to manage pain *(7,8)*. Low-cost, arthritis-appropriate, evidence-based interventions (AAEBIs) have been shown to decrease arthritis pain or improve its management and/or reduce other symptoms such as disability and improve quality of life (*9)*. These programs are available in geographic pockets across the US, but do not reach all people who can benefit from them. Lack of awareness about AAEBIs, their benefits, and how to access them remain a challenge and a barrier to participation in these programs. Increasing program offerings and delivery formats, with greater geographic dispersion and greater promotion, may increase participation.

The Division of Population Health, Healthy Aging Branch seeks to support the establishment and coordination of an Arthritis Management and Wellbeing Research Network (AMWRN). The purpose of the AMWRN is to exchange programmatic and scientific information, plan and implement collaborative research and evaluation activities, translate research into action, and broadly disseminate findings. The AMWRN consists of multiple Collaborating Centers and one Coordinating Center recipient. All recipients will conduct arthritis research to enhance surveillance, evaluate and refine intervention strategies and explore emerging data on arthritis management and outcomes. The Coordinating Center will engage in arthritis research and will

lead/guide the network through a collaborative model that engages key partners and fosters network coordination and collaboration. AMWRN Collaborating Center recipients will complete activities listed in Component A below. The AMWRN Coordinating Center recipient will complete activities listed for both Component A and B listed below.

Project Objectives/Outcomes

Component A: AMWRN Collaborating Centers (Required)

Project Objectives

- Conduct arthritis surveillance, research, and evaluation aimed at improving arthritis management and outcomes.
- Serve as a member of the AMWRN Community Advisory Group to identify arthritis research priorities and conduct research which aligns with the mission of the network.
- Collaborate with the other Coordinating Centers and other members of the AMWRN through conference calls, emails, on-line meetings, webinars, and other channels to share knowledge, best practices, and other resources.
- Utilize the *Science Impact Framework* and *Knowledge to Action Framework* to disseminate science, create awareness of AMWRN priorities, progress and findings, and catalyze action by infusing new knowledge into practice.

Project Outcomes

- Enhanced knowledge pertaining to arthritis risk factors, early diagnosis and treatment, intervention strategies and/or emerging evidence on promising arthritis management strategies.
- Enhanced collaboration among public health practitioners and other key stakeholders focused on arthritis management and wellbeing.
- Research study products, including but not limited to, evidence-based tools, strategies or programs, peer-reviewed manuscripts, presentations at national and international meetings/conferences, other resources such as briefs, research summaries, electronic communications and/or other applicable translation products that will benefit the public.

Component B: AMWRN Coordinating Center (Optional)

Project Objectives

- Establish and facilitate an AMWRN to coordinate arthritis research, translation and dissemination activities;
- Establish a community advisory group comprised of Collaborating Center members, non-members (e.g., scientific experts, healthcare providers, CDC-funded and non-funded state and national partners and other relevant stakeholders interested arthritis) and diverse individuals living with arthritis to identify research priorities that align with *A National Public Health Agenda for Osteoarthritis: 2020 Update* and develop plans for network sustainability and growth;
- Utilize the *Science Impact Framework* and *Knowledge to Action Framework* to plan and coordinate dissemination activities and increase awareness of the AMWRN and its priorities, progress and tools/resources.

Project Outcomes

- Development of a coordinated, research and evaluation network for arthritis;
- Enhanced collaboration among researchers, public health practitioners and other key stakeholders focused on arthritis management and wellbeing; and
- Coordination of translation and dissemination activities aligned with priorities.

Note: All applicants of SIP 24-009 are **REQUIRED** to apply for Component A (AMWRN Collaborating Centers).

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

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

Public Health Priorities

Healthy People 2030 Objectives

This project relates to the Healthy People 2030 topic area of Arthritis and the following objectives:

- A-01: Reduce the proportion of adults with arthritis who have moderate or severe joint pain
- A-02: Reduce the proportion of adults with arthritis whose arthritis limits their activities
- A-03: Reduce the proportion of adults with arthritis whose arthritis limits their work
- A-04: Increase the proportion of adults with arthritis who get counseling for physical activity

NCCDPHP Approach to Social Determinants of Health - SDOH Domains

Community-Clinical Linkages, ensuring that all people have equitable access to resources to prevent or manage disease.

Project Activities and Submission Requirements

Component A: AMWRN Collaborating Centers (Required)

Applicants must propose one research project from the following list of eight research priorities:

1. Develop or translate and pilot test an innovative or promising tool that will advance implementation of clinical and public health guidelines for arthritis diagnosis and management or improve arthritis-specific health outcomes (pain, physical function, disease progression, etc.).
2. Investigate the effectiveness of addressing personal and social determinants of health alongside clinic to community linkages to AAEBIs and other evidence-based arthritis interventions using a whole healthcare approach to personalize care for adults with arthritis.
3. Use objective monitoring data to evaluate the dose-response effects of physical activity on arthritis-attributable outcomes (e.g., pain, disease progression, health-related quality of life, physical function, depression) among adults with arthritis as listed in the Physical Activity Guidelines Scientific Report.
4. Determine the cost-effectiveness or conduct cost-benefit analysis of AAEBIS or other self-management interventions (OSMIs) for arthritis management and arthritis-related health outcomes. The selected OSMI must be recognized as evidence-based by at least

one federal agency and must emphasize physical activity, weight management, joint injury prevention and/or chronic disease self-management education.

5. Assess the role of specific diets (e.g., Mediterranean diet), dietary components, nutritional supplements, dietary restrictions, or modified nutrient sources in the prevention and management of arthritis.
6. Investigate the dissemination, implementation, and cost-effectiveness of primary, secondary, and tertiary prevention strategies or programs (e.g., biomechanical modifications, physical activity, weight management) for arthritis.
7. Explore links between opioid prescriptions among adults with arthritis and opioid-related health outcomes (e.g., transitioning to illicit opioids, opioid/substance use disorder, opioid/drug non-fatal overdose, opioid/drug fatal overdose).
8. Compare the relative effectiveness of non-pharmaceutical approaches (i.e., participation in evidence-based physical activity programs, Chronic Pain Self-Management Education, mindfulness, acceptance therapy) and pharmaceutical approaches (i.e., acetaminophen, NSAIDs, corticosteroids, opioids, etc.) for pain management among adults with arthritis.

Applicants should describe plans to use scientifically rigorous methods to address the selected research priority.

- Identify an appropriate research design methodology and justify why it is appropriate to address the research priority.
- Describe methods for community or organizational engagement that includes the use of community-based participatory research and needs assessments.
- Describe capacity and experience related to arthritis surveillance, research and/or evaluation, and the proposed research strategy.
- Discuss how findings will be translated into products that are relevant to various stakeholders (e.g., diverse individuals living with arthritis, public health practitioners, decision-makers, etc.).
- Identify the proposed staff who will work on the research project. Provide their relevant experience, a description of their roles, and the proportion of time each will spend on the project.

Component B – AMWRN Coordinating Center (Optional)

Applicants should describe how they will establish the AMWRN infrastructure and how coordination/implementation of the network will be achieved. Including the following:

- Description of the resources and processes that will facilitate linkages and activities among the AMWRN, such as convening network members, formation of the advisory group and/or topic-specific work groups, coordination of conference calls, distribution of network information and dissemination of research findings and products. Include the process and frequency by which the AMWRN will communicate and meet (virtually and/or in-person).
- Description of how the network will function to coordinate translation and dissemination activities rooted in the *Science Impact Framework* and *Knowledge to Action Framework* and raise awareness of the network and products developed.

Applicants should describe how they will provide strategic leadership to foster and expand the reach of the network.

- Identify the proposed staff who will work on Coordinating Center activities. Provide their relevant experience, a description of their roles, and the proportion of time each will spend on coordinating center activities. Examples of these personnel may include an administrator, project manager, data manager, Webmaster and others.

Study Design and Methods

In addition to the requirements above, the Research Plan for Component A should describe how applicants will use scientifically rigorous methods to address their research questions.

Target Population

The AMWRN is focused on US adults 18 years and over with doctor-diagnosed arthritis, especially populations disproportionally affected. Disproportionately affected populations can include, but are not limited to, populations and communities that are high-burdened and underserved, such as veterans, uninsured/underinsured adults or Medicaid beneficiaries; adults with lower incomes; adults with disabilities; adults living in rural/sparsely populated areas or other areas lacking health services or AAEBIs; adults with arthritis-attributable work or activity limitations, severe joint pain, or arthritis and moderate to serious mental distress; and/or adults from racial and ethnic minority groups with high arthritis prevalence or burden, e.g., American Indian, Alaska Native, African-American or Hispanic/Latino persons. The applicant should describe the target population and how the population is consistent with the AMWRN focus.

Collaboration/Partnerships

Component A: AMWRN Collaborating Centers (Required)

The following collaborations/partnerships are expected and should be considered in the development of the proposal for the AMWRN Research Project.

- Collaborate with existing arthritis partners, such as the Arthritis Foundation, Osteoarthritis Action Alliance, Y-USA, National Association of Chronic Disease Directors, National Recreation and Parks Association, Society for Public Health Education, CDC-funded state partners and other relevant stakeholders (e.g., American College of Rheumatology, American College of Sports Medicine, American Physical Therapy Association, non-funded state partners addressing arthritis, scientific experts, healthcare providers) to support the objectives of the research project.
- Include the perspectives and lived experiences of diverse individuals living with arthritis to help inform the study design.

Component B: AMWRN Coordinating Center (Optional)

In addition to the partnerships proposed for Component A, the following collaborations and/or partnerships should be addressed in the proposal for the AMWRN Coordinating Center:

- Collaborate with CDC program staff to provide strategic direction to AMWRN and advise on policy research gaps that have relevance to the field of public health practice.
- Collaborate with Prevention Research Centers (RFA-DP-24-004) who have research projects that focus on arthritis and/or its risk factors.

Recruitment Plan

The applicant should describe their plans to identify and engage experts in arthritis who could contribute topical knowledge to address this project. Collaboration with partners as described above will be key in the recruitment process.

Component A: AMWRN Collaborating Center (Required)

- Describe recruitment strategies or the plan to access existing data sources needed to carry out the research project.

Component B: AMWRN Coordinating Center (Optional)

- Describe how the applicant plans to engage experts in arthritis throughout the project to carry out the priorities of the AMWRN.

Annual Action Plan

The applicant should 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 for both component A and B that demonstrates how the recipient will fulfill the requirements described. A resource regarding evaluation can be found at: https://www.cdc.gov/eval/index.htm.

Component A: AMWRN Collaborating Centers (Required)

- Describe a plan to assess initial and ongoing activities that includes evaluation questions, milestones, and measurable outcomes.

Component B: AMWRN Coordinating Center (Optional)

- Describe a plan to monitor and evaluate network progress in achieving key milestones and major accomplishments.

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

Dissemination & Translation Plan

Component A: AMWRN Collaborating Centers (Required)

AMWRN Collaborating Center recipients are expected to disseminate science and translate research findings into public health practice; including but not limited to translation and implementation tools and resources, policy briefs and fact sheets, abstracts, presentations at national and international meetings/conferences, webinars, white papers, peer-reviewed manuscripts, continuing education opportunities, etc. Translation and dissemination strategies proposed by the applicant should address the following:

- How results will be translated into useful tools that can be utilized by various public health audiences.
- How the applicant will share results with partners, public health practitioners, study participants and broader arthritis practitioners.
- Key outputs planned for translation (e.g., number of manuscripts per year published in peer reviewed journals, number of tools/resources developed, number of presentations, etc.) based on the selected research priority.

Component B: AMWRN Coordinating Center (Optional)

The AMWRN Coordinating Center is expected to develop a plan to maximize efforts to disseminate and translate research findings into public health practice. The plan should include a coordinated dissemination strategy based on the research priorities and address the following:

- How the applicant will engage AMWRN members and others in the development of the plan.
- How the AMWRN will determine 1) which translation products are needed and 2) what activities will be implemented to help disseminate them and increase awareness; and
- How the AMWRN will work collaboratively to identify future needs and gaps.

Public Health Impact

The proposed AMWRN will conduct surveillance, research, and evaluation activities with the goal of reducing the burden of arthritis, especially among populations who are disproportionately affected.

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: AMWRN Collaborating Centers

- Does the research component focus on at least 1 of the 8 identified research priority topics (as identified above in the Study Design and Methods section)?
- Does the applicant describe the research activities and how these activities will address the selected research priority?
- Does the applicant demonstrate evidence that the project team will include staff with capacity and experience in chronic disease surveillance, research and/or evaluation?
- Does the applicant describe experience creating translation and dissemination products targeting public health practitioners, non-governmental organizations, and/or decision makers?
- Does the applicant describe how the results from the research findings will be translated, and disseminated?

- Does the applicant provide a memorandum of understanding demonstrating evidence of access to relevant data sources (if not publicly available) or access to the populations in which the study will be conducted?
- Does the applicant provide a letter of support or memorandum of understanding from at least one of the existing arthritis partners (as mentioned above in the Collaborations/Partnerships section) demonstrating partnership that specifies the collaborative role that the partner will have for the project?

Component B: AMWRN Coordinating Center

- Does the applicant demonstrate prior experience: Coordinating and/or managing a multi-site, collaborative research or evaluation initiative that was successfully sustained over multiple years.
- Leading groups and working with academic-community partners on multi-site projects around a common agenda.
- Evaluating the impact of public health interventions or programs.
- Translating and disseminating products that target various audiences (e.g., public health practitioners, community-based organizations, decision makers, etc.).

Funding Preferences

Component A: AMWRN Collaborating Centers

- Geographic diversity
- Arthritis research projects that address a variety of priorities (1-8) listed above.

Component B: AMWRN Coordinating Center

- None.

Research Plan Length and Supporting Material

- 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).
- Component A (Collaborating Center) applicants must identify the research priority to be studied (from the list of 8) at the beginning of the Specific Aims.
- Follow the research strategy page length provided below.

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

- To be funded for Component B: Coordinating Center, applicants must also apply for and be funded for Component A (Collaborating Center)
- One application should be submitted for one (Component A) or both components (A and B).

- Supporting material included as appendices may not exceed 10 PDF (maximum of 30 pages) attachments. The appendices may include materials that support the contents of the proposal (i.e., MOUs, questionnaires and surveys, blank data collection forms, blank survey forms and interview questions, budget breakdown for components). Appendices should not be used to circumvent page limits.
- Applicants applying for both Components A and B must include a budget breakdown for each component in the appendix.

Availability of Funds

The estimated total funding (direct and indirect) for the 5-year period of performance is $4,000,000 to support up to 3 awards. Awards issued under this NOFO are contingent upon availability of funds and enough meritorious applications. Funding available includes direct and indirect costs.

Component A: AMWRN Collaborating Centers:

Period of Performance: 5 years, 09/30/2024-09/29/2029

Estimated total funding (direct and indirect costs) per year: $500,000

Estimated funding (direct and indirect costs) per recipient per year: $250,000

Year-1 Ceiling: $250,000

Estimated total number of awards: 2

Component A & B: AMWRN Collaborating and Coordinating Center:

Period of Performance: 5 years, 09/30/2024-09/29/2029

Estimated total funding (direct and indirect costs) per year: $300,000

Estimated funding (direct and indirect costs) per recipient per year: $300,000

Year-1 Ceiling: $300,000

Estimated total number of awards: 1

Research Status

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

OMB/PRA

OMB/PRA is not expected to apply.

Award Administration

The CDC Project Scientist/Scientific Collaborator will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards. CDC staff will serve as consultants on this project, and will provide technical assistance, as requested, on project activities such as research/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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SIP-24-010 Mental Health and Chronic Disease Prevention Network (MHCDPN)

Project Description

Mental health conditions are common, and it is estimated that more than one in five US adults aged 18 or older live with a mental illness (57.8 million in 2021) (1). Poor mental health is a risk factor for multiple chronic diseases (2). For example, for individuals with depression, the risk of developing cardiac disease, hypertension, stroke, diabetes, metabolic syndrome, or obesity is

about 40% higher than in the general population (3). Mental health, emotional well-being, and social connectedness are protective factors that lay a foundation for health and play a critical role in prevention and health maintenance (4). Promotion of mental health strategies to prevent chronic disease is especially important due to the opportunity to address protective factors upstream. For example, social connectedness serves as a key factor in protecting, improving, and maintaining individual and community well-being. Although there is significant evidence that demonstrates the health impacts of social isolation and loneliness, there is less evidence for interventions and strategies for specific populations or settings (5). More research needs to be done to further identify, develop, and evaluate effective, evidence-based population health strategies that moderate the negative health effects of poor mental health, including social isolation and loneliness.

The Division of Population Health seeks to support the establishment and coordination of Mental Health and Chronic Disease Prevention Network (MHCDPN). The purpose of the MHCDPN is to further develop the understanding of the positive and protective role of mental health and emotional well-being on health outcomes, including chronic disease. The MHCDPN will engage CDC scientists, public health partners and funded PRCs (RFA24-004) conducting research that addresses upstream factors related to mental health, such as social connectedness. The MHCDPN Coordinating Center will complete activities that address Components A and B listed below.

Project Objectives and Outcomes

Component A: Conduct a Research Project on Social Connectedness

Project Objectives

- Identify effective social connectedness interventions for a diverse range of populations that are disproportionately at risk for social isolation and loneliness (SIL), including individuals such as those living with physical and mental disabilities, low-income, immigrants, LGBTQIA+, or rural-residing individuals.

Project Outcomes

- Build the evidence for effective population health strategies related to social connectedness that moderate the negative health effects of poor mental and physical health for broader dissemination and implementation of these strategies in public health practice.
- Identification of effective, evidence-based population health strategies to promote mental health, emotional well-being, and social connectedness and prevent chronic disease that address disparities in at-risk populations.

Component B: Develop, Lead, and Coordinate MHCDPN

Project Objectives

- Establish a network of public health partners and funded PRCs conducting research that addresses upstream factors relation to mental health, such as social connectedness, to identify and disseminate evidence-based population health strategies that can be brought to scale.

- Address MHCDPN priorities through the lens of policy, systems, and environmental (PSE) change approaches that foster social and environmental factors that support community resilience, especially within at-risk populations.
- Advance community-engaged research, practice, and policy around social determinants of health to reduce disparities and promote health equity.
- Provide a framework and platform to communicate, share, and translate and disseminate research findings.
- Collaborate and leverage the expertise of partners across sectors.

Project Outcomes

- Determine evidence-based population health strategies that can be brought to scale.
- Facilitate and support the MHCDPN.
- Build partnerships and translate and disseminate key research findings into public health practice.

Public Health Priorities

Healthy People 2030 Objectives

HIT-04: Health Communication/ Increase the proportion of adults who report having social support (i.e., having friends or family members with whom they talk to about their health).

NCCDPHP Approach to Social Determinants of Health - SDOH Domains

Social Connectedness: the degree to which people or groups have relationships that create a sense of belonging and being cared for, valued, and supported.

Project Activities and Submission Requirements

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

Component A: Research Project on Social Connectedness

The applicant should propose a research project to address social connectedness in at-risk populations.

The research plan should:

- Include analysis of SIL as a risk factor for poor health outcomes. Key research questions should address:
    - What are the unique social connectedness needs of individuals living with different types of physical and mental disabilities and chronic conditions, low income, immigrants, LGBTQIA+, or rural-residing individuals?
    - What are the most effective intervention strategies for improving social connectedness outcomes in populations identified as disproportionately at risk for SIL?
- Target population-based health strategies at the community level.

- Evaluate existing social connectedness interventions or develop, pilot test, or translate an innovative or promising tool for social connectedness that will advance implementation of population health strategies to improve health outcomes in at-risk populations.
- Be operationalized through a policy, systems, and environmental change approach.
- Ensure the research is relevant to public health practice for at-risk populations and describe strategies for dissemination and plan for scale-up.
- Describe how they intend to identify and evaluate effective evidence-based population health strategies that moderate the negative health effects of SIL.

Component B: Develop, Lead, and Coordinate MHCDPN

- Develop a collaborative model that facilitates and supports the work of the MHCDPN.
- Establishment of a forum for regular collaboration with members of the MHCDPN network through monthly conference calls/meetings, e-mail follow-ups, online meetings, or other channels to share knowledge, best practices, and other resources (e.g., survey instruments, protocols, program toolkits) to enhance scale-up, implementation, effectiveness, evaluation, program reach, and impact.
- Support development and dissemination of population health strategies focused on upstream factors related to mental health, such as social connectedness, belonging, emotional well-being, flourishing, and resiliency.
- Coordinate, lead, and host monthly MHCDPN conference calls/meetings, provide hosting platform, track action items, follow-ups, and outcomes.
- Host an annual meeting where MHCDPN members share their research with each other and public health practitioners.
- Establish a public-facing clearinghouse for MHCDPN member materials.
- Create plans for network sustainability and growth.
- Ensure activities are relevant to public health practice for at-risk populations.
- Establish and support partnerships, collaboration, translation, and dissemination.
- Collaborate with CDC program and network partners.
- Establish partnerships with impactful and relevant community-based and professional organizations and other stakeholders.
- Develop translation and implementation tools and resources targeting public health practitioners and/or decision makers.
- Promote and communicate progress and disseminate key research findings through policy briefs, fact sheets, commentaries, publications in peer-reviewed journals, white papers, presentations, and webinars.

The recipient will not be involved in activities related to changing federal, state, or local laws and must adhere to applicable anti-lobbying provisions.

Study Design and Methods

In addition to the requirements above, the Research Plan should describe how applicants will use scientifically rigorous methods to address their research questions.

Target Population

Component A: Research Project on Social Connectedness

Those individuals at highest risk for social isolation, loneliness, and poor mental health outcomes including people with disabilities or chronic diseases and conditions, living in rural or under-resourced communities, or immigrant and sexual minority populations.

Collaboration/Partnerships

The following collaborations/partnerships are expected for Components A and B.

- Cross-sector community-based organizations and agencies that represent the target population, such as health care delivery systems, social services, local public health, schools, departments of education, law enforcement, older adult services, civic or volunteer groups, youth-servicing organizations, and religious or fraternal organizations.
- Experts in mental health with knowledge in primary prevention, including emotional well-being and social connectedness.
- Public health practitioners to maximize the impact for their project, including mental health organizations, professional societies, and other networks as appropriate.
- Other funded PRCs within the PRC network (RFA-24-004), other related CDC-funded projects, as well as other organizational units at their institution.

Recruitment Plan

The applicant should describe a plan to recruit the relevant organizations for Components A and B through partner networks from the community-level sectors noted above, including those engaged in community mental health.

Annual Action Plan

The applicant should provide a 12-month action plan using Specific, Measurable, Achievable, Relevant, and Time-bound (SMART) goals and objectives that includes a timeline and milestones for both Component A and B. Key activities and milestones should also be addressed for the entire project period. This should include identification of key staff who will be devoted to this project and describe their demonstrated knowledge and experience relevance to this SIP.

Evaluation Plan /Performance Measurement

Applicants must provide an evaluation and performance measurement plan that demonstrates how the recipient will fulfill the requirements described above for Component A and B. The applicant should describe an evaluation plan that meets SMART goals, consistent with the CDC evaluation framework (http://www.cdc.gov/eval/framework/). CDC will work collaboratively with recipient to develop an evaluation framework to guide evaluation.

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

Dissemination & Translation Plan

The recipient should develop one Dissemination and Translation plan that addresses both Components A and B (as described below). The recipient should develop a dissemination and translation plan that:

- Describes strategies to translation and disseminate key findings. This may include publishing research articles, presenting at conferences and meetings, convening webinars, and other efforts.
- Includes key outputs, including translation and implementation tools and resources, policy briefs, fact sheets, abstracts, commentaries, publications in peer-reviewed journals, presentations, white papers, presentations, and webinars.
- Leverages established partnerships to assist in the development and scale-up of the plan and ensure dissemination through partner channels and the target population in the communities.
- Provides guidance to the network on methods to translate and implement network tools and findings for public health practitioners, scientists, mental health organizations, professional societies, health care systems, decision-makers, and other stakeholders.

Public Health Impact

This project will provide a framework and platform to promote primary prevention mental health strategies at the population level to prevent chronic disease, especially within at-risk populations. MHCDPN will contribute to the evidence base for recommended population health strategies. Research conducted by the grantee will also further strengthen population health strategies focused on upstream factors related to mental health.

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: Research Project on Social Connectedness

Does the applicant describe experience in:

- Conducting research on risk factors or interventions related to SIL.
- Evaluating the impact of evidence-based population health strategies in public health.
- Scaling up evidence-based population health strategies.
- Creating translation and dissemination products targeting public health practitioners, community-based, non-governmental organizations, and/or decision-makers. The applicant should include recent quantifiable examples where possible.
- Mental health primary prevention strategies and chronic disease prevention.

Component B: Develop, Lead, and Coordinate MHCDPN

Does the application demonstrate ability to:

- Manage, facilitate, and coordinate strategic partnerships on behalf of the network.
- Disseminate products that target public health practitioners.

- Maintain a web-based resource center to house network materials and platform to document monthly calls and workgroup action steps.

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.

Availability of Funds

It is anticipated that approximately $1,500,000 (direct and indirect) is available to fund one (1) Prevention Research Center for a five (5) year project period. It is anticipated that approximately $300,000 (direct and indirect) is available to fund 1 Prevention Research Center(s) in year one. The year-one ceiling is $300,000 (direct and indirect). Funding may vary and is subject to change. Funding available includes direct and indirect costs.

Research Status

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

OMB/PRA

OMB/PRA is not expected to apply.

Award Administration

CDC Project Scientist/Scientific Collaborator will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards. 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. Substance Abuse and Mental Health Services Administration. Key Substance Use and Mental Health Indicators in the United States: Results from the 2021 National Survey on Drug Use and Health (HHS Publication No. PEP22-07-01-005, NSDUH Series H-57). Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration; 2022. Accessed June 23, 2023. https://www.samhsa.gov/data/report/2021-nsduh-annual-national-report

2. Perry GS, Presley-Cantrell LR, Dhingra S. Addressing mental health promotion in chronic disease prevention and health promotion. Am J Public Health. 2010;100(12):2337-9. doi: 10.2105/AJPH.2010.205146
3. Firth J, Siddiqi N, Koyanagi A, et al. The Lancet Psychiatry Commission: a blueprint for protecting physical health in people with mental illness. Lancet Psychiatry. 2019;6(8):675-712. doi: 10.1016/S2215-0366(19)30132-4
4. Merlo G, Vela A. Mental health in lifestyle medicine: a call to action. Am J Lifestyle Med. 2021;16(1):7-20. doi: 10.1177/15598276211013313
5. National Academies of Sciences, Engineering, and Medicine. Social Isolation and Loneliness in Older Adults: Opportunities for the Health Care System. The National Academies Press; 2020

SIP-24-011: Assessment of MMR immunization interventions for children in close-knit communities with longstanding vaccine hesitancy

Project Description

Measles was declared eliminated from the United States in 2000 due to high 2-dose measles, mumps, and rubella (MMR) vaccine coverage attained. Measles elimination is defined as the absence of endemic measles virus transmission in a defined geographic area for at least 12 months in the presence of a well-performing surveillance system. However, vaccine hesitancy is a major social determinant that threatens America's measles elimination status. From 2018-2019, sustained measles outbreaks that persisted over 10 months across multiple states were attributed to travelers having contracted measles outside the U.S. and having subsequently transmitted the virus through pockets of unvaccinated children in close-knit U.S. communities with longstanding childhood MMR vaccine hesitancy.

Clinicians have noticed increased resistance to MMR vaccine among certain close-knit groups due, in part, to perpetuated dissemination of vaccine-related misinformation to these communities (1,2,3). Local efforts to understand and address vaccine hesitancy in such close-knit communities have been ongoing. However, evaluations of primary stakeholder exposure and perceptions of the implementation and effectiveness of these interventions have yet to be conducted or published.

The purpose of this SIP is to conduct research, in collaboration with key community stakeholders, to assess current intervention(s) to reduce MMR vaccine hesitancy and increase MMR vaccination among children in a close-knit community of focus with longstanding MMR vaccine hesitancy (e.g., American Somali, Anabaptist, American Orthodox Jewish, Ukrainian American).

Project Goal and Outcomes

Project Goal

The goal of this research is to identify and assess current intervention(s) or program(s) to improve routine MMR vaccine confidence and increase MMR vaccination among children in a close-knit community of focus with a history of MMR vaccine hesitancy.

Project Outcomes

• Inform the development of current and future interventions to effectively address MMR vaccine hesitancy in these communities of focus and prevent future measles outbreaks.

• Assist the Division of Viral Diseases with being able to effectively address and significantly reduce vaccine hesitancy in close-knit communities that are experiencing or are vulnerable to measles outbreaks due to high rates of unvaccinated children.

Public Health Priorities

Healthy People 2030 Objectives
This project relates to the topic area of vaccination and the following objectives:

- Reduce the proportion of children who get no recommended vaccines by age 2 years (IID-02)
- Maintain the vaccination coverage level of 1 dose of the MMR vaccine in children by age 2 years (IID-03)
- Maintain the vaccination coverage level of 2 doses of the MMR vaccine for children in kindergarten (IID-04)

NCCDPHP Approach to Social Determinants of Health - SDOH Domains

Community-Clinical Linkages: Connections made between health care, public health, and community organizations to improve population health.

Project Activities and Submission Requirements

Based on prior work towards understanding and addressing parental/guardian knowledge, attitudes, beliefs, and practices related to MMR vaccination for the children in their care, as well as factors that perpetuate vaccine hesitancy in their community of focus, the objectives of the project are to:

- Participate in the ARISe network (SIP 24-012) - a planned thematic network
- Assess the exposure of the interventions for the communities of focus;
- Understand the perceptions of the implementation of the interventions;
- Identify if there were significant differences in parental knowledge, attitudes, and beliefs related childhood MMR vaccination between those exposed to the interventions and those who were not exposed to the interventions; and
- Determine the impact of the interventions by measuring change in MMR doses received, vaccination coverage rates, and differences in 0-dose children between the intervention group and those that were not exposed to interventions.

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

- Utilize a rigorous mixed-methods research approach and articulate a clear description of key aspects of the intervention (e.g., how the intervention is tailored specifically for the close-knit community of focus based on literature or other research, why particular strategies are being utilized for the study).
- Assess exposure and perceptions of the implementation and effectiveness of tailored behavioral intervention(s) to reduce vaccine hesitancy and significantly increase childhood vaccination rates in a close-knit community with known longstanding MMR vaccine hesitancy that has experienced a measles or mumps outbreak in the last 10 years.

- Leverage prior and ongoing work around parental/guardian knowledge, attitudes, beliefs, and practices related to MMR vaccination for the children in their care to:
    - Assess exposure to tailored interventions for the specified community of focus.
    - Assess the perceptions of the implementation of the tailored behavioral interventions by interviewing key primary stakeholders (e.g., parents/guardians, healthcare providers, other identified trusted messengers and community opinion leaders).
    - Determine which elements of the intervention are critical to successful outcomes.
- Recipient should consider culturally appropriate translation of vaccine confidence materials and messages delivered in settings selected based on work with the community of focus or collaboration with trusted community partners and organizations that are well-positioned to improve vaccine confidence and access within their populations.
- Recipient may not fund broadscale communication campaigns designed for general public consumption.
- Researchers must engage with other CDC-funded PRCs within the PRC Network by attending regularly scheduled meetings and exchanging insights on challenges, successes, and best practices.
- Recipients are expected to participate in the Advancing Research in Immunization Services Network (ARISe Network) activities as agreed upon with the ARISe Coordinating Center (SIP 24-12). Potential activities include:
    - Participation in scheduled workgroup calls and activities.
    - Participation in the development of products such as policy briefs, fact sheets, abstracts, presentations, white papers, and peer-reviewed manuscripts, as planned by the respective workgroups.
    - Participation in synthesis documents/workshop proceedings that summarize current needs and knowledge gaps in immunization services research and create an actionable plan to address them.

Collaboration/Partnerships

The applicant should describe how they will carry out the following collaborations and partnerships:

- Identify who, within the community of focus, is knowledgeable about the people in the community (e.g., community opinion leaders, trusted messengers, community leaders, community physicians/healthcare providers).
- Collaborate with other researchers, healthcare practitioners, community-based organizations, and others who may be currently working on similar efforts, which is essential to successfully conducting this research.
- Partner closely with state and local health departments and relevant NGOs as allies--this is essential, as they may have critical knowledge of who the information gatekeepers are and who the community opinion leaders and trusted messengers may be. Applicants must demonstrate how they plan to work with these allies to conduct this research.
- Collaborate with CDC program staff, who will serve as consultants on this project and will provide technical assistance, as requested, on research activities such as research and

interview instrument design, data collection and analysis, and data interpretation and dissemination of results.
- Engage with other CDC-funded PRCs and/or other thematic networks working on health equity-focused research and collaborate where applicable.
- Participate in the ARISe Network activities (SIP 24-012).

Recruitment Plan

The applicant should describe the methods of how participants will be recruited for this research project. Recipients should collaborate with partners described above as appropriate.

Annual Action Plan

The applicant should provide a 12-month annual action plan that includes SMART goals and objectives, including 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 above and include a quality assurance plan as part of the application.
- Recipient will monitor the implementation of the mixed-methods research plan to ensure consistency with the original research design and to track implementation progress. Monitoring should provide early indications of progress or shortcomings.
- Recipient should describe how the translation and dissemination of intervention messages (see translation and dissemination plan below) will be evaluated to ensure intervention and messages are effective in reaching and affecting behavior change in their communities of focus.
- Qualitative research may be an iterative process by nature; modifications or other major changes made should be justified and documented.

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

Dissemination & Translation Plan

The recipient translation and dissemination plan for key findings should describe:

- Plans to develop fact sheets, abstracts, presentations, white papers, and peer-reviewed manuscripts.
- Suggestions for development of translation tools, resources, and materials, including:
    - audience(s), channels, and settings, to implement the interventions,
    - partners who will assist in effectively implementing and/or spreading messages about interventions.

Public Health Impact
This project will provide a framework to disseminate intervention findings related to vaccine confidence that can lead to policy, systems, or environmental changes and more rapidly move

evidence into intervention programs, shortening time from science to service in real world settings.

The applicant should describe how this research project will contribute to establishing the evidence base for effective intervention and program implementation components to address childhood vaccine hesitancy for all Americans, inform high-impact, scalable and cost-effective strategies for improving childhood MMR vaccination and reducing health and societal costs associated with measles and mumps outbreaks.

Special Eligibility and Responsiveness

- Evidence of accessibility to locales that provided vaccination services and conducted vaccine hesitancy work among close-knit communities with longstanding MMR vaccine hesitancy that have experienced a mumps or measles outbreak in past 10 years.

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:

- Does the applicant demonstrate experience in rigorous mixed-methods research?
- Does the applicant demonstrate accessibility to a close-knit community with known longstanding MMR vaccine hesitancy that has experienced a measles or mumps outbreak in the past 10 years?
- Does the applicant have intervention efforts in place to address vaccine hesitancy?

Fundings 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.

Availability of Funds

It is anticipated that approximately $400,000 (both direct and indirect costs) is available to fund up to two (2) Prevention Research Centers for a one (1)-year project period. The average award per recipient is estimated to be $200,000 (direct and indirect costs) per year. The ceiling amount for budget year one is $200,000. Funding may vary and is subject to change. Available funding includes direct and indirect costs.

Research Status

It is expected that 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 included in the project.

OMB/PRA

OMB/PRA is not expected to apply.

Award Administration

CDC Project Scientist/Scientific Collaborator will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards. CDC staff will serve as consultants on this project, and will provide technical assistance, as requested, on project activities such as research and interview instrument design, data collection and analysis, and data interpretation and dissemination of results. CDC staff may be co-authors on manuscripts, if invited and if they meet CDC authorship criteria. While CDC staff may have access to data collected from human subjects, CDC staff will not have contact with human subjects. CDC will provide consultation on the design and nature of the intervention, protocol development, co-authoring manuscripts, and the dissemination of results.

References

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2. Herzig van Wees, S., & Dini, S. (2023). The silent shot: An analysis of the origin, sustenance and implications of the MMR vaccine - autism rumour in the Somali diaspora in Sweden and beyond. Global public health, 18(1), 2257771. https://doi.org/10.1080/17441692.2023.2257771
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SIP-24-012 Advancing Research in Immunization Services Network (ARISe)

Project Description

Immunization services represent the body of work surrounding the provision and uptake of available vaccines. Recent years saw significant expansions in immunization services in the US (*1*), most notably in the provision and promotion of COVID-19 vaccines (*2*), but also in intensified immunization campaigns following localized outbreaks of vaccine-preventable diseases (*3*). However, coverage for many recommended vaccines remains sub-optimal, with notable disparities and even recent regressions for specific socio-demographic segments (*4*). CDC, along with other public health authorities, health care providers, and community partners, has worked to fund, implement, and evaluate evidence-based interventions to increase vaccination coverage. However, evidence-based interventions remain limited in number and in impact. More sustained research is needed to better understand barriers to immunization, develop interventions to increase vaccine uptake, and evaluate implemented immunization services among diverse populations and settings. Rigorous implementation research examining the

suitability of existing interventions for specific populations in which vaccination coverage is suboptimal can contribute to reducing inequities in vaccination uptake and health outcomes from vaccine-preventable disease.

CDC's National Center for Immunization and Respiratory Diseases (NCIRD), Immunization Services Branch seeks to support the establishment and coordination of an Advancing Research in Immunization Services Network (ARISe Network) to convene immunization researchers within and outside of PRC network and ARISe. The purpose of ARISE is to exchange scientific information, increase the quality and quantity of immunization services research, and provide a framework to translate research into practice and policy resulting in increased immunization uptake. The ARISe consists of multiple Collaborating Centers and one Coordinating Center recipient. All recipients will conduct research and develop expertise in one or more of the following four priority areas:

1. **In-depth social science research on drivers of vaccine hesitancy** – sociological and psychological research methods/framework are especially welcome here. The outcome of this research should inform development of interventions that can be executed by public health authorities, health care providers, and community-based organizations. Long-term, hard-to-address social determinants of health should contextualize, but not form the bulk of, these investigations.
2. Development and pilot testing of novel, **community-level interventions** that alter the community norms and perceptions surrounding immunizations, with a focus on community-based participatory approaches.
3. Development and pilot testing of novel, **individual-level interventions** that increase the individual uptake of immunizations. Expertise and approaches that are grounded in behavioral economics are especially welcome here.
4. Conducting **implementation science studies in diverse/varied settings or communities**, for example, of interventions previously found to effectively increase vaccine uptake in other contexts.

The coordinating center will lead the activities of the ARISe Network, including the identification of research priorities, technical assistance and training, evaluation, collaboration, and dissemination. ARISe Collaborating Center recipients will complete activities listed in Component A below. The ARISe Coordinating Center recipient will complete activities listed for both Component A and B listed below.

Project Objectives/Outcomes

Component A: ARISe Collaborating Centers (Required)

Project Objectives

- Expand knowledge base within immunization services research to focus on the following areas:
    - Sociological and psychological drivers of vaccine hesitancy.
    - Community-level interventions that seek to alter community norms and perceptions surrounding immunizations.
    - Individual-level interventions that increase immunization uptake.

- Conducting implementation science studies in diverse/varied settings or communities.

Project Outcomes

- Identification of novel strategies for increasing vaccination uptake across the lifespan in the United States
- Identification of promising practices for increasing vaccination uptake that can inform future research efforts by the CDC Immunization Services Division
- Increased publications in the peer-reviewed literature that contribute to the evidence base for strategies to increase vaccination uptake in the United States

Component B: ARISe Coordinating Center (Optional)

Project Objectives

- Advance a common understanding of the current needs and knowledge gaps in immunization services research and create an actionable plan to address them.
- Establish a forum for regular and sustained discussions and exchange of scientific information to promote progress in immunization services research and implementation.
- Accelerate identification of 1) best practices for increasing immunization uptake, 2) interventions worthy of further/expanded testing.
- Promote effective partnerships for increased community-based immunization services research.
- The coordinating center may provide small stipends to graduate-level or early career researchers support the activities denoted in Component A.

Project Outcomes

- Create sustainable collaborations that that can advance research along the Knowledge to Action Framework (https://www.cdc.gov/chronicdisease/pdf/k2a-framework-6-2015.pdf) for priorities of the CDC Immunization Services Division.
- Findings from the ARISe Network activities may be used by the Immunization Services Division to select strategies for large-scale testing, to identify topics for funded and intramural implementation research efforts, or to establish a compendium of evidence-informed interventions for increasing vaccination uptake across the lifespan.

All applicants of SIP24-012 are **REQUIRED** to apply for Component A (Collaborating Center).

Applicants MAY apply for Component B (Coordinating Center).

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

Public Health Priorities

Healthy People 2030 Objectives

IID-01: Maintain the elimination of measles, rubella, congenital rubella syndrome, and polio

IID-02: Reduce the proportion of children who get no recommended vaccines by age 2 years

IID-03: Maintain the vaccination coverage level of 1 dose of the MMR vaccine in children by age 2 years

IID-04: Maintain the vaccination coverage level of 2 doses of the MMR vaccine for children in kindergarten

IID-06: Increase the coverage level of 4 doses of the DTaP vaccine in children by age 2 years

IID-07: Reduce infections of HPV types prevented by the vaccine in young adults

IID-08: Increase the proportion of adolescents who get recommended doses of the HPV vaccine

IID-09: Increase the proportion of people who get the flu vaccine every year

IID-10: Reduce the rate of hepatitis A

IID-11: Reduce the rate of acute hepatitis B

IID-D01: Increase the proportion of women who get the Tdap vaccine during pregnancy

IID-D02: Increase the proportion of people with vaccination records in an information system

IID-D03: Increase the proportion of adults aged 19 years or older who get recommended vaccines

NCCDPHP Approach to Social Determinants of Health - SDOH Domains

Community-Clinical Linkages – Connections made between health care, public health, and community organizations to improve population health.

Project Activities and Submission Requirements

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

Component A: ARISe Collaborating Centers (Required)

Applicants must propose one research project from the following list of four research priorities.

1. In-depth, social science research on drivers of vaccine hesitancy – sociological and psychological research methods/framework are especially welcome here. The outcome of this research should inform development of interventions that can be executed by public health authorities, health care providers, and community organizations. Long-term, hard-to-address social determinants of health should contextualize, but not form the bulk of, these investigations.
2. Development and pilot testing of novel, community-level interventions that alter the community norms and perceptions surrounding immunizations, with a focus on community-based participatory approaches.
3. Development and pilot testing of novel, individual-level interventions that increase the individual uptake of immunizations. Expertise and approaches grounded in behavioral economics are especially welcome here.
4. Conducting implementation science study in diverse/varied settings or communities, for example, of interventions previously found to effectively increase vaccine uptake in other contexts.

Applicants should describe plans to use scientifically rigorous methods to address the selected research priority.

- Describe the theoretical framework surrounding the proposed research activity. The applicant should also describe briefly any empirical research around this theory as it relates to immunization services or other similar health behavior. (Background and theory)
- Provide a description of how the proposed activity fills a critical knowledge gap in immunization services research; alternatively, the applicant can describe how this proposed activity advances the understanding of immunization services.
- Identify the proposed staff who will be devoted to the applicant's efforts on this project. For each person, describe their demonstrated knowledge, experience, and ability in planning. and conducting research that is similar to the types proposed here in complexity, scope, and focus. Include the percentage of time each person will devote to project activities.
- Participate in the ARISe Network activities under the direction of the ARISe coordinating center. Potential activities may include:
    - ARISe workgroup calls and activities.
    - Development of products such as policy briefs, fact sheets, abstracts, presentations, white papers, and peer-reviewed manuscripts, as planned by the respective workgroups.
    - Synthesis documents/workshop proceedings that summarize current needs and knowledge gaps in immunization services research and create an actionable plan to address them.
    - Assist ISD awardees in analysis, evaluation, and implementation activities when appropriate.

Component B: ARISe Coordinating Center (Optional)

Applicants should describe how they will establish the ARISe infrastructure and how coordination/implementation of the network will be achieved. Including the following:

- Description of the resources and processes that will facilitate linkages and activities among the ARISe, such as convening network members, formation of the advisory group and/or topic-specific workgroups, coordination of conference calls, distribution of network information and dissemination of research findings and products. Include the process and frequency by which the ARISe will communicate and meet (virtually and/or in-person).
- Recruit and convene researchers (both within and outside of PRC network) and relevant partners to constitute the ARISe Network and advance immunization services research.
- Establish and lead an ARISe Network leadership group consisting of (but not limited to) CDC scientific collaborators, workgroup leads/liaisons, and advising researchers/partners.
- Establish and maintain workgroups as to facilitate discussions and collaborations advancing immunization services research. The workgroups within ARISe Network can be established, modified, and terminated in accordance with priorities agreed upon by the ARISe Network membership. The coordinating center should work with CDC to ensure that ARISe Network workgroups: a) address a set of activities that are informed by needs identified by public health authorities, health care providers, and community-based partners; b) include translational products targeting health care practitioners and/or

decision-makers which may include developing partnerships with public health departments (i.e., state, local, tribal, territorial), community-based organizations, and/or health system professionals; c) meet monthly.

- Coordinate strategic partnerships to synthesize and prioritize activities around immunization services research. Potential partners include organizations such as the Association of Immunization Managers; funders, such as the National Institutes of Health, Agency for Healthcare Research and Quality, philanthropic foundations; other networks/conveners such as the National Vaccine Advisory Committee, and the National Academies.
- Engage with other CDC-funded researchers and PRCs working on immunization services research and collaborate where applicable.
- Advance Immunization Services Research
    - Develop synthesis documents/workshop proceedings that summarize current needs and knowledge gaps in immunization services research and create an actionable plan to address them.
    - Develop products such as policy briefs, fact sheets, abstracts, presentations, white papers, and peer-reviewed manuscripts, as planned by the respective workgroups.
    - Through the established workgroups, propose and support topics for early-stage research/investigations in immunization services among early-career investigators (doctoral students and post-doctoral researchers).
    - Assist ISD awardees in analysis, evaluation, and implementation activities when appropriate and as requested by CDC staff.

- Manage administrative activities to support the ARISe Network
    - Host a monthly network call on cross-cutting topics (examples include research methods, translational science, implementation science).
    - Host an annual in-person meeting of the ARISe Network leadership group to conduct strategic planning that results in defined performance expectations and objectives for the ARISe Network.
    - Provide virtual platforms and administrative support for ARISe Network participants to host and attend regular meetings, webinars, and teleconferences.
    - Maintain an easy-to-access electronic repository for member materials (e.g., documents, calendars) and create and share minutes of monthly calls and workgroup action steps.
    - Document plans for network sustainability, network health, impacts, and needed supports including survey workgroup leads and members.
    - Administer small stipends/honorariums to staff/researchers who support workgroup administrative and organization functions.
    - Administer small stipends to graduate-level or early career researchers in support of identified topics for early-stage research. These stipends cannot be used to carry out activities associated with non-exempt Human Subjects Research.

- Identify key staff who will be devoted to your center's efforts on this project.
    - For each person, describe their demonstrated knowledge, experience, and ability relevant in executing the proposed activities above. Note that the coordinating center is expected to convene a new research network across multiple institutions

– prior experience convening multidisciplinary, multi-institution workgroups is especially critical.

Study Design and Methods

In addition to the requirements above, the Research Plan for Component A should describe scientifically rigorous methods to address their research questions over the course of the five-year project period. The proposed study designs and methods for the following groups of activities are defined below:

- In-depth, social science research on drivers of vaccine hesitancy – research utilizing established methods in anthropological, sociological, psychological, or behavioral economics that go beyond traditional survey or focus group methodology.
- Development and pilot testing of novel, community-level interventions that alter community norms and perceptions surrounding immunizations. Research should either 1) include rigorous measurement of changing vaccine uptake or shifting community norms or 2) propose interventions that go beyond messaging campaigns typically employed by public health authorities.
- Development and pilot testing of novel, individual-level interventions that increase the individual uptake of immunizations. Expertise and approaches grounded in behavioral economics are especially welcome here. Research should either 1) propose novel interventions or 2) propose rigorous testing that can identify specific elements of commonly used interventions.
- Conducting implementation science studies in diverse/varied settings or communities, for example, of interventions previously found to effectively increase vaccine uptake in other contexts.

Applicants should incorporate community-based participatory research methods when appropriate (*5*).

Target Population

Component A: Collaborating Center (Required)

The following collaborations/partnerships are expected and should be considered in the development of the proposal for the ARISe Research Project.

- Populations disproportionately affected by vaccine preventable diseases (e.g., rural populations, racial/ethnic minority populations, pregnant persons, medically-underserved populations, etc.)
- Communities that have experienced outbreaks of vaccine-preventable diseases previously considered eliminated in the US.
- Populations that have seen significant drops in routine childhood immunization or rises in vaccine hesitancy since 2020.

Component B: Coordinating Center (Optional)

In addition to the partnerships proposed for Component A, the following collaborations and/or partnerships should be addressed in the proposal for the ARISe Coordinating Center:

- Organizations such as the Association of Immunization Managers

- Funders, such as the National Institutes of Health, Agency for Healthcare Research and Quality
- Philanthropic foundation
- Other networks/conveners such as the National Vaccine Advisory Committee and the National Academies.

Collaboration/Partnerships

The applicant is expected to participate in collaborations/partnerships as set out by the ARISe Network, potentially including:

- Collaborations with CDC program staff.
- Partnerships with other Collaborating Centers that form the ARISe Network.
- Partnerships with public health authorities, community organizations.
- Collaborations with topic area workgroups aligned around policy and evaluation needs of ISD awardees.
- Collaborations with State and/or local-level CDC funded program awardees.
- Collaborations with other researchers in immunization services.

Recruitment Plan

The applicant should describe their plans to identify and engage experts in immunization who could contribute topical knowledge to address this project. Collaboration with partners as described above will be key in the recruitment process.

Component A: Collaborating Center

- Describe recruitment strategies or the plan to access existing data sources needed to carry out the research project.

Component B: Coordinating Center (Optional)

- Describe how the applicant plans to engage experts in immunization throughout the project to carry out the priorities of the ARISe.

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 for both component A and B that demonstrates how the recipient will fulfill the requirements described. A resource regarding evaluation can be found at: https://www.cdc.gov/eval/index.htm.

Component A: Collaborating Center (Required)

- Describe a plan to assess initial and ongoing activities that include evaluation questions, milestones and measurable outcomes.

Component B: Coordinating Center (Optional)

- Describe a plan to monitor and evaluate network progress in achieving key milestones and major accomplishments.
- CDC will work collaboratively with awardee to develop an evaluation framework to guide evaluation of the ARISe Network.

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

Dissemination & Translation Plan

Component A: Collaborating Centers (Required)
ARISe Collaborating Center recipients are expected to disseminate and translate research findings into public health practice including, but not limited to, translation and implementation tools and resources, policy briefs and fact sheets, abstracts, presentations at national and international meetings/conferences, webinars, white papers, peer-reviewed manuscripts, continuing education opportunities, etc. Translation and dissemination strategies proposed by the applicant should address the following:

- How results will be translated into useful tools that can be utilized by various public health audiences.
- How the applicant will share results with partners, public health practitioners, study participants and broader immunization practitioners.
- Key outputs planned for translation (e.g., number of manuscripts per year published in peer-reviewed journals, number of tools/resources developed, number of presentations, etc.) based on the selected research priority.

Component B: Coordinating Center (Optional)

ARISe Coordinating Center is expected to develop a plan to maximize efforts to disseminate and translate research findings into public health practice. The plan should include a coordinated dissemination strategy based on the research priorities and address the following:

- How the applicant will engage ARISe members and others in the development of the plan;
- How the ARISE will determine 1) which translation products are needed and 2) what activities will be implemented to help disseminate them and increase awareness; and
- How the ARISe will work collaboratively to identify future needs and gaps.

Specific elements that should be included in the plan are:

- The role to be played by each ARISe Network member (e.g., coordinating center, collaborating centers, external partners) in disseminating ARISe Network outputs
- A rubric or decision framework for determining the most effective dissemination pathways (publication, conference presentation, fact sheet, web posting, etc.) for each output based on the intended audience.

- Proposed timelines for dissemination of network outputs through various pathways following completion of a project (e.g., presentation at a conference within 12 months of completion, social media postings within 4 weeks of completion, etc.).
- Proposed methods for identifying and reaching desired audiences through product dissemination – although some audiences will not be identified until projects are completed, the plan should include likely audiences for this type of research (e.g., healthcare providers, public health officials, etc.). For every output, research/evaluation participants should be included as an audience and plans to share results with participants should be outlined.

Public Health Impact
The proposed ARISe will advance the state of immunization services science including new interventions for increasing vaccine uptake.

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: Collaborating Centers (Required)

- The extent to which the proposed research activity uses study design and methods as described below:
    - In-depth, social science research on drivers of vaccine hesitancy – research utilizing established methods in anthropological, sociological, psychological, or behavioral economics that go beyond traditional survey or focus group methodology.
    - Development and pilot testing of novel, community-level interventions that alter community norms and perceptions surrounding immunizations – research should either 1) include rigorous measurement of increased vaccine uptake or shifting community norms or 2) propose interventions that go beyond messaging campaigns typically employed by public health authorities.
    - Development and pilot testing of novel, individual-level interventions that increase the individual uptake of immunizations. Expertise and approaches grounded in behavioral economics are especially welcome here. Research should either 1) propose novel interventions or 2) propose rigorous testing that can identify specific elements of commonly adopted interventions.
    - Conducting implementation science studies in diverse/varied settings or communities, for example, of interventions previously found to effectively increase vaccine uptake in other contexts.
    - Utilization of community-based participatory research methods when applicable.

Component B: Coordinating Center (Optional)

- The extent to which the applicant describes experience with:

- Collaborating with multidisciplinary experts, including psychologists, sociologists, anthropologists, behavioral scientists, communication scientists, and/or economists. This can be evidenced by prior publications/committee reports with multi-disciplinary authorship.
- Collaborating with experts across different institutions. This can be evidenced by prior publications/committee reports with authorship across multiple institutions.
- Working with community-based organizations and public health authorities on the design, implementation, or evaluation of immunization programs.
- Creating translation and dissemination products targeting public health practitioners, non-governmental organizations, health care practitioners and/or decision makers.
- Conducting immunization services research as evidenced by peer-reviewed publications that clearly depict sole or joint authorship on a paper that demonstrates immunization services implementation, practice, and evaluation.

- The extent to which the applicant describes the ability to:
  - Convene a wide group of researchers across different academic disciplines to reach actionable consensus.
  - Coordinating and/or managing similar multi-site, collaborative research, evaluation, or the preparation of committee reports.
  - Facilitate and coordinate strategic partnerships on behalf of the network.
  - Advance immunization services research as stated in the project description.
  - Perform the administrative activities to support the ARISe network as stated in the project description.

Funding Preferences

Component A: Collaborating Centers
The following preferences specific to this SIP will be considered in the funding decision:

- Geographic diversity
- Immunization research projects that address a variety of priorities (1-4) listed above.

Component B: Coordinating Center
None.

Research Plan Length and Supporting Material

- 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).
- Component A (Collaborating Center) applicants must identify the research priority to be studied at the beginning of the Specific Aims
- Follow the Research Strategy page length provided below:

Research Strategy Length	
Components	**Maximum Number of Pages**
A	12

A & B	18

- To be funded for Component B: Coordinating Center, applicants must also apply for and be funded for Component A (Collaborating Center)
- One application should be submitted for one (Component A) or both components (A and B).
- 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.
- Applicants applying for both Components A and B must include a budget breakdown for each component in the appendix.

Availability of Funds
The estimated total funding (direct and indirect) for the 5-year period of performance is $5,500,000 to support 3 awards. Awards issued under this NOFO are contingent upon availability of funds and enough meritorious applications. Funding available includes direct and indirect costs.

Component A: Collaborating Centers

Period of Performance: 5 years, 09/30/2024-09/29/2029
Estimated total funding (direct and indirect costs) per year: $700,000
Estimated funding (direct and indirect costs) per recipient per year: $350,000
Year-1 Ceiling: $350,000
Estimated number of awards: 2

Component A and B: Collaborating and Coordinating Center
Period of Performance: 5 years, 09/30/2024-09/29/2029
Estimated total funding (direct and indirect costs) per year: $400,000
Estimated funding (direct and indirect costs) per recipient per year: $400,000
Year - Ceiling: $400,000
Estimated number of awards: 1

Research Status
It is expected that this project will comprise non-exempt research. It is anticipated that this project will require local IRB approval. Applicants should provide a federal-wide assurance number.

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

Award Administration

Component A:

The CDC Project Scientist/Scientific Collaborator will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards. CDC staff will serve as consultants on this project, and will provide technical assistance, as requested, on

project activities such as research/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.

Component B:

CDC staff will serve as collaborators and/or co-investigators on this project and will have joint responsibility for strategic direction of the ARISe Network, participation and guidance in workgroups. CDC staff may be co-authors on manuscripts and/or provide subject matter expertise on specific elements of the ARISe Network products.

References

1. Roper L, Hall MA, Cohn A. Overview of the United States' immunization program. The Journal of infectious diseases. 2021 Oct 1;224(Supplement_4):S443-51.
2. Diesel J, Sterrett N, Dasgupta S, Kriss JL, Barry V, Esschert KV, Whiteman A, Cadwell BL, Weller D, Qualters JR, Harris L. COVID-19 vaccination coverage among adults—United States, December 14, 2020–May 22, 2021. Morbidity and Mortality Weekly Report. 2021 Jun 6;70(25):922.
3. Ortega-Sanchez IR, Vijayaraghavan M, Barskey AE, Wallace GS. The economic burden of sixteen measles outbreaks on United States public health departments in 2011. Vaccine. 2014 Mar 5;32(11):1311-7.
4. Centers for Disease Control and Prevention. AdultVaxView Publications and Resources. Available from: https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/pubs-resources/index.html
5. Viswanathan M, Ammerman A, Eng E, et al. Community-Based Participatory Research: Assessing the Evidence: Summary. 2004 Aug. In: AHRQ Evidence Report Summaries. Rockville (MD): Agency for Healthcare Research and Quality (US); 1998-2005. 99. Available from:https://www.ncbi.nlm.nih.gov/sites/books/NBK11852/

SIP-24-013 Understanding the potential of schools in promoting non-mandated childhood vaccinations

Project Description

Schools are central in the lives of families with children and are trusted sources of information. Although schools play a clear role in ensuring students receive vaccines mandated by law, there is potential for them to play an additional role in promoting other ACIP-recommended vaccines not required for school entry, such as influenza, COVID-19, and human papillomavirus (HPV) vaccines. COVID-19 vaccination coverage among school-aged children lags that of older age groups, with particularly low coverage among those residing in rural areas and those who are uninsured and/or living below the poverty level. Although there are differences by vaccine type, coverage for influenza and other routine vaccines is also generally lower among these populations of children. Disparities by race/ethnicity also exist. Schools and school districts can 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 in backpacks, and during grade/class/school events that include parents.

There is little information about whether and to what extent school-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. One study found that adding an HPV vaccination recommendation to the standardized letters from school nurses about required vaccination had no effect, and the authors conclude that more intense interventions may be required (1).

The purpose of this project is to assess the potential of school-originating, vaccination-related education, communications, and/or other simple interventions to impact parent attitudes about and student vaccination coverage with non-mandated childhood vaccines (e.g., HPV, COVID-19, influenza, serogroup B meningococcal vaccines). The project will focus on public schools/districts in rural areas and areas classified as having high social vulnerability (i.e., in the highest tertile of the Social Vulnerability Index [SVI], please see https://www.atsdr.cdc.gov/placeandhealth/svi/index.html) and which have low coverage for COVID-19 or other non-mandated vaccines.

Project Objectives and Outcomes

Objectives

- The primary objective will be to assess, via a randomized trial, the effectiveness of various parent/caregiver-focused, school-originating education, communications and/or other simple interventions to increase student coverage of non-mandated but ACIP-recommended vaccines.
- Secondary objectives will include assessing the intervention's acceptability/feasibility from the perspective of the parent, school staff, and potentially the health department staff. Cost of the intervention will also be assessed by intervention arm.

Outcomes

Specific interventions will be designed by the awardee, but the primary outcome will be increased vaccination coverage with non-mandated but CDC-recommended vaccines in the intervention arms vs. control arm. Secondary outcomes will be related to intervention effectiveness, acceptability, feasibility, and intervention cost.

Public Health Priorities

Healthy People 2030 Objectives

- IID-08: Increase the proportion of adolescents who get recommended doses of the HPV vaccine
- IID-09: Increase the proportion of people who get the flu vaccine every year
- IID-07: Reduce infections of HPV types prevented by the vaccine in young adults

NCCDPHP Approach to Social Determinants of Health - SDOH Domains

- Community-Clinical Linkages – Connections made between health care, public health, and community organizations to improve population health.

Project Activities and Submission Requirements

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

- Awardee will solicit participation of schools/districts located in areas with low COVID-19 vaccination coverage and/or routine vaccination coverage, and high SVI, with at least half being in rural areas
- Awardee will conduct formative research to inform an intervention trial
- An intervention trial will be carried out
- Awardee will assess intervention effectiveness, feasibility, acceptability, and cost

Study Design and Methods

Intervention trial informed by formative research.

Target Population

Public schools serving students kindergarten through twelfth grade residing in areas with low COVID-19 vaccination coverage and/or low routine vaccination coverage and high SVI, with at least half being in rural areas.

Collaboration/Partnerships

As part of this project, propose the awardee collaborate with the following:

- CDC program staff
- PRC core grantees that have projects that include immunizations/vaccines
- Public health and education authorities at the state and local levels, school and/or school district staff

Recruitment Plan

Applicants must provide details on how states and schools/school districts will be recruited for participation.

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 a monitoring and evaluation plan as part of the application.

The awardee will monitor the implementation of the intervention or program to ensure consistency with the original intervention design and to track implementation progress via periodic data collection. The goal of monitoring is to provide early indications of progress or shortcomings.

At the conclusion of the program implementation, awardees must assess the effectiveness of the intervention, as well as estimate its cost.

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

Dissemination & Translation Plan

Applicants should provide a translation and dissemination plan for their intervention, should it be proven to be effective. Describe the materials, the audience(s), the channels through or settings in which to implement the intervention, and any partners who will be helpful in effectively implementing or spreading the messages about your intervention.

Public Health Impact

Although schools play a clear role ensuring students receive vaccines mandated by law, there is potential for them to play an additional role in promoting other ACIP-recommended vaccines not required for school entry, such as influenza, COVID-19, and human papillomavirus (HPV) vaccines. Schools and school districts have the ability to 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 in backpacks, and during grade/class/school events that include parents. School-originating, vaccination-related education, communications, and/or other simple interventions could positively impact parent attitudes and student vaccination coverage with non-mandated childhood vaccines and lead to higher vaccination coverage, including in rural and high SVI areas where coverage is particularly low.

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:

- Experience collaborating with public school or school district staff (e.g., school health professionals, principals, school district administrative staff) on school-related research or evaluation projects
- Applicant's experience working on health services research, particularly involving vaccination
- Experience designing and evaluating communications-related materials and interventions is preferred

Funding Preferences

NA

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 attachments (maximum of

30 pages). 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.

Availability of Funds

It is anticipated that approximately $1,500,000 (both direct and indirect costs) is available to fund 1 Prevention Research Center(s) for a 3-year project period. The amount of funding for year one is estimated to be $500,000 (direct and indirect costs). The ceiling for budget year one is $500,000 (direct and indirect costs). Funding may vary and is subject to change. Funding available includes direct and indirect costs.

Research Status

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

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 design, data collection and analysis, and data interpretation and dissemination of results. CDC staff may be co-authors on manuscripts. While CDC staff may have access to data collected from human subjects, CDC staff will not have contact with human subjects. CDC will provide consultation on the design and nature of the intervention, protocol development, co-authoring manuscripts, and the dissemination of results.

References

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