

Centers for Disease Control

National Center for Chronic Disease Prevention and Health Promotion Extramural Research Program Office

Health Promotion and Disease Prevention Research Centers: 2019 Special Interest Project Competitive Supplements (SIPS)
RFA-DP-19-006
Application Due Date: 02/26/2019

Health Promotion and Disease Prevention Research Centers: 2019 Special Interest Project Competitive Supplements (SIPS)

RFA-DP-19-006

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Part 1. Overview Information

Participating Organization(s)

Centers for Disease Control

Components of Participating Organizations

National Center for Chronic Disease Prevention and Health Promotion Extramural Research Program Office (NCCDPHP ERPO)
National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP)

Notice of Funding Opportunity (NOFO) Title

Health Promotion and Disease Prevention Research Centers: 2019 Special Interest Project Competitive Supplements (SIPS)

Activity Code

U48

Amendment 1:

* Questions from Potential Applicants and CDC Responses added to Section VIII. Other Information.

Amendment 2: Application updates Page 4,15,22 of 120

Notice of Funding Opportunity Type

Reissue of DP19-001

Agency Notice of Funding Opportunity Number

RFA-DP-19-006

Assistance Listings (CFDA) Number(s)

93.135

Category of Funding Activity:

Health

NOFO Purpose

This NOFO will provide supplemental funding to Prevention Research Centers (PRCs) to conduct Special Interest Projects (SIPs) to design, test, evaluate, disseminate, and translate effective applied public health prevention research strategies to include interventions (i.e. programs, practices, policies, or strategies) and tools developed in real-world settings to address the leading causes of illness, disability, and death in the United States. Research strategies align with public health priorities such as the Healthy People 2020 topic areas: Aging, Dementias and Alzheimer's Disease; Epilepsy; Cancer; Nutrition and Physical Activity; and Substance Abuse - Alcohol.

Key Dates

Publication Date:

To receive notification of any changes to RFA-DP-19-006, 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:	**01/21/2019**
Application Due Date:	**02/26/2019**

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 5:00 PM U.S. Eastern Time. Applications must be submitted using the Application Submission System & Interface for Submission Tracking (ASSIST) module which is a web-based service used for the preparation and submission of grant applications to CDC through Grants.gov. ASSIST provides the ability for applicants to prepare their applications online, and offers the applicant additional capabilities including the ability to preview the application image, validate the application against required business rules, and prepopulate data from an applicant organization's records, therefore identifying issues earlier in the application submission process.

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:	**05/01/2019**
Secondary Review:	**06/03/2019**
Estimated Start Date:	**09/30/2019**
Expiration Date:	**02/27/2019**
Due Dates for E.O. 12372:	**Executive Order 12372 does not apply to this program.**

Required Application Instructions

ELECTRONIC APPLICATION SUBMISSION VIA ASSIST IS PREFERRED

It is recommended that applicants use ASSIST for the electronic preparation and submission of applications through Grants.gov to CDC. ASSIST is an alternative method to prepare and submit applications, and provides many features to facilitate the application submission process which improves data quality (e.g., pre-population of organization data, pre-submission validation of business rules, and preview of the application image used for review). Use of the Grants.gov downloadable Adobe application packages and submission process will still be supported.

It is critical that applicants follow the instructions in the SF 424 (R&R) 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 12 pages.

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

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

(See Part 2, Section IV, 7. Page Limitations).

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

A link to this NOFO will be available at https://www.cdc.gov/chronicdisease/programs-impact/nofo/index.htm

Executive Summary

- **Purpose.** Public health practioners need scalable, feasible intervention and tools. Applied public health prevention researchers can engage communities to develop and evaluate health promotion and disease prevention interventions, disseminate new science, and translate proven effective interventions into public health practice and policy for population health benefit. This NOFO will provide supplemental funding to Prevention Research Centers (PRCs) to conduct Special Interest Projects (SIPs) to design, test, evaluate, disseminate, and translate effective applied public health prevention research interventions (i.e. programs, practices, policies, or strategies) and tools developed in real-world settings that address 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 level of funding (direct and indirect for entire project period in dollars) that is available for the NOFO is $32,725,000. The estimated total funding (direct and indirect) for the first year (12 month budget period for all SIP proposals is $7,095,000. It is anticipated that up to 24 awards will be made. Awards issued under this NOFO are contingent upon availability of funds and a sufficient number of meritorious applications. Because the nature and scope of the proposed research will vary from application to application, it is also anticipated that the size and duration of each award may also vary. The total amount awarded and the number of awards will depend upon the number, quality, duration and cost of the applications received.
    - **Budget and Project Period.** The estimated total funding (direct and indirect) for the first 12 month budget period, 9/30/2019 - 9/29/2020, is $7,095,000. The estimated total funding (direct and indirect) for the entire project period, 9/30/2019 to 9/29/2024, is $32,725,000.
- **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, 1.A. 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.** Applications may include more than one PI; however, the first PI listed on the application will be the contact PI for all correspondence. Any additional PIs are permitted, but would be referred to as Co-PIs.**The PI may be different from the prime grant (DP19-001) as long as the PI is registered in eRA Commons, and the application is submitted by an eligible institution (normally identified by a unique DUNS number).**
- **Number of Applications.** Applicants may apply to more than one SIP; however, a separate application is required for each SIP.
- **Application Type.** New
- **Special Date(s).Informational conference calls for eligible applicants:**
    - January 10, 2019, 2:00-4pm EST; webinar link/conference number/participant code information will be provided at a later date.
    - **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY: 1-888-232-6348.
- Application Materials. See Section IV.1 for application materials. Please note that Form D is to be used when downloading the application package. http://grants.nih.gov/grants / how-to-apply-application-guide/forms-d/general-forms-d.pdf%20

Part 2. Full Text

Section I. Funding Opportunity Description

Statutory Authority

Section 1706 of the Public Health Service Act, as amended, 42 U.S.C. 300u-5, academic health centers, as defined in 42 U.S.C 300u-5(d) and Section 799B, as amended 42 U.S.C 295p.

1. Background and Purpose

The 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 are able to compete for SIPs, research projects sponsored by CDC, HHS, and other federal agencies, to conduct research and other activities in priority areas. Funded PRCs are encouraged to apply for SIPs that expand and strengthen their PRC's mission and increase

their applied public health research activities.

The purpose of the PRC program's SIP mechanism is to support supplemental projects in health promotion and disease prevention research. A major focus of this supplemental funding program is to design, test, evaluate, translate and/or disseminate effective applied public health prevention research strategies. The SIP mechanism, created in 1993, allows the PRCs to compete for research projects sponsored by CDC organizational units and other HHS agencies.

Prevention research includes applied public health research that develops and evaluates health promotion and disease prevention and control strategies that are community- and population-based. It can involve testing interventions for efficacy, effectiveness, or translational power; 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. Prevention research may provide initial evidence of the efficacy or effectiveness of a health promotion or prevention strategy, raise current evidence to a higher level, or provide evidence of the effectiveness of a practice-based strategy.

Healthy People 2020 and other National Strategic Priorities

This NOFO supports efforts that align with the following public health priorities:

Healthy People 2020

- Social Determinants of Health: economic stability; education; social and community context; health and health care, neighborhood and built environment.
- Health topics: cancer, dementia including Alzheimer's disease; disability and health (includes epilepsy); educational and community based programs; health-related quality of life and well-being; nutrition and weight status; older adults; physical activity; sexually transmitted disease; substance abuse - alcohol.

CDC's Health Impact in 5 Years (HI-5) Initiative

- Interventions addressing the social determinants of health, and interventions changing the context. https://www.cdc.gov /policy/hst/hi5/interventions/index.html.

National Center for Chronic Disease Prevention and Health Promotion's Four Domains of Chronic Disease Prevention -

- Domain 1: epidemiology and surveillance;
- Domain 2: environmental approaches that promote health and support and reinforce healthful behaviors;
- Domain 3: health system interventions to improve the effective delivery and use of clinical and other preventive services; and
- Domain 4: strategies to improve community-clinical linkages.

https://www.cdc.gov/chronicdisease/resources/publications/four-domains.htm.

This NOFO is expected to fund research that will focus on developing and evaluating the evidence for strategies that improve population health outcomes. Information on specific Healthy People 2020 and other National Strategic Priorities are described for each Special Interest Projects in Section IX. Special Interests Project Descriptions. This NOFO includes the Healthy People 2020 topic areas of Healthy Aging, Dementias and Alzheimer's Disease; Epilepsy; Cancer; Nutrition, Obesity, and Physical Activity. The following are the current SIPs and associated topic areas:

- Healthy Aging, Dementias and Alzheimer's Disease: 19-001
- Epilepsy: 19-002, 19-003
- Cancer Prevention and Care: 19-004, 19-005, 19-006, 19-007, 19-008, 19-009
- Nutrition, Obesity, and Physical Activity: 19-010, 19-011
- Substance Abuse - Alcohol: 19-012

Public Health Impact

Accomplishing the objectives of these projects will result in improvements in the delivery and outcomes of public health programs and practice:

SIP 19-001. Improving Cognitive Impairment Detection and Referral to Resources among Older Adults: Applying the KAER Model in a Clinical Health Care System

This project will conduct research in which the project findings may help to inform future health care system approaches towards better detection and diagnosis of cognitive impairment among older adults. These findings can be used to improve care management for people with cognitive impairment and connect those people with a cognitive impairment and their families with available resources.

SIP 19-002. Managing Epilepsy Well 2.0 (MEW) Network - Coordinating Center

This project will support and conduct epilepsy self-management intervention research and dissemination. The Coordinating Center will lead activities to foster collaboration across, and evaluate the impact of multiple MEW Network Collaborating Centers engaged in conducting replication studies of epilepsy self-management programs. Additionally, the Coordinating Center will lead partnerships with epilepsy and chronic disease stakeholders to raise awareness of epilepsy self-management strategies and program, and lead public awareness and dissemination strategies for the MEW Network programs and resources.

SIP 19-003. Managing Epilepsy Well 2.0 (MEW) Network - Collaborating Center

More effectiveness studies of epilepsy self-management programs are essential prior to widespread program adoption by health care providers or community-based providers. The project will fund the Managing Epilepsy Well Network Collaborating Centers to conduct replication studies and related research to increase the evidence of CDC Managing Epilepsy

Well (MEW) Network epilepsy self-management programs.

SIP 19-004. Cancer Prevention and Control Research Network Coordinating Center

This project will coordinate the efforts of the Cancer Prevention and Control Research Network (CPCRN), a national network of academic, public health, and community partners that work together, with the ultimate goal to reduce the burden of cancer, especially among those disproportionately affected. The project will support a coordinating center that will facilitate collaborative research and network discussions related to the development of research expertise in the application of proven cancer prevention and control interventions,

SIP 19-005. Cancer Prevention and Control Research Network Collaborating Center

This project will fund the Cancer Prevention and Control Research Network, a national network of academic, public health, and community partners that work together to conduct community engaged research, with the ultimate goal to reduce the burden of cancer, especially among those disproportionately affected.

SIP 19-006. Evaluating Community Clinical Linkage Interventions in the National Breast and Cervical Cancer Early Detection Program (NBCCEDP)

This project will evaluate the implementation, effectiveness, costs, cost-effectiveness, and potential scalability of CCL interventions. If found effective, these interventions can be scaled to increase screening among underserved women who are traditionally hard-to-reach and not accessing primary care services. Expanding effective and cost-effective CCL interventions nationally will increase the overall reach and impact of the NBCCEDP.

SIP 19-007. Improving cancer survivor treatment and outcomes by ensuring appropriate emergency/acute care treatment

This project seeks to improve care and outcomes among all US cancer survivors by providing an evaluation of implementation practices for reducing hospital related infections among survivors, and improving overall care for survivors. This will translate into increasing the length and quality of life among all US men and women with cancer. This results of this project will enable recipients of the National Comprehensive Cancer Control Program actively engaged in survivorship work (i.e., to improve improving care and outcomes) to engage with medical organizations who serve clinical providers treating cancer survivors and educate and raise awareness for recommended activities related to reducing and/or informing avoidable and unavoidable acute care.

SIP 19-008. Feasibility Testing of a Model Cancer Surveillance Report Using Electronic Health Record Data

The project will demonstrate the feasibility of a model cancer surveillance report on performance measures that state and CDC cancer prevention and control programs could use to

plan interventions to improve cancer prevention and control.

SIP 19-009. Assessing the Lifetime Economic Burden in Men with Metastatic Prostate Cancer, including Pain Management

The results of this project will provide information to understand the full economic impact of mPC in different life stages on the society, health care system, patient, and their family. Further, economic data would also provide information to decision makers on costs related to palliative care, psychological support, other forms of symptom management, pain management, and therapeutic interventions to treat mPC. In addition, by using mathematical modeling, results can provide policy-makers with needed evidence about the expected future burden of mPC in the U.S. from 2020 to 2030 by life stage and race/ethnicity. The results of this study will provide public health policymakers with new insights about the future trajectory of mPC resource use and cost, and how this might differ for patients across life stages and in different racial/ethnic groups. Findings can thereby inform the development of interventions, outreach programs, or other actions targeted to addressing drivers of mPC morbidity, mortality, and cost specific to life stage and race/ethnicity. Further, by using mathematical modeling to evaluate the cost-effectiveness of new treatments for mPC, the value of new treatments by life stage and by race/ethnicity for prostate cancer cancer survivors can be assessed.

SIP 19-010. Nutrition and Obesity Policy Research and Evaluation Network (NOPREN)

This project seeks to conduct a research study for nutrition and obesity policy research and evaluation addressing food insecurity. It will build the evidence base for effective policy implementation components to prevent obesity and improve nutrition for all Americans, informs high impact, scalable and cost-effective strategies for preventing obesity and improving nutrition and reducing health and societal costs associated with overweight and obesity. It will also provide a framework and platform to communicate and disseminate research findings related to nutrition and obesity 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.

SIP 19-011. Physical Activity Policy Research and Evaluation Network (PAPREN)

This project will inform high impact, scalable and cost-effective strategies for increasing population levels of physical activity and reducing health and societal costs associated with inadequate levels of physical activity. The Coordinating Center will conduct physical activity research. It will also provide a framework and platform to communicate and disseminate research findings related to physical activity 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.

SIP 19-012. Supporting and Evaluating Initiatives to Prevent Overservice of Alcohol

The proposed research would broaden the scientific base regarding the effectiveness of varying

approaches to preventing overservice or overservice enforcement to reduce binge drinking and related harms.

Relevant Work

As appropriate, this information will be provided for each SIP in the individual descriptions contained in **Section IX. 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 IX.

Special Interests Project Descriptions of this announcement to include:

- Objectives/Outcomes
- Public Health Priorities
- Target Population
- Collaboration/Partnerships
- Recruitment Plan
- Annual Action Plan
- Evaluation*/Performance Measurement
- Dissemination Plan
- Translation Plan

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.

References:

References for individual SIPS can be found in the Section IX. Special Interest Project Descriptions.

Objectives/Outcomes

See individual SIPS in the Section IX. Special Interest Project for detailed information.

Target Population

See individual SIPS in the Section IX. Special Interest Project for detailed information.

Collaboration/Partnerships

See individual SIPS in the Section IX. Special Interest Project for detailed information.

Evaluation/Performance Measurement

See individual SIPS in the Section IX. Special Interest Project for detailed information.

Translation Plan

See individual SIPS in the Section IX. Special Interest Project for detailed information.

Section II. Award Information

Funding Instrument Type:	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:	$32,725,000
Anticipated Number of Awards:	24

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

Award Ceiling:	$7,095,000 Per Budget Period
Award Floor:	$0 Per Budget Period
Total Period of Performance Length:	5 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 (http://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.

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:	Public and State controlled institutions of higher education Private institutions of higher education

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

Additional Eligibility Category:

The following types of Higher Education Institutions are always encouraged to apply for CDC support as Public or Private Institutions of Higher Education:

Hispanic-serving Institutions
Historically Black Colleges and Universities (HBCUs)
Tribally Controlled Colleges and Universities (TCCUs)
Alaska Native and Native Hawaiian Serving Institutions

2. Foreign Organizations

Foreign Organizations are not eligible to apply.

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

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

3. Special Eligibility Requirements

Only organizations meeting the following characteristics are eligible to apply for Special Interest Projects (SIP) supplemental funding:

Applicants currently funded under CDC PRC Program Notice of Funding Opportunity RFA-DP-19-001 are eligible to compete for SIP supplemental funding. Competition is limited to PRCs funded under RFA-DP-19-001 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.

For an applicant to be even considered they must be responsive to the information here.

Special eligibility requirement(s) may apply to each SIP proposal (see Section IX. Special Interest Project Descriptions).

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.

4. Justification for Less than Maximum Competition

Competition is limited to recipients funded under RFA-DP-19-001 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

An application will be responsive if it meets the following requirements:

- Complies with items 1, 2, 3, and 10 of this section (see Section III. Eligibility Information).
- The application's budget for the first 12 months does not exceed the ceiling amount for the specific SIP (see Section II. Award Information).

If an application is incomplete or does not meet these requirements, it will be considered nonresponsive 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 Dun and Bradstreet Universal Numbering System (DUNS) number in order to begin each of the following registrations.

- (Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: https:// eportal.nspa.nato. int/ AC135Public/ Docs/ US%20Instructions%2 0for%20NSPA%20NCAGE.pdf
- System for Award Management (SAM) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, https://www.sam.gov/portal/SAM/.
- 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 Program Directors/Principal Investigators (PD/PIs) must also work with their institutional officials to register with the eRA Commons or ensure their existing Principle 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 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 DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services. An AOR should be consulted to determine the appropriate number. If the organization does not have a DUNS number, an AOR should complete the US D&B D-U-N-S Number Request Web Form or contact Dun and Bradstreet by telephone directly at 1-866-705-5711 (toll-free) to obtain one. A DUNS number will be provided immediately by telephone at no charge. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a DUNS number. Additionally, all applicant organizations must register in the **System for Award Management (SAM)**. 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 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 the SAM internet site at https://www.sam.gov/index.html.
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 DUNS 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 FOA 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.

Only applicants funded as a PRC under CDC RFA-DP-19-001 are eligible to compete for Special Interest Projects (SIPs) supplemental funding.

Only one SIP application is permitted per PRC institution (normally identified by a unique DUNS number).

As defined in the HHS Grants Policy Statement, (http://dhhs.gov/asfr/ogapa/aboutog/grantsnet.html), applications received in response to the same funding opportunity announcement generally are scored individually and then ranked with other applications under peer review in their order of relative programmatic, technical, or scientific merit. HHS/CDC will not accept any application in response to this NOFO that is essentially the same as one currently pending initial peer review unless the applicant withdraws the pending application.

Section IV. Application and Submission Information

1. Address to Request Application Package

In order to use ASSIST, applicants must visit https://public.era.nih.gov/assist 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:

- E-mail: http://grants.nih.gov/support/index.html
- Phone: 301-402-7469 or (toll-free) 1-866-504-9552. The NIH eRA Service desk is available Monday - Friday, 7 a.m. to 8 p.m. Eastern Time, excluding federal holidays.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF-424 (R&R) Application Guide http://grants.nih.gov/grants/how-to-apply-application-guide.htm and here: https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf, 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 (R&R) 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.

Duplication of Effort

Applicants are responsible for reporting if this application will result in programmatic,

budgetary, or commitment overlap with another application or award (i.e. grant, cooperative agreement, or contract) submitted to another funding source in the same fiscal year.

Programmatic overlap occurs when (1) substantially the same project is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific objective and the project design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source. Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source. Commitment overlap occurs when an individual's time commitment exceeds 100 percent, whether or not salary support is requested in the application. Overlap, whether programmatic, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted.

Any overlap will be resolved by the CDC with the applicant and the PD/PI prior to award.

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

Do not include "hyperlinks" in any part of your submission, as they do not show when the application is uploaded into Grants.gov.

Separate Application Submissions Required

Applicants must submit a separate application package for each selected Special Interest Project (SIP) through www.Grants.Gov, including pertinent, required PDF attachments.

SF 424 Research & Related (R&R) Face Page Form

Instructions for completing the SF424 Research and Related (R&R) Face Page form are provided in the SF424 (R&R) Application Guide. In addition, applicants must complete four fields on the Face Page as follows:

- Field # 4.a. (Federal Identifier): Enter the 8-character, alpha-numeric portion only of your organization's grant number (located on the Notice of Grant Award). Example: DP001234 (Do not enter spaces or other characters in this field).
- Field # 4.b. (Agency Routing Identifier): Enter the SIP Project Number (for example, SIP 11040) and a descriptive title for the SIP. Field 4.b. will accommodate a maximum of 75 characters.
- Field # 8 (Type of Application): **Select "NEW" only for each submission. An introduction is not required.**
- Field # 11 (Descriptive Title of Applicant's Project): Applicants must enter the title of their SIP application. **If an applicant selects NEW on #8 (Type of Application) of the RR SF424 Cover Page, as Introduction file in the Research Plan is not required.**
- These responses are necessary for SIP applications to be submitted and processed electronically. If your application is incomplete or non-responsive to these four

requirements, it will not be processed. NOTE: These special instructions have been changed for this announcement. Please read carefully and include these required changes in your application.

3. Letter of Intent

Due Date for Letter of Intent: **01/21/2019**

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

By the date listed above and in Part 1. Overview Information, prospective applicants are asked to submit a letter of intent that includes the following information:

- Name of the Applicant
- SIP number and title
- Descriptive title of proposed SIP research project
- Name, address, and telephone number of the Lead SIP PD/PI
- Name, address, and telephone number of the PRC PD/PI
- Names of other key personnel
- Participating institutions
- Number and title of this funding opportunity: RFA-DP-19-006, Health Promotion and Disease Prevention Research Centers 2019 Supplemental Special Interest Projects (SIPS)

The letter of intent should be sent electronically to:

Natalie Darling

Scientific Program Official

Extramural Research Program Operations and Services

Centers for Disease Control and Prevention

4770 Buford Highway, NE

Mailstop F-80

Atlanta, GA 30342

Telephone: (770)-488-5740

Email: ndh6@cdc.gov

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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 https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/generalforms-e.pdf and https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf 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 https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf and here: https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf 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:
• Descriptions of the data to be produced in the proposed project
• How access will be provided to the data (including provisions for protection of privacy, confidentiality, security, intellectual property, or other rights)
• 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
• Plans for archival and long-term preservation of the data, or explaining why long-term preservation and access cannot be justified
Examples of DMPs may be found here: University of California https://dmp.cdlib.org/, or USGS, http://www.usgs.gov/datamanagement/plan/dmplans.php

Component 4 (Inclusion Enrollment Report) applies only to Renewal and Revision applications for clinical research. Clinical research is that which is conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies).

Follow the page limits in the SF 424 (R&R) Application Guide unless otherwise specified in the FOA. All instructions in the SF424 (R&R) Application Guide http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general-forms-d.pdf must be followed along with any additional instructions provided in the FOA.

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:

- Descriptions of the data to be produced in the proposed project
- How access will be provided to the data (including provisions for protection of privacy, confidentiality, security, intellectual property, or other rights)
- 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
- Plans for archival and long-term preservation of the data, or explaining why long-term preservation and access cannot be justified

Examples of DMPs may be found here: University of California https://dmp.cdlib.org , or USGS, http://www.usgs.gov/datamanagement/plan/dmplans.php

RESEARCH PLAN

The applicant's research plan should address activities that will be conducted over the entire project period. The Research Plan narrative is comprised of components 2 and 3 above. Note that the Research Strategy is divided into three parts: 1) Significance, 2) Innovation, and 3) Approach.

Research Plan components for each SIP are listed in Section IX. Special Interest Project Descriptions of this NOFO. The performance period of one to five years for each SIP is also specified in Section IX.

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 publically 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 12 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.

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** https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf and here: https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf.

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.

Organizations must submit applications using the ASSIST web-based application preparation and submission process.
ASSIST will validate applications before submission. If the system detects errors, then the applicant must correct errors before their application can be submitted.
Applicants are responsible for viewing their application 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 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)
If the applicant encounters problems that prevent the ability to submit an application which cannot be resolved by Grants.gov or NIH eRA Service Desks, then applicants must contact CDC Technical Information Management Section (TIMS) at 770-488-2700; ogstims@cdc.gov for guidance at least 3 calendar days before the deadline date. Therefore, 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**", 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 and ogstims@cdc.gov explaining why the submission failed.
b. If there is time before the deadline, correct the problem(s) and resubmit as soon as possible.

Due Date for Applications: **02/26/2019**

Electronically submitted applications must be submitted no later than 5:00 p.m., ET, on the listed application due date.

10. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review (http:// www. whitehouse.gov/ omb/ grants_spoc).

11. Funding Restrictions

All HHS/CDC awards are subject to the federal regulations, 45 CFR 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.
In accordance with the United States Protecting Life in Global Health Assistance policy, all non-governmental organization (NGO) applicants acknowledge that foreign NGOs that receive funds provided through this award, either as a prime recipient or subrecipient, are strictly prohibited, regardless of the source of funds, from performing abortions as a method of family planning or engaging in any activity that promotes abortion as a method of family planning, or to provide financial support to any other foreign non-governmental organization that conducts such activities. See Additional Requirement (AR) 35 for applicability (https://www.cdc.gov/grants/additionalrequirements/ar-35.html).
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.
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. 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/additionalrequirements/ar-25.html for revised AR-25.

Applicants are advised that any activities involving information collection (i.e., surveys, questionnaires, etc.) from 10 or more non-Federal individuals/entities are subject to OMB/PRA requirements and may require the CDC to coordinate an OMB Information Collection Clearance.

12. 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 DUNS.

The CDC Risk Questionnaire should be completed and included in the application package. No additional documents are required. 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 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.
The applicant organization must ensure that the DUNS 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 (http:// 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?

- Does the work address a scientific problem of great importance to public health research and/or practice?
- What is the potential or actual impact of the research on public health in the US?
- Will the work be influential in that it will build upon current knowledge, lead others to investigate the problem, open new areas of research, or change the scientific approach or public health practice? If so, how will this improve and be of value to public health?
- If successful, do the research results have the potential to be scalable and reach a larger portion of the population at risk?

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?

- Does the application challenge and seek to shift current public health practice paradigms or approaches?
- Is the proposed research innovative and yet offer reasonable potential for concrete applications of interest and value to CDC?
- Does the project have the potential to increase efficiency or lead to cost savings?

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?

- Does the application propose to use evidence-based interventions or strategies in the research plan?
- If the project is in the latter stages of development, will the strategy establish scalability?
- If the NOFO requires an evaluation plan, are outputs identified and are measures/metric to assess outcomes included?
- If the NOFO requires a translation plan, does the application describe how the results

from the research will be translated and sustained?

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?

- Does the project use critical partnerships or collaborations?
- Does the project support key stakeholder involvement throughout the research process?
- If the applicant proposes subcontracts, is the process open to all qualified entities, including nonprofit organizations, small businesses, and for-profit organizations as well as involve such entities in community-based collaborative efforts relevant to the SIP's objective and public health priorities?

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/additionalrequirements/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/maso/Policy/Policy_women.pdf 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 five 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) adequacy of veterinary care; 4) 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 5) 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.

Overall review criteria: Does the applicant adequately address the additional review criteria detailed in the Special Interest Project?

Individual SIP's Review Criteria: See Section IX 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 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. Applicants should not include live

vertebrate animals.

Sub-awards and Community Involvement

Reviewers will consider an applicant's proposed plan to competitively award subcontracts through an open process that is available to all qualified entities, including nonprofit organizations, small businesses, and for-profit organizations as well as involve such entities in community-based collaborative efforts relevant to the SIP's objective and public health priorities.

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/additionalrequirements/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:

• Type of data to be produced in the proposed project;
• Mechanisms for providing access to and sharing of the data (including provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights);
• 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.

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.

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 guidance for completing a detailed justified budget on the CDC website, at the following Internet address: http://www.cdc.gov/grants/interestedinapplying/applicationresources.html
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 decisions:

- 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 may apply to each SIP proposal (see Section IX. Funding preferences).

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

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

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

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

(1) Financial stability;
(2) Quality of management systems and ability to meet the management standards prescribed in this part;
(3) History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;
(4) Reports and findings from audits performed under subpart F 45 CFR 75 or the reports and findings of any other available audits; and
(5) The applicant's ability to effectively implement statutory, regulatory, or other requirements

imposed on non-Federal entities.

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

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 DUNS, 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).

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

Administrative and National Policy Requirements, Additional Requirements (ARs) outline the administrative requirements found in 45 CFR Part 75 and the HHS Grants Policy Statement and other requirements as mandated by statute or CDC policy. Recipients must comply with administrative and national policy requirements as appropriate. For more information on the Code of Federal Regulations, visit the National Archives and Records Administration: http://www.access.gpo.gov/nara/cfr/cfr-table- search.html.

Specific requirements that apply to this NOFO are the following:

AR-1: Human Subjects Requirements

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

AR-9: Paperwork Reduction Act Requirements

AR-10: Smoke-Free Workplace Requirements

AR-11: Healthy People 2010

AR-12: Lobbying Restrictions

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

AR-14: Accounting System Requirements

AR-16: Security Clearance Requirement

AR-22: Research Integrity

AR-24: Health Insurance Portability and Accountability Act Requirements

AR-25: Data Management and Access

AR-26: National Historic Preservation Act of 1966

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

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

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

AR-31: Distinguishing Public Health Research and Public Health Nonresearch

AR-32: FY 2015 Enacted General Provisions

AR-6: Patient Care

Organization Specific ARs:

AR-8: Public Health System Reporting Requirements

AR-15: Proof of Non-profit Status

AR-23: Compliance with 45 C.F.R. Part 87

3. Additional Policy Requirements

The following are additional policy requirements relevant to this NOFO:

HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items and Printing Publications This policy supports the Executive Order on Promoting Efficient Spending (EO 13589), the Executive Order on Delivering and Efficient, Effective, and Accountable Government (EO 13576) and the Office of Management and Budget Memorandum on Eliminating Excess Conference Spending and Promoting Efficiency in Government (M-35-11). This policy apply 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: http://www.plainlanguage.gov/plLaw/index.cfm.

Pilot Program for Enhancement of Employee Whistleblower Protections All applicants will be subject to a term and condition that applies the terms of 48 CFR section 3.908 to the award and requires that grantees inform their employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. 4712.

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 the 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/additionalrequirements/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/additionalrequirements/ar-36.html.

4. Cooperative Agreement Terms and Conditions

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

- The rights and responsibilities of the Principal Investigator are delineated in each Special Interest Project description contained in Section IX Special Interest Project Descriptions of this NOFO.
- Obtaining appropriate Institutional Review Board approvals for research involving human subjects for all participating sites.
- Coordinating of 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 IX of this announcement. Additional responsibilities include:

- Assisting the PI, as needed, in complying with the Investigator responsibilities described in the Policy on Public Health Research and Nonresearch 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 performance against 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 Grant 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:

Named in the Notice of Grant Award (NGA) as the Scientific Program Official. Provide for 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. Assure 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 provide HHS/CDC with an original, plus one hard copy of the following reports:

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** (https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.htm) is required and must be submitted through eRA Commons **within 90 days after the end of the calendar quarter in which 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 contributed 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 IX. 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.

2. 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.

3. Additional Reporting Requirements

- Information for the PRC Program Evaluation Reporting System (PERS).

4. Annual Federal Financial Report (FFR)

- FFRs should report separate unobligated balances for each PRC award and SIP award(s).

https://era.nih.gov/docs/Commons_UserGuide.pdf

2. Annual Federal Financial Reporting The Annual Federal Financial Report (FFR) SF 425 is required and must be submitted through eRA Commons within 90 days after the end of the calendar quarter in which the budget period ends. 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.
The due date for final FFRs will continue to be 90 days after the Period of Performance end date.
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 end of grant period. 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).

FFR (SF 425) instructions for CDC recipients are now available at https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.htm. For further information, contact GrantsInfo@nih.gov. Additional resources concerning the eFSR/FFR system, including a User Guide and an on-line demonstration, can be found on the eRA Commons Support Page: https://grants.nih.gov/support/index.html

FFR Submission: The submission of FFRs to CDC will require organizations to register with eRA Commons (Commons) (https:// commons. era.nih.gov/ commons/). CDC recommends that this one time registration process be completed at least 2 weeks prior to the submittal date of a FFR submission.

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.

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

CDC Technical Information Management Section (TIMS)
Telephone 770-488-2700
Email: ogstims@cdc.gov
Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Standard Time

Application Peer Review Contact(s)

Jaya Raman, Ph.D., Scientific Review Official

Extramural Research Program Operations and Services

Centers for Disease Control and Prevention

4770 Buford Highway, NE

Mailstop F-80

Atlanta, GA 30342

Telephone: (770) 488-6511

Email: kva@cdc.gov

Scientific/Research Contact(s)

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 30342
Telephone: (770) 488-5740
Email: ndh6@cdc.gov

Financial/Grants Management Contact(s)

Sharon Cassell,
Grants Management Specialist
Office of Grants Services/Office of Financial Resources
Centers for Disease Control and Prevention
4770 Buford Highway, NE
Mailstop F-80
Atlanta, GA 30342
Telephone: 770-488-2703
Email: zpr0@cdc.gov

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 Federal Regulations.

Awards for the NOFO are made under the authorization of Section 301(a) of the Public Health Service Act as amended, 42 U.S.C. 241(a), and Section 1706 of the Public Health Service Act, 42 U.S.C. 300u-5.

Section IX. Special Interest Project Descriptions:

SIP 19-001. Improving Cognitive Impairment Detection and Referral to Resources among Older Adults: Applying the KAER Model in a Clinical Health Care System

Background

The growing number of older adults in the U.S. population has already placed unprecedented demands on aging services and the public health and health care systems. By 2030, 1 in 5 Americans, or 72.7 million, will be aged 65 years or older, and by 2050 the number of adults aged 65 years or older in the United States is projected to reach 83.7 million. [1] As people age, their risk of cognitive decline, including Alzheimer's disease and other dementias, increases.

Alzheimer's disease is a devastating, progressive, and ultimately fatal disease that begins with mild memory loss and leads to the loss of the ability to carry on a conversation, respond to the environment, and is ultimately fatal. People with Alzheimer's gradually lose the ability to care for themselves and to remain independent. An estimated 5.7 million Americans of all ages are living with Alzheimer's dementia in 2018. [2] This number includes an estimated 5.5 million people aged 65 and older and approximately 200,000 people under age 65 who have younger-onset Alzheimer's. [2] By 2050, the total number is projected to rise to 14 million people. [3] Racial, gender and socioeconomic status disparities exist. African Americans and Hispanics have the highest prevalence of Alzheimer's. [3] Women are also more likely than men to develop Alzheimer's. [3] And persons who attain higher levels of education are at reduced risk for developing Alzheimer's disease. [3]

Along with the fact that there is no cure for Alzheimer's disease, it is often the case that a diagnosis is made late in the disease progression, when palliative measures are less effective. Lack of diagnosis seriously reduces the person's access to available treatments and deprives the person and family of information that could help them understand the person's symptoms and plan for the future.

To bolster physician recognition and diagnosis of Alzheimer's disease and other dementias, the Gerontological Society of America developed the KAER(***K**ickstart, **A**ssess, **E**valuate, **R**efer)* model. The KAER model is described as follows:

The Gerontological Society of America Workgroup on Cognitive Impairment Detection and Earlier Diagnosis developed the KAER Toolkit for primary care providers, a 4-step process to detecting cognitive impairment and earlier diagnosis of dementia. This KAER model aims to reduce the number of older adults whose cognitive impairment goes undetected. If individuals with cognitive impairment are not diagnosed, this can exacerbate any other treatable conditions individuals may have. With a diagnosis, older adults with dementia and their families can access and receive community resources that may lead to improved health and well-being outcomes. [4] Although there are many diagnostic tools available for detecting cognitive impairment, the KAER Toolkit is a comprehensive framework for primary care providers that ensures that patients receive appropriate testing and referral. Furthermore, GSA has provided the KAER toolkit free of charge and with no restrictions for further changes and refinement for implementation by other entities. Additionally, the KAER toolkit was developed collaboratively

by numerous stakeholders that included federal agencies (including CDC), as well as provider and payer organizations.

The KAER toolkit is designed to aid and assist providers in beginning a dialogue about evaluating for potential cognitive impairment with patients, their families, and/or caregivers where appropriate. The toolkit also aids in referring those with impairment to the relevant resources. The toolkit was developed consistent with requirements regarding detection of cognitive impairment during Annual Wellness Visits. However, this toolkit should not replace existing guidelines and protocols for medical treatment (See Pages 15, 53, 93, and 135 for more information).

The first step of KAER is to ***K****ickstart the Cognition Conversation* by raising the topic of brain health and asking about memory and cognition. The National Academies of Sciences developed an Action Guide for Health Care Providers that can help facilitate this dialogue between providers, older adults and their families.

The second step is to ***A****ssess for Cognitive Impairment* through the use of a brief cognitive test or other structured assessments in order to detect any cognitive impairment. A questionnaire should also be used to obtain family member perceptions regarding the individual's cognition.

The third step is to ***E****valuate for Dementia*. In this step, a diagnostic evaluation should be conducted to diagnosis and/or identify the cause(s) of any diagnosed dementia. This diagnosis should be documented and disclosed to the patient and family unless otherwise indicated.

The final step is to ***R****efer for Community Resources.* At this point, individuals with a dementia diagnosis and family should be connected with the appropriate primary care provider and other community resources. Patient and family needs should also be identified.

Purpose

The purpose of this special interest project is to review and refine the KAER toolkit for application and use within a healthcare system as it was developed for primary care settings. This project will examine the effectiveness of the KAER Toolkit in practical use by providers to detect cognitive impairment and assess the model for any gaps or potential improvements. Improving detection of cognitive impairment can help patients and their families plan for the future and better manage any other chronic conditions. This may lead to improved health and wellbeing outcomes for patients and families and avoid unnecessary hospitalizations.

Project Objectives/Outcomes

The objective of this SIP is to 1) review the KAER toolkit and if necessary, refine and adapt the materials for use by its primary care providers. Successful applicants will describe how they will integrate the KAER model into their standard protocol for older adult encounters within the healthcare system as well as other materials to encourage people with memory loss to consult with their healthcare provider for an assessment. The applicant will provide evaluation of the KAER model for its ease of use and prepare a report ready for dissemination that details their evaluation findings.

Public Health Priorities

Healthy People 2020 Objective

Dementias, including Alzheimer's Disease:

- DIA-1: Increase the proportion of adults aged 65 years and older with diagnosed Alzheimer's disease and other dementias, or their caregiver, who are aware of the diagnosis.

The project objectives will help meet this priority by improving detection and diagnosis of dementias, including Alzheimer's and improving treatment by connecting persons diagnosed and/or their caregivers with the appropriate resources.

Project Activities and Submission Requirements

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

Study design and methods

The applicant should describe a plan to incorporate the KAER guidelines into their patient protocols for older adult encounters. This includes, but is not limited to, encouraging older adults with memory concerns to consult a healthcare provider, developing and carrying out educational sessions for healthcare providers on the KAER model, selecting a diagnostic instrument from the list of approve KAER questionnaires, developing system prompts for primary care providers on patient encounter systems (e.g., electronic medical record), and developing feedback mechanisms to facilitate dialogue between providers and project managers to better refine and improve the application of the model.

Target population

The applicant should identify and demonstrate access (with an MOU or other documentation) to healthcare providers, including primary care physicians and nurse-practitioners, who see older adults as part of a healthcare system through a healthcare system. The applicant should provide information on the socioeconomic characteristics of the older adult patients with respect to gender, race, and income. It is important that the target population is diverse with respect to these characteristics due to the disparities in the prevalence of Alzheimer's disease that exist across these characteristics.

Collaboration/Partnerships

The Applicant should engage in collaboration with brain or cognitive health and aging subject matter experts and other stakeholders such as the Gerontological Society of America to develop and implement the project and to conduct outreach regarding any findings.

Recruitment Plan

The applicant should describe the manner in which they plan to recruit healthcare providers within their healthcare system to adopt the KAER model within their practice with older adults.

Annual Action Plan

The applicant will provide a 2 year action plan using SMART goals and objectives that includes a timeline and milestones. Key activities and milestones should also be addressed for the entire project period. Identify key staff who will be devoted to this project and describe their demonstrated knowledge and experience relevant to the proposed study. It is expected that progress towards achieving these milestones will be included in progress reports and conference calls with CDC staff.

Evaluation Plan/Performance measurement

The applicant should describe an evaluation plan that meets SMART goals. The evaluation plan should include as a component but is not limited to:

1. The number of healthcare providers who were trained in the KAER model
2. The number of training sessions for them
3. The number of patient encounters where the KAER model was used
4. A Description of community resources provided for patients and families (referrals)
5. What resources and costs were needed to implement the KAER model into the system

The applicant should describe how they will assess the ease of use and the effectiveness of the KAER Toolkit in practical use by providers to detect cognitive impairment and assess the model for any gaps or potential improvements.

The applicant should provide a timeline for completion of the proposed activities.

Dissemination Plan

The applicant is expected to publish the results of findings publicly (for example, through a scholarly article and at a national conference) and to prepare a detailed report of findings for dissemination. Published results and findings should be for the benefit of the general public and not solely for the project applicant. All results, findings, reports or processes developed under this cooperative agreement should be shared with CDC. CDC has the right to review, update and disseminate all information to the general population.

Public Health Impact

Project findings may help to inform future health care system approaches towards better detection and diagnosis of cognitive impairment among older adults. These findings can be used to improve care management for people with cognitive impairment and connect those people with a cognitive impairment and their families with available resources.

Eligibility Criteria

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

The applicant should be connected to or part of a large healthcare system with more than 500 total physicians and 30,000 annual discharges according to the Agency for Healthcare Research and Quality 2016 Compendium of U.S. Health Systems (https://www.ahrq.gov/chsp/compendium/index.html). A current Memorandum of Understanding (MOU) or collaborator letter of support is required which identifies the healthcare system, confirms the system meets the above physician and discharge minimums, and which confirms access to the healthcare providers serving older adults being used in the study.

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 the availability of experts in brain or cognitive health through current resumes or curricula vitae describing relevant presentations and peer-reviewed publications?
- Does the applicant identify and confirm access to a large patient treatment system with appropriate health care providers to be used for the purposes of this study?
- Does the patient treatment system identified appear sufficient to achieve the goals and objectives of testing the KAER toolkit?
- Does the applicant provide evidence of access to an adequate number of older adult primary care patients to accomplish the goals of this study?
- Does the applicant provide information about the socioeconomic status of the older adult primary care patient population?

Funding Preferences

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

- The geographic distribution of multiple applicants
- The generalizability of the older adult patient population to the U.S. in terms of gender, race/ethnicity, and socioeconomic status.

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. 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 $800,000 may be available to fund up to two (2) Prevention Research Center for a 2-year project period. The average award for the recipient is expected to be approximately $200,000 for year one. The year one ceiling is $200,000. Funding may vary and is subject to change.

Research Status

It is expected that this project will not involve human subjects research; therefore, it is expected that it will not require local or CDC IRB approval.

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 activities such as study design, and survey instruments as well as any products that may arise from this award such as scientific papers or other forms or written documentation. CDC staff will only act as coauthors if CDC staff meet the CDC authorship criteria policy.

References

1. U.S. Census Bureau. An aging nation: the older population in the United States, population estimates and projections. Washington, DC; 2014 May.
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SIP 19-002. Managing Epilepsy Well 2.0 (MEW) Network - Coordinating Center

Background

In its 2012 report, Epilepsy across the Spectrum, the Institute of Medicine recommended the "development, evaluation, replication, and expanded use of self-management and educational programs, including those developed through the "Managing Epilepsy Well Network" in order to improve quality of life for people with epilepsy" [1]. Since its inception in 2007, CDC's Managing Epilepsy Well (MEW) Network (www.managingepilepsywell.org) has provided national leadership in developing, testing, and distributing innovative self-management programs, tools, and trainings for epilepsy professionals [2]. The MEW Network has included a coordinating Prevention Research Center (PRC) ("coordinating center") and several collaborating PRCs ("collaborating centers"). The coordinating center's primary goal is to provide leadership and coordination of efforts across the MEW Network. The coordinating center is also engaged in program development and evaluation. The collaborating PRCs are responsible for a variety of tasks including program development and evaluation, professional training, and collaboration within the network (e.g., participation in monthly conference calls to share updates and resources). MEW Network members also include associate members (previously funded [2007-2012] MEW network sites that remain active in network-specific research such as conducting systematic reviews), and at large-members (organizations or groups that represent partners or agencies not funded under the Special Interest Project cooperative agreement, e.g., national Epilepsy Foundation, American Epilepsy Society) [3]. Community members including people who have epilepsy and/or their caregivers also participate in the network through their local MEW Network coordinating or collaborating center.

The MEW Network has developed and tested several programs (e.g., HOBSCOTCH, Project UPLIFT, MINDSET, PACES, TIME, WebEase) demonstrating promising or positive outcomes related to improving self-management domains [2]. The MEW Network has also supported provider trainings for program adoption. Despite this progress, research gaps exist regarding these programs' effects over an extended period of time (e.g., >12 months); in relation to clinical outcomes (e.g., seizure frequency, medication adherence, comorbidity); efficacy in new settings or epilepsy subpopulations; and strength of evidence [4]. Additionally, because epilepsy affects only about 1% of the population, researchers are often challenged with obtaining a large enough sample size to test specific research questions, limiting some conclusions. Common, but narrow approaches for maximizing participant recruitment and retention in interventions have also limited sample size [5]. Although the MEW Network has trained dozens of providers for program delivery, gaps exist regarding potential program adopters' perceptions of, and capacity for, program adoption. Collectively, this suggests a need for more efficacy studies that incorporate and study best practices to maximize participant recruitment and retention, and assessments of potential program adopters' perception of intervention attributes (e.g., program complexity, benefits) to ensure a program fits with their organizational capacity for delivery [4-8].

The Division of Population Health, National Center for Chronic Disease Prevention and Health Promotion seeks to support a MEW-2 Network ("version 2.0") to: 1) conduct a replication study of an existing evidence-based MEW Network program to enhance knowledge about program efficacy; 2) incorporate best practices or recommended strategies for enhancing participant

recruitment and retention throughout the study and evaluate associations between a selected strategy and patient-related factors (e.g., health literacy) to inform best practices for the epilepsy field; and 3) identify and assess potential program adopters' perceived characteristics of the intervention to inform implementation and dissemination strategies.

Because most of the MEW Network interventions have only been tested in one or two randomized control trials, sometimes following pilot testing, replication studies conducted in the next phase of the MEW Network (MEW 2.0) will tell us whether MEW Network programs consistently improve self-management behaviors across new epilepsy subgroups or settings so that we can be sure an intervention works as intended. MEW 2.0 researchers will apply best practices for recruitment strategies into their study design and examine any associations with patient-related factors to enhance our understanding of which recruitment and retention strategies are most effective during different study phases. MEW 2.0 researchers will also assess what potential program adopters think about a selected MEW Network intervention and their capacity to adopt and deliver an evidence-based epilepsy self-management intervention in their community.

Purpose

The purpose of this special interest project is to develop a **Coordinating Center** for the Managing Epilepsy Well 2.0 Network to support and conduct epilepsy self-management intervention research and dissemination. The coordinating center will lead collaboration through among up to five MEW Network Collaborating Centers that will compose the MEW Network 2.0, and that will complete a set of activities that address Component 1 and Component 2 listed below.

Project Objectives/Outcomes

Component 1: Sustain and support the continuation of the Managing Epilepsy Well (MEW) Network 2.0 for Epilepsy Self-Management Research

- The coordinating center is expected to coordinate the PRC MEW-2 Network for Epilepsy Self-Management Intervention Research. Applicants are expected to describe how interactions will be forged with current and proposed MEW collaborating centers and discuss the relationship and interactions they have, or will create, with national, state and local social service agencies or other stakeholders. 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
    - Use the Internet and other communication tools to develop and support the communication infrastructure, including a MEW Network website.
    - Coordinate and lead annual evaluation of MEW Network processes and outcomes

- Promote MEW Network programs, resources, and activities at professional meetings and through social media and traditional communication efforts to raise professional and public awareness of MEW Network programs, resources, and tools.

Component 2: Research, Dissemination, and Evaluation

- Examine the status and evidence of CDC Prevention Research Centers' MEW Network programs or projects;
- Support research activities on items A or B:
  - Item A: A replication study of an existing evidence-based MEW Network program in a population with the same or very similar epilepsy-related characteristics where the intervention was previously tested.
  - Item B: A replication study in a new setting (e.g., geographic location; recruitment venue) or new population subgroup of people with epilepsy while maintaining core content and overall program fidelity to support inferences regarding effectiveness.
- Examine the literature and incorporate best practice or other recommendations to maximize patient recruitment and retention throughout the study.
- Assess the effects of the intervention on epilepsy outcomes (e.g., seizure frequency), self-management behaviors, comorbidity (e.g., depressive symptoms), and related outcomes (e.g., medication adherence).
- Assess patient-related factors (e.g., attitudes, preferences, learning styles, social context), associated with recruitment and retention to understand how and when people with epilepsy decide to participate in (or not) and complete (or not) a self-management program.
- Identify and assess potential program adopters' perceived characteristics of the selected intervention, and enabling factors and barriers related to program adoption, to understand the drivers of program adoption.
- Collaborate with other members of the MEW Network through monthly conference calls, e-mail, on-line meetings, or other channels to share knowledge, best practices, and other resources (e.g., survey instruments, provider training protocols, program toolkits) to enhance intervention implementation, effectiveness, evaluation, program reach, 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.
- Support Dissemination Activities on items A and/or B:
  - Item A: Publish findings in peer-reviewed journals, present findings in local or national meetings, and develop and share technical assistance products (e.g., program briefs, program information videos) for epilepsy health and social service providers.
  - Item B: Support and evaluate provider training on program implementation.

Public Health Priorities

Healthy People 2020 Objective

- Increase the proportion of people with epilepsy and uncontrolled seizures who receive appropriate medical care.
- Increase the proportion of persons who use electronic personal health management tools
- Increase the proportion of adults who report high levels of health-related quality of life.

NCCDPHP Domains

- Domain 4: Community programs linked to clinical services

Project Activities and Submission Requirements

Applications submitted in response to this SIP should present a Research Plan for the Coordinating Center that addresses Components 1 and 2 and that includes:

- Study design and methods
- Target population
- Collaboration/Partnerships
- Recruitment and Retention Plan
- Annual Action Plan
- Evaluation Plan/Performance measurement
- Dissemination Plan
- Translation plan

Note: The award recipient of SIP 19-002 will function as the MEW Network Coordinating Center and will serve as a member of the network thus a separate application to SIP 19-003 (MEW Network Collaborating Centers) is not required. However, an institution that applies to SIP 19-002 may want to consider applying to SIP 19-003 in the case that they are not selected as the Coordinating Center and would like to be considered as a collaborating center.

Applications submitted in response to this SIP should present information that address Component 1 (items 1-6) and Component 2 (A or B) listed below.

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

Public Health Impact

Seminal reports from consensus conferences on public health and epilepsy (1997, 2003), and the recent (2012) Institute of Medicine Report on epilepsy (Epilepsy across the Spectrum), 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. The

network is intended to address applied research needs in priority areas identified by epilepsy stakeholders that advance the application of evidence-based epilepsy self-management programs. Replication studies and related research can increase the evidence-base for MEW Network Programs' effectiveness which is essential for program adoption by health care providers or other community-based providers. Expanded implementation of MEW Programs can meet a gap in the widespread availability of evidence-based epilepsy self-management programs. 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.

Eligibility Criteria

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

1. The institution must provide evidence that the project team will include experts in epilepsy or neuroscience as evidenced in the Research & Related Senior/Key Person Section of the SF424 (R&R).
2. The institution must provide a letter of support demonstrating evidence of access to the study population assuring access to the populations in which the study will be conducted.

Additional Review Criteria

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

1. Does the applicant have a research team that demonstrates sufficient experience in developing, planning, and implementing chronic disease self-management research, epilepsy self-management research, or public health prevention research in hard to reach populations?
2. Does the applicant provide a compelling demonstration of their readiness to serve as the Coordinating Center?
3. Does the applicant provide a compelling approach for accomplishing the research objectives?
4. Does the applicant provide documentation of all necessary permissions (e.g., approval from the respective program's university intellectual property office, and/or from the original MEW Network program investigators to obtain or adapt the epilepsy self-management program protocol and material for program implementation)?
5. Does the applicant demonstrate evidence of successful experience with recruitment and retention of hard to reach populations?
6. Does the applicant demonstrate evidence of successful experience leading groups and working with partners, including a group of academic institutions around a common agenda?
7. Does the applicant demonstrate successful experience working with federal, state, or

local public health and other social service agencies?
8. Does the applicant demonstrate successful experience working in priority public health settings such as health care, work sites, communities, or schools?
9. Does the applicant demonstrate successful experience evaluating the impact of public health interventions?
10. Does the applicant demonstrate successful experience using technology to support collaborative projects?

Funding Preferences

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

- Diversity of study population and geographic location

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. 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 $2,000,000 is available to fund one (1) Prevention Research Center(s) for a 5-year project period. The average award for each recipient is expected to be approximately $400,000 for year one. The year one ceiling is $400,000. Funding may vary and is subject to change.

Research Status

It is expected that this project will be non-exempt research. It is anticipated that this project will require local IRB approval and review by the CDC IRB. 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 activities such

as identifying survey instruments, sharing best practices from new research, facilitating collaborations with subject matter experts, reviewing and commenting on manuscript drafts.

References

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SIP 19-003. Managing Epilepsy Well 2.0 (MEW) Network - Collaborating Center

Background

In its 2012 report, Epilepsy across the Spectrum, the Institute of Medicine recommended the "development, evaluation, replication, and expanded use of self-management and educational programs, including those developed through the "Managing Epilepsy Well Network" in order to improve quality of life for people with epilepsy" [1]. Since its inception in 2007, CDC's Managing Epilepsy Well (MEW) Network (www.managingepilepsywell.org) has provided national leadership in developing, testing, and distributing innovative self-management programs, tools, and trainings for epilepsy professionals [2]. The MEW Network has included a coordinating Prevention Research Center (PRC) ("coordinating center") and several collaborating PRCs ("collaborating centers"). The coordinating center's primary goal is to provide leadership and coordination of efforts across the MEW Network. The coordinating center is also engaged in program development and evaluation. The collaborating PRCs are

responsible for a variety of tasks including program development and evaluation, professional training, and collaboration within the network (e.g., participation in monthly conference calls to share updates and resources). MEW Network members also include associate members (previously funded [2007-2012] MEW network sites that remain active in network-specific research such as conducting systematic reviews), and at large-members (organizations or groups that represent partners or agencies not funded under the Special Interest Project cooperative agreement, e.g., national Epilepsy Foundation, American Epilepsy Society) [3]. Community members including people who have epilepsy and/or their caregivers also participate in the network through their local MEW Network coordinating or collaborating center.

The MEW Network has developed and tested several programs (e.g., HOBSCOTCH, Project UPLIFT, MINDSET, PACES, TIME, WebEase) demonstrating promising or positive outcomes related to improving self-management domains [2]. The MEW Network has also supported provider trainings for program adoption. Despite this progress, research gaps exist regarding these programs' effects over an extended period of time (e.g., >12 months); in relation to clinical outcomes (e.g., seizure frequency, medication adherence, comorbidity); efficacy in new settings or epilepsy subpopulations; and strength of evidence [4]. Additionally, because epilepsy affects only about 1% of the population, researchers are often challenged with obtaining a large enough sample size to test specific research questions, limiting some conclusions. Common, but narrow approaches for maximizing participant recruitment and retention in interventions have also limited sample size [5]. Although the MEW Network has trained dozens of providers for program delivery, gaps exist regarding potential program adopters' perceptions of, and capacity for, program adoption. Collectively, this suggests a need for more efficacy studies that incorporate and study best practices to maximize participant recruitment and retention, and assessments of potential program adopters' perception of intervention attributes (e.g., program complexity, benefits) to ensure a program fits with their organizational capacity for delivery [4-8].

The Division of Population Health, National Center for Chronic Disease Prevention and Health Promotion seeks to support a MEW-2 Network ("version 2.0") to: 1) conduct a replication study of an existing evidence-based MEW Network program to enhance knowledge about program efficacy; 2) incorporate best practices or recommended strategies for enhancing participant recruitment and retention throughout the study and evaluate associations between a selected strategy and patient-related factors (e.g., health literacy) to inform best practices for the epilepsy field; and 3) identify and assess potential program adopters' perceived characteristics of the intervention to inform implementation and dissemination strategies.

Because most of the MEW Network interventions have only been tested in one or two randomized control trials, sometimes following pilot testing, replication studies conducted in the next phase of the MEW Network (MEW 2.0) will tell us whether MEW Network programs consistently improve self-management behaviors across new epilepsy subgroups or settings so that we can be sure an intervention works as intended. MEW 2.0 researchers will apply best practices for recruitment strategies into their study design and examine any associations with patient-related factors to enhance our understanding of which recruitment and retention

strategies are most effective during different study phases. MEW 2.0 researchers will also assess what potential program adopters think about a selected MEW Network intervention and their capacity to adopt and deliver an evidence-based epilepsy self-management intervention in their community.

Purpose

The purpose of this special interest project is to support up to 5 **Collaborating Centers** that will be a part of the MEW Network 2.0 and that will conduct epilepsy self-management intervention research and dissemination. Grantees will not be involved in activities related to changing federal, state, or local laws and must adhere to applicable anti-lobbying provisions.

Project Objectives/Outcomes

- Conduct research activities on items A or B:
    - Item A: A replication study of an existing evidence-based MEW Network program in a population with the same or very similar epilepsy-related characteristics where the intervention was previously tested
    - Item B: A replication study in a new setting (e.g. geographic location; recruitment venue) or new population subgroup of people with epilepsy while maintaining core content and overall program fidelity to support inferences regarding effectiveness.
- Examine the literature and incorporate best practice or other recommendations to maximize patient recruitment and retention throughout the study.
- Assess the effects of the intervention on epilepsy outcomes (e.g., seizure frequency), self-management behaviors, comorbidity (e.g., depressive symptoms), and related outcomes (e.g., medication adherence).
- Assess patient-related factors (e.g., attitudes, preferences, learning styles, social context), associated with recruitment and retention to understand how and when people with epilepsy decide to participate in (or not) and complete (or not) a self-management program.
- Identify and assess potential program adopters' perceived characteristics of the selected intervention, and enabling factors and barriers related to program adoption, to understand the drivers of program adoption.
- Collaborate with other members of the MEW Network through monthly conference calls, e-mail, on-line meetings, or other channels to share knowledge, best practices, and other resources (e.g., survey instruments, provider training protocols, program toolkits) to enhance intervention implementation, effectiveness, evaluation, program reach, 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.

- Support Dissemination Activities on items A and/or B:
    - Item A: Publish findings in peer-reviewed journals, present findings in local or national meetings, and develop and share technical assistance products (e.g., program briefs, program information videos) for epilepsy health and social service providers.
    - Item B: Support and evaluate provider training on program implementation.

Public Health Priorities

Healthy People 2020 Objective

- Increase the proportion of people with epilepsy and uncontrolled seizures who receive appropriate medical care.
- Increase the proportion of persons who use electronic personal health management tools
- Increase the proportion of adults who report high levels of health-related quality of life

NCCDPHP Domains

- Domain 4: Community programs linked to clinical services

Project Activities and Submission Requirements

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

- Study design and methods
- Target population
- Collaboration/Partnerships
- Recruitment and Retention Plan
- Annual Action Plan
- Evaluation Plan/Performance measurement
- Dissemination Plan
- Translation plan

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

Public Health Impact

More effectiveness studies of epilepsy self-management programs are essential prior to widespread program adoption by health care providers or other community-based providers. The project will fund the Managing Epilepsy Well Network Collaborating Centers to conduct replication studies and related research to increase increase the evidence of CDC

Managing Epilepsy Well (MEW) Network epilepsy self-management programs.

Eligibility Criteria

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

1. The institution must provide evidence that the project team will include experts in epilepsy or neuroscience as evidenced in the Research & Related Senior/Key Person Section of the SF424 (R&R).
2. The institution must provide a letter of support demonstrating evidence of access to the study population (e.g., via a state Epilepsy Foundation chapter, regional accredited epilepsy center, or other healthcare organization) assuring access to the populations in which the study will be conducted.

Additional Review Criteria

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

- Does the applicant have a research team that demonstrates sufficient experience in developing, planning, and implementing chronic disease self-management research, epilepsy self-management research, or public health prevention research in hard to reach populations?
- Does the applicant provide a compelling approach for accomplishing the research objectives?
- Does the applicant provide documentation of all necessary permissions (e.g., approval from the respective program's university intellectual property office, and/or from the original MEW Network program investigators to obtain or adapt the epilepsy self-management program protocol and material for program implementation)?
- Does the applicant demonstrate evidence of successful experience with recruitment and retention of hard to reach populations?
- Does the applicant demonstrate evidence of successful experience working with partners, including a group of academic institutions around a common agenda?
- Does the applicant demonstrate successful experience working with federal, state, or local public health and other social service agencies?
- Does the applicant demonstrate successful experience working in priority public health settings such as health care, work sites, communities, or schools?
- Does the applicant demonstrate successful experience evaluating the impact of public health interventions?

Funding Preferences

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

- Geographic diversity of Collaborating Center sites
- Diversity of study population and geographic location

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. 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 $8,500,000 is available to fund five (5) Prevention Research Center(s) for a 5-year project period. The average award for each recipient is expected to be approximately $340,000 for year one. The year one ceiling is $340,000. Funding may vary and is subject to change.

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 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 on activities such as review of study instruments, make recommendations on recruitment and retention plans, participate on network-wide monthly teleconference calls, share public health partnership opportunities and training resources.

References

1. Institute of Medicine. Epilepsy across the Spectrum: Promoting health and understanding. National Academies Press 2012. Available at: http://www.iom.edu/Reports/2012/Epilepsy-Across-the-Spectrum.aspx.

2. Sajatovic M, Jobst BC, Shegog R, et al. The Managing Epilepsy Well Network: advancing epilepsy self-management. Am J Prev Med. 2017;52(3S3):S241-S245.
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4. National Academy of Sciences, Engineering, and Medicine. (2018). Improving Health Research on Small Popualtions: Proceedings of a Workshop. Washington, DC: The National Academies Press. doi: https://doi.org/10.17226/25112.
5. Patient Recruitment, Enrollment, and Retention in Clinical Trials – FDA. Available at: https://www.fda.gov/.../PatientEngagementAdvisoryCommittee/UCM580191.pdf
6. Proceedings from the 10th Annual Conference on the Science of Dissemination and Implementation: S137 Systematic review of adaptations of public health evidence-based interventions. *Implementation Science* 2018 13:728. Available at: https://implementationscience.biomedcentral.com/articles/10.1186/s13012-018-0728-7
7. U.S. Department of Health & Human Services. Office of the Assistant Secretary for Planning and Evaluation. Core Intervention Components: Identifying and Operationalized What Makes Programs work. Available at: https://aspe.hhs.gov/system/files/pdf/180286/rb_CoreIntervention.pdf

SIP 19-004. Cancer Prevention and Control Research Network – Coordinating Center

Background

The Cancer Prevention and Control Research Network (CPCRN) is a national network of academic, public health, and community partners who work together to reduce the burden of cancer, especially among those disproportionately affected. The CPCRN was initiated in October 2002, with funding from the Centers for Disease Control and Prevention (CDC) and the National Cancer Institute (NCI), as a thematic research network of the Prevention Research Centers (PRCs). The focus of the network is to more effectively translate research into practice. The CPCRN conducts community-based, implementation research related to cancer prevention and control across its network centers. Through the cross-site projects, CPCRN extends the knowledge base of translation processes that facilitate the translation of evidence into practice, develop measures and outcomes for evidence-based cancer prevention and control activities to reduce the cancer burden, and establish partnerships with major health care systems and other sectors. The broad geographic reach, diverse target populations and strong relationships among CPCRN investigators allows the network to achieve a larger impact than any individual center could achieve on its own.

Purpose

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. Furthermore, the CPCRN engages in enhancing large-scale efforts to reduce

cancer risk, improve screening utilization, cancer survival, and ameliorate health disparities in the community and within health systems that serve the medically underserved.

Project Objectives/Outcomes

The project objectives are: 1) to support one center as a coordinating center to facilitate the activities of the network to enhance coordination and communication across all collaborating centers and foster multi-center collaborations; and 2) to participate in the work of the network as a collaborating center. The mission of the CPCRN is to build knowledge to accelerate the adoption and implementation of evidence-based cancer prevention and control strategies in communities and actively engage in enhancing large-scale efforts to reach underserved populations and reduce their burden of cancer.

Furthermore, the goals of the cross-center projects are to extend the knowledge base of processes that facilitate the translation of evidence into practice, develop measures and outcomes for evidence-based cancer prevention and control activities, and establish partnerships with major health care systems and other sectors. The CPCRN also contributes to the field of implementation science from primary prevention and early detection through to cancer survivorship. For more information about the mission, vision, and logic model of the CPCRN see www.cpcrn.org.

The Coordinating Center will:

- Lead and facilitate network discussions related to the development of research expertise in the application of proven cancer prevention and control interventions in community and clinical settings and implementation science,
- Provide staff and technological support to help facilitate collaborative research activities with network members, their partners and affiliates,
- Facilitate linkages among network members as well as non-members such as national, state and local partners to work together on the mission of the network, and
- Coordinate and conduct evaluation of network activities and its impact.

Affiliate members are individuals and organizations that wish to participate in CPCRN but are not funded directly by CDC/NCI as CPCRN Centers. Affiliate Members can include, but are not limited to, faculty members, researchers, universities, nonprofit organizations, or community partners who are not currently CPCRN Members. Affiliate Members do not become eligible to receive Special Interest Project funding from CDC. The Coordinating Center will bear the cost of Affiliate Members' participation in workgroup or Steering Committee calls; however, the Coordinating Center is unable to cover travel, lodging, transportation, or food costs for Affiliate Members' participation in CPCRN meetings.

Public Health Priorities

Healthy People 2020 Objective

Objectives C15 through C17 focus on increasing the proportion of the population who receive either cervical, colorectal or breast cancer screening, respectively, based on the most recent

guidelines. The ultimate goal of this project is to reduce cancer incidence (C9-C11) and mortality (C1-C8) through community-based participatory research.

NCCDPHP Domains

- Domain 3: Health system strategies to improve the delivery and use of clinical and other preventive services
- Domain 4: Community programs linked to clinical services

Cancer Moonshot

This project aligns with the recommendations from the Blue Ribbon Panel to expand use of proven cancer prevention and early detection strategies through implementation science. The network centers conduct research to reduce cancer risk and cancer health disparities through approaches in development, testing and broad adoption of proven prevention strategies.

Project Activities and Submission Requirements

Applications submitted in response to this SIP should present a plan that addresses the following:

Coordinating Center

1. Describe how the coordinating center will support the CPCRN infrastructure, including but not limited to the following items:

- Description of the resources and processes that will facilitate linkages and activities among 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 workgroups.
- Description of 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.
- Description of the process for collecting and distributing products and results from CPCRN members to Prevention Research Centers, and other peers.
- Description of the methods for transitioning current resources (evaluation databases, websites, etc.) to insure smooth transition and maintenance of historical documents.
- Description of plan to monitor and evaluate the network's progress in achieving key milestones and major accomplishments including a description of expectations of workgroups and how the impact will be evaluated.
- Description of communication plans to promote network-wide impact, including but not limited to publication of peer-reviewed articles network newsletters and progress reports.

2. Describe how the CPCRN Coordinating Center will provide leadership strategies to foster

and expand the reach of the network.

- Indicate how this will be assessed and monitored during the project period.
- Discuss how additional partners will be identified and involved in the network, including support to participate in CPCRN activities and how the Coordinating Center will foster this participation of non-funded affiliate members on select workgroups.

3. Describe the activities the Coordinating Center would undertake to ensure collaboration occurs among the CPCRN, federal, state, and local partners in engaging experts and relevant stakeholders to advance the use of evidence-based interventions in national, state, community or local organizations involved in cancer prevention and control.

4. 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 master, scientists and others.

Collaborating Center

1. Describe the activities your institution will undertake and how these activities will contribute to the advancement of the vision, mission, activities, and outcomes of the CPCRN.

- Provide a description of prior research, practice, and evaluation experiences in intervention and implementation science in the community
- Describe experiences related to the detection, prevention and control of cancer, particularly for screen-detectable cancers, within existing health systems (including federally qualified health centers, Centers for Medicare and Medicaid Services, etc.), the community (YMCA, call centers, aging services) and in rural settings.
- Describe how you will study the implementation of cancer control interventions directed at one or more levels of the health care context (community, health care system, health care provider, individual patients), and measure effects of the intervention on their target population. Please include the change process and metrics to measure implementation at any given level.
- Include experiences with other academic-community partners in a multi-site project and how your center distributes resources and support to large-scale network project.

2. Describe established or pending resources in areas relevant to public health, implementation science and cancer within or available to you. Discuss how these resources could be enhanced through the CPCRN to develop implementation science and improve local cancer prevention and control outcomes.

- Describe your particular experience with community-based participatory research, specifically with regard to addressing health disparities through partnerships with community-based organizations.
- Describe your experience with implementation science.
- Provide evidence of 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.

3. Identify key staff who will be devoted to CPCRN efforts.

- 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. 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 leadership and experiences in conducting and being funded for behavioral interventions, environmental, or systems-wide strategies that address cancer control implementation in medically underserved, minority and other populations.

4. Document your experience related to strengthening the capacity of health programs. Discuss the potential for collaborations with public health departments, community-based organizations, and foundations.

5. In addition to the requirements above, the Research Plan should include:

- Study design and methods
    - The applicant should describe their use of scientifically rigorous methods to address their research questions.
- Target population
    - The CPCRN is focused on those who are disproportionately affected by cancer (e.g. medically underserved, racial/ethnic minorities). The applicant should describe the target population and how the population is consistent with CPCRN focus.
- Collaboration/Partnerships
    - The applicant is expected to collaborate/partner with organizations that can help them achieve the goals of the CPCRN. These partners may include existing health systems (e.g. federally qualified health centers), the community (e.g. YMCA, call centers) and non-traditional partners that may allow them to address social determinants of health (e.g. housing, transportation).
- Recruitment Plan
    - The applicant should describe their plans to recruit research participants.
- 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
    - The applicant should describe their planned efforts to monitor and evaluate activities.
- Dissemination Plan
    - The applicant should describe the strategies they will use to disseminate their research findings. This may include presentations, journal publications, and other

modes of communication.

- Translation plan
    - The applicant should describe the strategies to translate the findings of the research.

Note: The award recipient of SIP 19-004 will function as the CPCRN Coordinating Center and will serve as a member of the network, thus a separate application to SIP 19-005 (CPCRN Collaborating Centers) is not required. However, an institution that applies to SIP 19-004 may want to consider applying to SIP 19-005 in the case that they are not selected as the Coordinating Center and would like to be considered as a collaborating center.

Public Health Impact

This project will coordinate the efforts of the Cancer Prevention and Control Research Network, a national network of academic, public health, and community partners that work together, with the ultimate goal to reduce the burden of cancer, especially among those disproportionately affected.

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 the ability to work with other academic-community partners on multi-site projects?
- Does the applicant demonstrate the ability to manage multi-center collaborations?
- Does the applicant demonstrate experience conducting participatory research implementation science, and evaluation of complex interventions or programs?
- Does the applicant demonstrate interest or support from groups that may be involved or impacted by this network?

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 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 $3,375,000 is available to fund one (1) Prevention Research Center(s) for a 5-year project period. The average award for each recipient is expected to be approximately $675,000 for year one. The year one ceiling is $675,000. Funding for this SIP may vary and is subject to change. Funding for this SIP is in part supported by the National Cancer Institute.

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 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 on activities, as requested, such as the development and evaluation of the network and workgroups.

References

1. Cancer Prevention and Control Research Network. cpcrn.org. Accessed September 12, 2018.
2. Cancer Moonshot Blue Ribbon Panel. https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/blue-ribbon-panel. Accessed September 12, 2018.
3. Ribisl KM, Fernandez ME, Friedman DB, Hannon PA, Leeman J, Moore A, Olson L, Ory, Risendal B, Sheble L, Taylor VM, Williams RS, Weiner BJ. 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. doi: 10.1016/j.amepre.2016.08.026
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5. Harris JR, Brown PK, Coughlin S, Fernandez ME, Hebert JR, Kerner J, Prout M,

Schwartz R, Simoes EJ, White C, Wilson K. The Cancer Prevention and Control Research Network. Prev Chronic Dis [serial online] 2005 Jan [date cited]. Available from: URL: http://www.cdc.gov/pcd/issues/2005/jan/04_0059.htm.

SIP 19-005. Cancer Prevention and Control Research Network – Collaborating Center

Background

Over the past two decades, efficacious interventions have been developed to promote recommended cancer screening and tobacco cessation. Currently, major work is underway to address cancer risk factors such as obesity, inadequate physical activity, radiation and other recognized carcinogens. These efforts address factors at the community, workplace, health system, healthcare provider and individual levels. To meet national Healthy People 2020 cancer-specific objectives, evidence-based and other promising interventions can be implemented at different levels of the social ecological framework and coordinated across interventions. A better understanding of the multilevel intervention implementation process is necessary to inform cancer control research and practice. Implementation science can study how multilevel strategies to implement evidence-based cancer control interventions operate to achieve the goals of the National Prevention Strategy. Health interventions based on individual education and counseling are less likely to affect the health of a population, given their reliance on individual-level behavior change, while interventions that change the community context for health or address social determinants of health are more likely to have an impact at the population level. Interventions in cancer prevention and control can achieve greater health impact by expanding beyond educational approaches with individuals to change how care is provided, the quality of the food available, the physical organization of a community, or the organizational infrastructure available for education. 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.

Purpose

CDC will fund collaborating centers of the Cancer Prevention and Control Research Network (CPCRN) to focus on the study of implementation of interventions across the multilevel context of cancer prevention and control. The CPCRN is a national network of academic, public health, and community partners who work together to reduce the burden of cancer, especially among those disproportionately affected. The CPCRN conducts community-based, participatory cancer research across its network centers. The CPCRN was initiated in October 2002, with funding from the Centers for Disease Control and Prevention (CDC) and the National Cancer Institute (NCI), to more effectively translate research into practice. For more information about the mission, vision, and logic model of the CPCRN, visit www.cpcrn.org. The key objectives of the cross-center projects are to extend the knowledge base of processes that facilitate the translation of evidence into practice, develop measures and outcomes for evidence-based cancer prevention and control activities, and establish partnerships with major health care systems and other

sectors. Through multicenter collaboration, CPCRN leverages the expertise, partnerships and resources of participating centers. The broad geographic reach, diverse target populations, and strong relationships among CPCRN investigators allows the network to achieve greater impact than any individual center could achieve on its own.

Project Objectives/Outcomes

The objectives of this project are to speed up the use of evidence-based cancer prevention and control strategies in communities and strengthen multi-center efforts to reach underserved populations to: 1) reduce the incidence of preventable cancers; 2) increase the impact of cancer screening; and 3) improve the health of cancer survivors.

The research to be conducted will expand our understanding of the factors that drive the achievement of these goals and build a workforce capable of disseminating and implementing effective cancer prevention and control strategies. The collaborating centers will strengthen the science underlying the implementation of effective, community-based interventions for cancer prevention and screening into practice.

The focus of the work of the CPCRN is research, training, and technical assistance based on implementation science theories and models and using established organizational infrastructure, strong community relationships, and cross-center projects. The applied research approaches supported by this project will include the study of 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.

Public Health Priorities

Healthy People 2020 Objective

- Objectives C15 through C17 focus on increasing the proportion of the population who receive either cervical, colorectal or breast cancer screening, respectively, based on the most recent guidelines.
- Objective to reduce cancer incidence (C9-C11) and mortality (C1-C8) through community-based, participatory research.

NCCDPHP Domains

- Domain 3: Health system strategies to improve the delivery and use of clinical and other preventive services
- Domain 4: Community programs linked to clinical services

Cancer Moonshot

This project aligns with the recommendations from the Blue Ribbon Panel to expand use of

proven cancer prevention and early detection strategies through implementation science. The network centers conduct research to reduce cancer risk and cancer health disparities through approaches in development, testing and broad adoption of proven prevention strategies.

Project Activities and Submission Requirements

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

1. The applicant is expected to provide a description of proposed activities and how these activities contribute to the advancement of the vision, mission, activities, and outcomes of the CPCRN.

- Provide a description of prior research, practice, and evaluation experiences in intervention and implementation science in the community.
- Describe experiences related to the detection, prevention and control of cancer, particularly for screen-detectable cancers, within existing health systems (e.g. federally qualified health centers, Centers for Medicare and Medicaid Services, etc.), the community (YMCA, call centers, etc.) and rural settings.
- Describe proposed strategies for studying the implementation of cancer control interventions directed at one or more levels of the health care context (community, health care system, health care provider, individual patients), and the measure effects of the intervention on the target population. Include a description of the change process and the metrics to be used to measure implementation at any given level.
- Describe experiences with other academic-community partners in a multi-site project, and how your center distributes resources and support to large-scale network projects.

2. Describe established or pending resources in areas relevant to public health, implementation science and community-based cancer prevention and control within or available to your center. Discuss how dissemination and implementation efforts of these resources could be enhanced through the CPCRN to improve local cancer prevention and control outcomes.

- Describe experiences with community-based participatory research, specifically with regard to addressing health disparities through partnerships with community-based organizations.
- Describe experience with implementation science (knowledge translation).
- Provide evidence of 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.

3. 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 in planning and conducting research that is similar to 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 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.

4. Describe experience related to strengthening the capacity of public health programs. Discuss the potential for collaborations of your center with public health departments, community-based organizations, and foundations.

5. The purpose of the network is to foster multi-center collaborations, by leveraging the expertise, partnerships and resources of participating centers. Therefore, 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 workgroup projects.

6. In addition to the requirements above, the Research Plan should include:

- Study design and methods
    - The applicant should describe their use of scientifically rigorous methods to address their research questions.
- Target population
    - The CPCRN is focused on those who are disproportionately affected by cancer (e.g. medically underserved, racial/ethnic minorities). The applicant should describe the target population and how the population is consistent with the CPCRN focus.
- Collaboration/Partnerships
    - The applicant is expected to collaborate/partner with organizations that can help them achieve the goals of the CPCRN. These partners may include existing health systems (e.g. federally qualified health centers), the community (e.g. YMCA, call centers, aging services) and non-traditional partners that may allow them to address social determinants of health (e.g. housing, transportation).

- Recruitment Plan
    - The applicant should describe their plans to recruit research participants.
- 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
    - The applicant should describe their planned efforts to monitor and evaluate activities.
- Dissemination Plan
    - The applicant should describe the strategies they will use to disseminate their research findings. This may include presentations, journal publications, and other modes of communication.
- Translation plan
    - The applicant should describe the strategies to translate the findings of the research.

Public Health Impact

This project will fund the Cancer Prevention and Control Research Network, a national network of academic, public health, and community partners that work together to conduct community-based participatory research, with the ultimate goal to reduce the burden of cancer, especially among those disproportionately affected.

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 the ability to work with other academic-community partners in a multi-site effort where the partners as a whole have determined operating procedures, leadership structure, and priority projects?
- Does the applicant demonstrate experience in 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 that focus on innovative approaches and multi-level coordination?

Funding Preferences

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

- Geographic distribution of centers.
- Diversity of populations represented in the network (e.g. vulnerability based on race/ethnicity, socioeconomic status, rural/urban residence).

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. 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 $10,500,000 is available to fund five to seven (5-7) Prevention Research Center(s) for a 5-year project period. The average award for each recipient is expected to be approximately 300,000 for year one. The year one ceiling is $300,000.

Funding may vary and is subject to change. Funding for this SIP is in part supported by the National Cancer Institute.

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 the project.

OMB/PRA

OMB/PRA is not expected to apply.

Award Administration

The CDC Scientific Collaborator will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards. NCI also provides funding for this network. Therefore, both CDC and NCI staff will serve as consultants on this project, and will provide technical assistance 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 at the PI's discretion and in compliance with the CDC authorship guidelines, but will not have contact with human subjects or with identifiable data collected about human subjects.

References

1. Cancer Prevention and Control Research Network. cpcrn.org. Accessed September 12, 2018.
2. Cancer Moonshot Blue Ribbon Panel. https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/blue-ribbon-panel. Accessed September 12, 2018.
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SIP 19-006. Evaluating Community Clinical Linkage Interventions in the National Breast and Cervical Cancer Early Detection Program (NBCCEDP)

Background

In 2015, female breast cancer had the highest incidence rate among all cancers and was the second most common cause of cancer deaths among women. [1] Racial disparities persist as Non-Hispanic Whites and Non-Hispanic Blacks have higher incidence and mortality in breast cancer compared other ethnic groups, with Non-Hispanic Black women having disproportionately higher mortality. [2] Similarly, cervical cancer incidence and mortality rates are considerably higher among Hispanic and Non-Hispanic Black women. [3] Women in low socioeconomic groups have higher breast and cervical cancer mortality compared to more affluent groups and deaths from these diseases occur disproportionally among uninsured and underinsured women. [4,5]

For more than 25 years, CDC's National Breast and Cervical Cancer Early Detection Program (NBCCEDP) has provided underserved women access to timely breast and cervical cancer screening and diagnostic services. NBCCEDP supports planning, implementation, and evaluation activities to increase breast and cervical cancer screening rates among all women of appropriate screening age. In 2017, CDC funded a new 5-year cooperative agreement that encourages development of community-clinical linkages (CCLs) to increase cancer screenings among unscreened, hard-to-reach populations. [6] CCLs support the coordination of services among health systems, communities, and public health using community-based and/or clinic-based health workers to increase access to clinical care and promote health behaviors. NBCCEDP awardees may use community-based and/or clinic-based health workers/lay advisors, native language speakers, or health educators to identify women for screening, provide culturally-appropriate interventions including patient education about risk factors and preventive health behaviors, and address barriers to care.

NBCCEDP awardees must implement CCL interventions that identify unscreened, hard-to-reach women in the community, link them to primary care, and ensure screening completion. CCLs represent partnerships or networks of relationships between health care providers, communities, and public health agencies to improve individual and community health. [7] NBCCEDP awardees are expected to implement varied, unique, and novel CCL interventions to increase cancer screening among their priority populations. However, the effectiveness of CCL interventions in increasing cancer screening among underserved populations is largely unknown as is the cost, cost-effectiveness, and scalability of these interventions.

The NBCCEDP aims to increase breast and cervical cancer screening for low-income underserved women. While the NBCCEDP has screened many women since its inception, many more remain unscreened. CCL interventions identify hard-to-reach populations not up-to-date with USPSTF screening recommendations and link them to primary care for preventive services. These interventions concentrate on underserved communities where women lack

access to preventive services.

Purpose

The purpose of this project is to evaluate the effectiveness and cost of two to three CCL interventions implemented by NBCCEDP awardees that are likely to increase cancer screenings within hard-to-reach populations. CDC is interested in learning whether CCL interventions are effective at increasing screening completion among hard-to-reach women and if the interventions are cost-effective. The selected PRC will determine the number of CCL interventions to be evaluated subject to available resources. CDC will support a PRC in identifying potential CCL interventions to be evaluated by providing access to program documents, coordinating communications between the selected PRC and NBCCEDP awardees, and conducting internal analysis of program data to assess strong candidate CCL interventions (i.e., likely to increase screening completions).

Project Objectives/Outcomes

Specific objectives include (1) evaluating the effectiveness of two to three CCL interventions in increasing breast and cervical cancer screening completions among hard-to-reach women, (2) describing the intervention and related factors, such as facilitators and challenges to implementation, (3) assessing the costs of planning and implementing the interventions, (4) determining cost-effectiveness using appropriate models, and (5) assessing potential scalability. Results of the project will inform potential scale-up of effective interventions across NBCCEDP awardees.

Public Health Priorities

Healthy People 2020 Objective

- AHS-7: (Developmental) Increase the proportion of persons who receive appropriate evidence-based clinical preventive services.
- C-15: Increase the proportion of women who receive breast cancer screening based on most recent guidelines.
- C-17: Increase the proportion of women who receive cervical cancer screening based on the most recent guidelines.

NCCDPHP Domains

- Domain 4: Community programs linked to clinical services

Project Activities and Submission Requirements

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

Study design and methods:

- Describe the proposed theoretical framework for the project.
- Define key evaluation questions.
- Describe an approach to identify two to three CCL interventions and assess promise (i.e., likelihood of achieving program outcomes) and evaluability (i.e., can the intervention be evaluated?).
- Describe potential evaluation design(s) that address processes, outcomes, and costs.
- Describe an approach to evaluate cost-effectiveness using potential models based on different perspectives (e.g., societal, public health, health system).
- Describe potential data sources to evaluate the effectiveness and cost of the CCL interventions and an approach for developing data collection tools.
- Describe an approach for assessing scalability of the CCL interventions to be evaluated.
- Describe possible approaches to confirm completed cancer screening via medical record.
- Identify key staff who will be devoted to the project. For each person describe their demonstrated knowledge, experience, and ability in planning and conducting the project activities described above.

Target population:

- Describe the population(s) prioritized for this project concentrating on hard-to-reach women in the community not up-to-date with breast and cervical cancer screening pursuant to United States Preventive Services Task Force (USPSTF) screening recommendations.

Collaboration/Partnerships:

- Describe prior experience collaborating with CDC-funded state, tribal, or territorial awardees.
- Explain prior experience collaborating with community entities (e.g., local health departments, community-based organizations, faith organizations, health clinics) including for prior evaluations.
- Describe a proposed approach for collaborating with NBCCEDP awardees and community entities to evaluate the CCL interventions.

Recruitment Plan:

- Describe plans to recruit evaluation participants, if appropriate.

Annual Action Plan:

- Describe a 12-month action plan using SMART goals and objectives including a progressive timeline to complete activities.
- Describe a proposed approach for periodic project updates and findings to SIP primary points of contact and other pertinent stakeholders.

Evaluation Plan/Performance measurement

- Describe a proposed approach to develop individual evaluation plans for each CCL intervention to be evaluated, consistent with the CDC Evaluation Framework (http://www.cdc.gov/eval/framework/).

Dissemination Plan

- Describe a dissemination plan that includes products and presentations appropriate to unique stakeholder groups including CDC, NBCCEDP awardees, and the public.
- Describe a plan to develop manuscripts for peer review publication.
- Describe a plan to disseminate tools for evaluating CCLs based on the evaluations conducted.

Translation plan

- Describe a plan to identify and describe key components of effective CCL interventions to facilitate translation with appropriate fidelity.
- Describe a plan to explain how key components of effective CCL interventions could be adapted to different settings or contexts, while still maintaining a strong likelihood of achieving outcomes, to facilitate scalability.

Public Health Impact

This project will evaluate the implementation, effectiveness, costs, cost-effectiveness, and potential scalability of CCL interventions. If found effective, these interventions can be scaled to increase screening among underserved women who are traditionally hard-to-reach and not accessing primary care services. Expanding effective and cost-effective CCL interventions nationally will increase the overall reach and impact of the NBCCEDP.

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 to determine the scientific merit and priority score. Specifically, does the proposed research team:

- Does the applicant propose a rigorous study design and identify appropriate potential data sources to accomplish the required objectives?
- Does the applicant demonstrate an understanding of all aspects of the evaluation (i.e., evaluating implementation, costs, effectiveness, scalability)?
- Does the research team includes a health economist with sufficient expertise and experience conducting cost and cost effectiveness evaluations?
- Does the proposed research team demonstrate expertise in cancer prevention and control initiatives, policies, and research?
- Does the proposed research team demonstrate experience designing and conducting rigorous implementation, effectiveness, cost, and cost-effectiveness evaluations?
- Does the proposed research team demonstrate a familiarity or understanding of community level interventions that involve patient navigators and community health workers;
- Does the proposed research team demonstrate the ability to study and manage multi-site interventions;
- Does the proposed research team demonstrate competency to evaluate networks and complex relationships between organizations (e.g., between communities and health systems)?
- Does the applicant identify any anticipated barriers to conducting the study and how these will be addressed?

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 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 (1) Prevention Research Center for a 4-year project period. The average award for the recipient is expected to be approximately $300,000 for year one. The year one ceiling is $300,000. Funding may vary and is subject to change. Funding for this SIP is impart supported by the National Cancer Institute.

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 the project.

OMB/PRA

OMB/PRA is 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 including, 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. U.S. Cancer Statistics Working Group. U.S. Cancer Statistics Data Visualizations Tool, based on November 2017 submission data (1999-2015); www.cdc.gov/cancer/dataviz, June 2018.
2. DeSantis, C. E., Ma, J., Goding Sauer, A., Newman, L. A., & Jemal, A. (2017). Breast cancer statistics, 2017, racial disparity in mortality by state. *CA: a cancer journal for clinicians*, *67*(6), 439-448.
3. Saslow D, Solomon D, Lawson HW, et al. American Cancer Society, American Society for Colposcopy and Cervical Pathology, and American Society for Clinical Pathology screening guidelines for the prevention and early detection of cervical cancer. *CA Cancer J Clin.* 2012;62: 147-172.
4. Singh, G. K., & Jemal, A. (2017). Socioeconomic and racial/ethnic disparities in cancer mortality, incidence, and survival in the United States, 1950–2014: over six decades of changing patterns and widening inequalities. *Journal of environmental and public health*, *2017*.
5. National Breast and Cervical Cancer Early Detection Program (NBCCEDP). (2016, January 04). Retrieved June 2, 2018, from https://www.cdc.gov/cancer/nbccedp/about.htm
6. Cancer Prevention and Control Programs for State, Territorial, and Tribal Organizations. (2016, December 15). Retrieved November 29, 2017, from https://www.grants.gov/web/grants/search-grants.html?keywords=nbccedp
7. AHRQ (2016) Clinical-Community Linkages. Content last reviewed December 2016. Agency for Healthcare Research and Quality (AHRQ), Rockville, MD. http://www.ahrq.gov/professionals/prevention-chronic-care/improve/community/index.html

SIP 19-007. Improving cancer survivor treatment and outcomes by ensuring appropriate emergency/acute care treatment

Background

Unplanned visits to hospital emergency rooms (ER) for acute care are substantially higher among cancer survivors (10-60%) compared to the general population (20%) [1,2]. As many as 50% of cancer survivors currently seek care after hours, outside of their cancer treatment center. Common causes for ER visits among survivors include pain, anemia, fatigue, nausea, fever, neutropenia, shortness of breath, and dehydration [2-3]. Cancer survivors who visit the ER often have long wait times, increased exposure to infectious agents, and get treatment by medical staff who may lack expertise in managing chemotherapy-related side effects. The Centers for Medicare & Medicaid Services (CMS) is currently encouraging efforts that decrease and limit survivor acute care visits through new payment and delivery models designed to reward high-quality cancer care. CMS has also developed a quality improvement measure for survivor acute care visits which will be effective in 2020 for all patients receiving chemotherapy in a hospital outpatient department [1]. Recent studies by Ramsey et al. in Washington confirmed that a high level of survivor acute care visits are preventable, but ways to improve care delivery are not entirely understood [4,5].

Five strategies were recently recommended to reduce unplanned acute care for cancer survivors [6]. 1) identify patients at high risk for unplanned acute care; 2) enhance access and care coordination; 3) standardize clinical pathways for symptom management; 4) develop new loci for urgent cancer care; and 5) use early palliative care.

Purpose

The purpose of this SIP is to evaluate recommended strategies for preventing unplanned acute care visits for cancer survivors and to develop new strategies for cancer survivors who are unable to avoid acute care. This project will provide information helpful to comprehensive cancer control programs actively engaged in survivorship work (i.e., improving care and outcomes), will guide collaborations with medical organizations who serve clinical providers treating cancer survivors, and educate and raise awareness for recommended activities related to reducing and/or informing avoidable and unavoidable acute care. This project will leverage population-level analyses of acute care visits (i.e., number of and reasons for survivor acute care visits) to inform the evaluation and development of identified strategies.

Project Objectives/Outcomes

Recent best practice strategies and the pending CMS quality measures to decrease unplanned ER visits have not been evaluated for their implementation. This will ensure that survivors have the best possible cancer care and outcomes and have increased length and quality of life. Characterize population-level acute care visits among cancer survivors (e.g., leverage

syndromic surveillance data) to determine recommended strategies to reduce unplanned acute care among cancer survivors to be evaluated, and develop implementation practices that reduce unplanned acute care among cancer survivors for: 1) cancer treatment centers and acute care settings and 2) other healthcare settings that may treat cancer survivors (i.e., primary care providers). Recommendations should inform: a) Implementation of strategies to reduce avoidable acute care among cancer patients, b) Scalability of similar strategy implementation in different settings, and c) Treatment and care for unavoidable acute care among cancer patients.

Public Health Priorities

Healthy People 2020 Objective

- C-13 Increase the proportion of cancer survivors who are living 5 years or longer after diagnosis
- C-14 (developmental) Increase the mental and physical health-related quality of life of cancer survivors

NCCDPHP Domains

- Domain 1: Epidemiology and surveillance
- Domain 3: Health care system interventions
- Domain 4: Community programs linked to clinical services

Project Activities and Submission Requirements

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

Study design and methods

The applicant is expected to develop the study protocol. The protocol should address approaches such as a population-based assessment, a quantitative evaluation study, and/or a qualitative evaluation study. The quantitative and/or qualitative evaluation studies outlined should include the examination of recommended activities implemented to reduce acute care received (and associated costs) of cancer survivors within 30 days of a chemotherapy treatment. The applicant is expected to develop all materials necessary to include and outline a robust evaluation of 2 or more (of 5) recommended strategies (see Handley et al, 2018) to reduce unplanned acute care visits and develop new strategies to inform receipt of unavoidable acute care.

Target population

Cancer survivors who seek unplanned care within cancer treatment centers or other healthcare

settings.

Collaboration/Partnerships

Applicants are expected to establish and maintain partnerships necessary to achieve the goals and objectives of this study. These partnerships are expected to include groups such as cancer treatment healthcare professionals, primary care providers, and emergency department care providers who can inform important considerations and challenges related to acute care visits for cancer patients.

Recruitment Plan

The applicant is expected to identify the healthcare system/cancer treatment center that will be used for the study. The centers should have recently implemented or will implement strategies to reduce unplanned acute care visits.

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

Researchers should document completion of all performance milestones through periodic progress reports and communication, to include presentation of the desired outcome associated with each action outlined in the annual action plan. The applicant is expected to develop an evaluation plan outlining how they propose to evaluate strategies to reduce unplanned acute care visits among cancer survivors. The applicant should develop a power analysis calculation to estimate minimum sample size required to achieve statistical significance.

Dissemination Plan

The applicant is expected to develop a dissemination plan that addresses a summary of evaluation framework, processes, measures, and data use to inform cancer treatment centers making or planning for similar implementation of strategies. Summarize translation of barriers, challenges, and successes associated with implementation of strategies to reduce unplanned acute care among cancer survivors to inform researchers and/or cancer treatment centers making or planning for similar implementation of strategies. Develop strategies for unavoidable treatment and care of survivors in acute care settings. Summarize recommendations for unavoidable acute care among survivors and inform ER staff about their condition.

Translation plan

The applicant is expected to develop a translation plan that should summarize findings for a number of intended audiences, including cancer survivors and their providers, particularly ER

staff who treat cancer survivors. The funded PRC should consider relevant challenges, barriers, and recommendations applicable to all of these intended audiences, as well as other types of communication (e.g, webinar, fact sheet, talking points).

Public Health Impact

This project seeks to improve care and outcomes among all US cancer survivors by providing an evaluation of implementation practices for reducing hospital-related infections among survivors, and improving overall care for survivors. This will translate into increasing the length and quality of life among all US men and women with cancer. The results of this project will enable recipients of the National Comprehensive Cancer Control Program actively engaged in survivorship work (i.e., to improve improving care and outcomes) to engage with medical organizations who serve clinical providers treating cancer survivors and educate and raise awareness for recommended activities related to reducing and/or informing avoidable and unavoidable acute care.

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:
    - Identify a healthcare system/treatment center to carry out the study?
    - Provide a letter of support or other documentation that demonstrates adequate commitment of staff or other resources to accomplish the goals of the study?

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 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 (1) Prevention Research Center(s) for a 2-year project period. The average award is expected to be approximately

$250,000 for year one. The year one ceiling is $250,000. Funding may vary and is subject to change.

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 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 activities such as design and nature of research, protocol development, co-authoring manuscripts, and dissemination of results.

References

1. Centers for Medicare & Medicaid Services. *Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy Measure Technical Report.* 2016.
2. Lash RS, Bell JF, Reed SC, et al. A Systematic Review of Emergency Department Use Among Cancer Patients. *Cancer Nurs.* 2017;40(2):135-144.
3. Mayer DK, Travers D, Wyss A, Leak A, Waller A. Why do patients with cancer visit emergency departments? Results of a 2008 population study in North Carolina. *J Clin Oncol.* 2011;29(19):2683-2688.
4. Hutchinson Institute for Cancer Outcomes Research. *Community Cancer Care in Washington State: Quality and Cost Report 2018.* Seattle, WA: Fred Hutchinson Cancer Research Center;2018.
5. Panattoni L, Fedorenko C, Greenwood-Hickman MA, et al. Characterizing Potentially Preventable Cancer- and Chronic Disease-Related Emergency Department Use in the Year After Treatment Initiation: A Regional Study. *J Oncol Pract.* 2018;14(3):e176-e185.
6. Handley NR, Schuchter LM, Bekelman JE. Best Practices for Reducing Unplanned Acute Care for Patients With Cancer. *J Oncol Pract.* 2018;14(5):306-313.

SIP 19-008. Feasibility Testing of a Model Cancer Surveillance Report Using Electronic Health Record Data

Background

The CDC National Comprehensive Cancer Control Program (NCCCP) supports comprehensive cancer control programs in U.S. states, Pacific Island Jurisdictions, territories, and tribes and tribal organizations.[1] The NCCCP provides funding and technical advice to help programs create, carry out, and evaluate comprehensive cancer control plans, which address issues like cancer prevention, detection, treatment, survivorship, and health disparities. Comprehensive cancer control programs: build coalitions of stakeholders who are willing to share resources and expertise to fight cancer; use data from cancer registries, behavioral risk factor surveys, and other sources to learn more about the cancers and risk factors that impact their communities; and develop and implement evidence-based strategic plans to address the cancer burden.

The use of electronic health records is increasing in the United States, and offers the potential to support data-driven decisions to improve cancer prevention and control. Ambulatory care encounters for cancer patients involve multiple types of data, including: patient demographics such as age, gender, smoking history, and place of residence; diagnoses and comorbidities; details on cancer characteristics (e.g., stage, tumor extent, lymph nodes, and metastases); procedures performed; laboratory test values; radiology reports; pathology reports; and the medications and doses prescribed. Currently, each patient data information source often has different computer codes and formats, and the different data may be maintained on unique and separate computer systems in different locations. Public health surveillance based upon electronic health records is a considerable challenge for staff in state cancer prevention and control programs because different coding systems are used for different information sources, and different institutions use different computer systems.

The Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM) has been developed to standardize and support analysis of electronic health records from different data sources, and from different locations with different computer systems.[2,3] The OMOP CDM transforms data from different electronic databases into a common format (data model) with a common representation (terminologies, vocabularies, coding schemes), and enables analyses using a library of standard analytic routines that have been written based on the common format.[3] Additionally, the standardization provided by the OMOP CDM enables the different types of data from different institutions with different computer systems to be networked and rapidly analyzed at the individual patient level. The ability to network and analyze different types of data sets from different locations with different computer systems is a unique advantage of the OMOP CDM. The US Food and Drug Administration (FDA) has supported the development of OMOP CDM electronic health record databases, to facilitate FDA surveillance of adverse drug reactions across a network of US institutions with OMOP CDM databases.

Purpose

The purpose of this project is to demonstrate the feasibility of a model surveillance report on measures of the performance and the quality of cancer prevention and control in ambulatory care, based on OMOP CDM electronic health record data or equivalent, that could be used by state and CDC cancer prevention and control programs to plan and evaluate interventions to

improve cancer prevention and control.

If the applicant proposes an equivalent database to OMOP CDM electronic health record data, the applicant must document why the applicant's proposed database is equivalent or advantageous compared to OMOP CDM.

Project Objectives/Outcomes

The project objectives are to demonstrate the feasibility of a model surveillance report on performance measures and the quality of cancer prevention and control in ambulatory care, using Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM) (or equivalent) electronic health record data.

Public Health Priorities

Healthy People 2020 Objectives

- C-2. Reduce the lung cancer death rate
- C-3. Reduce the female breast cancer death rate
- C-5. Reduce the colorectal cancer death rate
- C-7. Reduce the prostate cancer death rate

NCCDPHP Domains

- Domain 1: Epidemiology and surveillance
- Domain 3: Health system interventions to improve the effective delivery use of clinical and other preventive services;
- Domain 4: Strategies to improve community-clinical linkages.

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:

- Demonstrate access to and necessary intellectual property rights (e.g., license) to one or more OMOP CDM electronic health record databases (or equivalent) for ambulatory care and sufficient ability to analyze its data.
    - Each data base must meet the criteria for finding that the proposed project research activity would be exempt under 45 CFR 46.101(b)(4), where human subjects cannot be identified, directly or through identifiers linked to the subjects. The applicant should describe the name of the original OMOP CDM data base (or equivalent); the administrator or contact person for the original data base; the methods that will be used to prepare the de-identified data file for

project activities; the number of records, years of data, and variables that would be included in the de-identified file for project activities; and the proportion of the study population by race and ethnicity, insurance coverage, and income.
    - Additionally, the applicant should include a statement no one having access to the project data will attempt to learn the identity of any persons in these data and/or their physicians or treating hospitals.
- Include ambulatory care measures that span the cancer control continuum including: prevention, early detection, treatment, survivorship, and health disparities.
- Describe the project team's experience with OMOP CDM electronic health record databases (or equivalent).
- Describe the performance and quality measures that would be included in the model surveillance report, including details on any new surveillance measures that the analysis of OMOP CDM data (or equivalent) would enable. The new measures would add value to existing cancer surveillance information collected by CDC and state cancer prevention and control programs from other data sources.
- Describe how the feasibility of the model surveillance report would be pilot tested and evaluated.

Target population: Describe the characteristics of the patients included in the existing OMOP CDM data bases that will be analyzed in the model surveillance report. For each data base, describe the total number of cases, the years of data, and the characteristics of the study population by race-ethnicity, insurance status, and income level.

Collaboration/Partnerships: Describe any plans for collaboration or partnership in the development and evaluation of the model surveillance report. The collaboration/partnership would be to evaluate whether the proposed measures or report are useful to state cancer prevention and control programs. The most appropriate state partner(s) would depend on the specific measures proposed by the applicant for the surveillance report. Examples of state cancer prevention and control programs include: the state Comprehensive Cancer Control Program; the state central cancer registry; the state Breast and Cervical Cancer Early Detection Program; and the state Colorectal Cancer Screening Program.[4]

Recruitment Plan: The project is limited to analysis of existing computerized data collected for other purposes, and does not involve any recruitment or direct contact with human subjects.

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: Provide an evaluation plan with performance measures for the 12-month project period. Describe how the applicant will partner with CDC project technical advisors on scientific manuscripts.

Dissemination Plan: Provide plans for dissemination activities for the model cancer surveillance report, including posting on the OHDSI GitHub repository.[5]

Translation plan: The applicant is expected to develop a translation plan that includes posting the study protocol and final computer code to the OHDSI GitHub repository for open access by others. Additionally, the applicant is expected to prepare at least one scientific article that describes project activities and conclusions.

Public Health Impact

The project will demonstrate the feasibility of a model cancer surveillance report on performance measures that state and CDC cancer prevention and control programs could use to plan interventions to improve cancer prevention and control.

Eligibility Criteria

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

- In Appendix A, the applicant will document access to a de-identified analytic data file for project activities, that has been derived from an OMOP CDM electronic health record data base (or equivalent) for ambulatory care from one institution.
    - The project data base must meet the criteria for finding that the proposed project research activity would be exempt under 45 CFR 46.101(b)(4), where human subjects cannot be identified, directly or through identifiers linked to the subjects. The applicant should describe the name of the original data base; the administrator or contact person for the original data base; the methods that will be used to prepare the de-identified data file for project activities; the number of records, years of data, and variables that would be included in the de-identified file for project activities; and the proportion of the study population by race and ethnicity, insurance coverage, and income. Evidence of access for the study should be provided in the form of a letter of support, memorandum of agreement, or other documentation. Additionally, the applicant should include a statement that no one having access to the project data will attempt to learn the identity of any persons in these data and/or their physicians or treating hospitals.

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 document at least one of the project team members has prior experience with analysis of OMOP CDM electronic health record databases (or equivalent).
- Does the proposed OMOP CDM electronic health record database include populations that are underinsured, low income, and racially or ethnically diverse.

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 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 $300,000 is available to fund one (1)Prevention Research Center(s) for a one-year project period. The average award for each recipient is expected to be approximately $300,000 for year one. The year one ceiling is $300,000. Funding may vary and is subject to change.

Research Status

It is anticipated that this project will require local Institutional Review Board (IRB) approval, and that the study data set for this project would meet the criteria for exempt research under 45 CFR 46.101(b)(4). 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

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 technical consultants on this project, as requested, and as co-authors of scientific articles for peer reviewed scientific journals.

References

1. Centers for Disease Control and Prevention. National Comprehensive Cancer Control Program. Available at: https://www.cdc.gov/cancer/ncccp/
2. Falconer T, Chen R, Hripcak G. Running an Observational Health Data Sciences and Informatics (OHDSI) Network Study. Available at: http://www.ohdsi.org/web/wiki/lib/exe/fetch.php?media=research:nci-ohdsi_instruction_manual2.pdf
3. Observational Health Data Sciences and Informatics (OHSDI) Observational Medical

Outcomes Partnership (OMOP) Common Data Model. Available at: https://www.ohdsi.org/data-standardization/the-common-data-model/
4. Centers for Disease Control and Prevention. Cancer Prevention and Control. National Programs. Available at: https://www.cdc.gov/cancer/dcpc/about/programs.htm
5. Observational Health Data Sciences and Informatics (ODHSI). GitHub Repository. Available at: https://github.com/OHDSI/StudyProtocols

SIP 19-009. Assessing the Lifetime Economic Burden in Men with Metastatic Prostrate Cancer, including Pain Management

Background

In the United States, prostate cancer is the most commonly diagnosed invasive cancer in males, and the second leading cause of cancer-related deaths among males.[1] Older age (>45), African American race, and family history are the most important risk factors for the development of prostate cancer.[2] In 2014, there were 172,258 new prostate cancer cases.[1] Following the introduction of the prostate-specific antigen test for prostate cancer screening in the United States, the incidence of the disease increased rapidly from 1988 to a peak in 1992, and then began to decline.[3] Although the overall incidence of prostate cancer has decreased about 6.5% per year from 2007, the incidence of distant-stage disease has increased from 2010 to 2014.[3]

In past decades, there has been sustained decline in prostate cancer death rates with 28,343 cases reported in 2014. [1,4,5]. However, in recent studies, researchers have reported that there has been an increase in incidence of late-stage or metastatic prostate cancer (mPC). [3,6,7] Further, studies have also reported that the burden of mPC is increasing, projected to be more than 40% by 2025, and the burden will be greater among men age 45-55 years. [6] However, limited or no information is available on the economic burden of treating mPC by different phases of aging. Patients with mPC often suffer fractures that require pain management and limited or no information is available on the quality of life of these patients.

Improved information on the economics of mPC would be useful in highlighting key cost drivers in mPC by life stages (age group). Further, the outcome could motivate new and effective population-level prevention and early detection interventions, and direct value-driven mPC treatment decision making to reduce the impact of mPC at individual/family, health system, and societal levels. In addition, the findings could enable additional research and investments to improve mPC prevention and treatment. Further, the economic cost estimates could be useful to clinicians who are considering different treatment options for their patients.

Purpose

The purpose of this SIP is to estimate the economic cost and health-related quality of life of mPC over a lifespan for midlife (ages 40–64 yrs), young-old (ages 65–74 yrs), middle-old (ages 75-84 yrs), and the old-old (ages ≥85 yrs) men and by race/ethnicity from the individual/family, health system and socitial perspectives. The economic and human burden of mPC can vary substantially by life stage at diagnosis. Therefore, estimating more specific breakdowns of phases of aging will be helpful in understanding the economic burden of mPC in the elderly. sually, ages 65+ are often lumped together, however, a 65-year-old's experience of life is much

different than an 85-year-old's experience. For instance, old-old men with mPC may have significant comorbidities requiring more intensive personal caregiving. Asset depletion and increased financial burden have very different implications for midlife vs. old-old men with mPC. These issues may in turn impact choices about treatment, monitoring, and palliative care. Currently, we know very little about how interactions between life stage at diagnosis and treatment choice influence economic burden. Therfore, there is a critical need for comprehensive analysis of the clinical (includes pain management) and economic impacts of mPC across life stages and among race/ethnic groups. Our goal is to provide data that can inform clinical and policy choices that minimize the human and economic burden of mPC in the United States. Also to provide data that could help to motivate new and effective interventions to prevent or detect prostate cancer at early stages.

Project Objectives/Outcomes

- The objectives of this project are to:
    - Estimate the lifetime direct treatment costs, indirect productivity costs, health-related quality of life, and years of potential life lost due to mPC for four different life stages (midlife, young-old, middle-old, and old-old men) and by race/ethnicity.
    - Project the estimated economic burden costs to 2030 by life stages and by race/ethnicity.
    - Estimate the cost-effectiveness and budget impact analysis in the use of different therapeutic alternatives in the treatments of mPC patients including pain management by life stages and by race/ethnicity.
- The clinical and economic outcomes from this project are:
    - To provide information on economic cost data that could help decision makers better allocate public health resources (e.g., program support, health promotion, etc.) to mPC patients including pain management.
    - To provide data that can serve as a resource available to patients, clinicians, public health practitioners, and program managers for use in support of decision making to improve the lives of men living with mPC.
    - To better understand the cost drivers of mPC treatment including pain management in order to optimize healthcare expenditure and to help inform appropriate prevention and early detection strategies.
    - To help identify cost-effective treatment pathways and health-related quality of life of men of all ages with mPC.

Public Health Priorities

Healthy People 2020 Objective

This project addresses the Healthy People 2020 national objectives on prostate cancer mortality (C-7) and increasing the proportion of cancer survivors who are living 5 years or longer after diagnosis (C-13).

As the population of men who develop mPC increases, it is important to understand the economic burden of mPC by different life stages and compare with their counterparts without mPC.

NCCDPHP Domains

Domain 1: Epidemiology and Surveillance

Project Activities and Submission Requirements

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

Study design and methods

- The applicant should describe study rationale, design and methods to be used in this project.
- Describe detailed proposed approach(es), which will include modeling strategies in estimating lifetime economic burden of mPC including pain management that will be used to achieve the objectives and outcomes of this project.

Target population

- The applicant is expected to describe and provide evidence of access to existing population-based cancer data with mPC including pain management for the target population of this project (i.e., midlife, young-old, middle-old, and old-old men with information on racial/ethnic groups) and a non-mPC comparison group of similar age-groups.
- The applicant should describe and provide evidence of access to other datasets including economic costs and data on pain management.

Collaboration/Partnerships

- The applicant is expected to describe and provide evidence of sufficient institutional and other necessary support for carrying out this project, including identification of key staff. For each staff, describe and provide evidence of their knowledge, skills, experience, and ability in planning and conducting similar research that is described in this proposal.
- The applicant should describe collaboration(s)/relationship(s) with other colleagues who have knowledge, skills experience, and ability to conduct the research that is described in this proposal with whom the applicant plans to collaborate on this project.

Recruitment Plan

This project will not involve recruitment of new research participants.

Annual Action Plan

The applicant should describe and provide a detailed 12 months action plan with SMART goals and objectives for this project and provide description and timeline for key activities for entire project period if they meet authorship criteria in accordance with CDC's authorship policy.

Evaluation Plan/Performance measurement

The applicant should provide detailed evaluation plan to assess project performance and progress, including a detailed timeline for completing the proposed activities within the 24-month project period. The evaluation plan should also include potential manuscripts to be published from this project. CDC staff may collaborate as co-author on all the potential peer-reviewed manuscripts if they meet authorship criteria in accordance with CDC's authorship policy.

Dissemination Plan

The applicant should describe a detailed dissemination plan to be used in disseminating the outcomes of this project to the potential stakeholders, such as CDC, cancer survivorship organizations on prostate cancer, the US Congress, public health decision-makers, medical organizations (e.g., American Society for Clinical Oncology, Society of Urologic Oncology), and other partners.

Translation plan

The applicant should describe a detailed translation plan to be used in translating this project to the potential stakeholders, such as CDC, cancer survivorship organizations on prostate cancer, the US Congress, public health decision-makers, medical organizations (e.g., American Society for Clinical Oncology, Society of Urologic Oncology), and other partners.

Public Health Impact:

The results of this project will provide information to understand the full economic impact of mPC in different life stages on the society, health care system, patient, and their family. Further, economic data would also provide information to decision makers on costs related to palliative care, psychological support, other forms of symptom management, pain management, and therapeutic interventions to treat mPC. In addition, by using mathematical modeling, results can provide policy-makers with needed evidence about the expected future burden of mPC in the U.S. from 2020 to 2030 by life stage and race/ethnicity. The results of this study will provide public health policymakers with new insights about the future trajectory of mPC resource use and cost, and how this might differ for patients across life stages and in different racial/ethnic

groups. Findings can thereby inform the development of interventions, outreach programs, or other actions targeted to addressing drivers of mPC morbidity, mortality, and cost specific to life stage and race/ethnicity. Further, by using mathematical modeling to evaluate the cost-effectiveness of new treatments for mPC, the value of new treatments by life stage and by race/ethnicity for prostate cancer cancer survivors can be assessed.

Eligibility Criteria

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

- Access to population-based data on mPC necessary to conduct the proposed study demonstrated by a letter of support or memorandum of agreement and should be included in Appendix A of the application.
- A research team including 1) a urologist with experience and expertise in treating advanced prostate cancer; and 2) a health economist and outcomes researcher with expertise in health economic outcomes research and modelling. Evidence of expertise of team members should be shown in the Research & Related Senior/Key Person Section of the SF424 (R&R).

Additional Review Criteria

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

- Does the applicant demonstrate:
  - An approach to conducting the economic study that will sufficiently achieve the NOFO goals and objectives?
  - Evidence that the project team will include staff with experience and expertise in use of outcomes research methods and different modeling techniques in economic evaluation studies?
  - Experience conducting recent or ongoing studies in prostate cancer disease that includes pain management?
  - Experience in conducting research in clinical settings?
  - Strategies for how findings from this study could advance scientific knowledge that would facilitate effective interventions and health care policy related to preventing the progression of mPC including pain management?

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 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 1 (one) Prevention Research Center for a 2-year project period. The average award for the recipient is expected to be approximately $300,000 for year one and $200,000 in year two. The year one ceiling is $300,000. Funding may vary and is subject to change.

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 sit 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.

References

1. U.S. Cancer Statistics Working Group. United States Cancer Statistics: 1999-2014 Incidence and Mortality Web-based Report. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute; 2017. Available at: http://www.cdc.gov/uscs
2. US Preventive Services Task Force. Final recommendation statement. Prostate cancer: screening. 2018. Available at: https://screeningforprostatecancer.org/
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7. Li J, Siegel DA, King JB. Stage-specific incidence rates and trends of prostate cancer by age, race, and ethnicity, United States, 2004-2014. Ann Epidemiol. 2018;28(5):328-330.
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SIP 19-010. Nutrition and Obesity Policy Research and Evaluation Network (NOPREN)

Background

In 2009, in response to the continued problem of poor diet and obesity in the U.S. and the need for solutions [1], CDC's Division of Nutrition, Physical Activity, and Obesity (DNPAO) created the Nutrition and Obesity Policy Research and Evaluation Network (NOPREN), an applied research network [2]. The NOPREN network model:

- Provides a platform for transdisciplinary policy researchers and evaluators guided by practitioner input to collectively inform science and practice.
- Accelerates methods for studying the implementation of a variety of policies that may increase supports for food insecurity, early nutrition including breastfeeding and infant feeding, and increase access to quality, affordable, healthy food options in key settings.
- Leverages cross-sector expertise from federal agencies (i.e. CDC, USDA, NIH), multi-disciplinary academics, state and local health evaluators, non-governmental organizations, healthcare professionals, non-health partners, and public health practitioners to facilitate assessment of policy as a strategy within the socioecological model to improve nutrition for all Americans at a variety of levels and settings.
- 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 and School Health).
- Has established 7 topic-specific, voluntary workgroups with partners that align with current NCCDPHP/CDC priority strategies and have evolved as the priorities of CDC,

the Department, and partners changed.

In previous SIP cycles, the NOPREN operated as a thematic network of the PRC [2-5]. DNPAO funded small individual research projects through 4 funded PRC projects, termed "collaborating centers" and one "coordinating center" who also managed the multisite initiative.

Purpose

The purpose of this SIP is to fund one PRC to both conduct research and act as "network coordinator" PRC to coordinate actions of the NOPREN (i.e. CDC program, network partners, and topical workgroups) to build upon the success of past SIP cycles, and to continuously improve and accelerate nutrition- and obesity-related policy research and evaluation approaches to achieve goals and desired outcomes. The awarded applicant will guide the network through a pragmatic, practitioner-informed learning collaborative model that engages key partners and fosters coordination and collaboration with other PRC funded projects. A key role of the funded PRC will be to maintain and support all NOPREN workgroups. The network coordinating center may provide small stipends to support workgroup administrative and organizational functions; these stipends cannot be used to carryout activities associated with Human Subjects Research.

Project Objectives/Outcomes

- Enhanced understanding of policy implementation and the effects of nutrition policy strategies as practiced in real world settings within the U.S.
- A process and platform for easy access and sharing of scientific information that widely and rapidly promotes NOPREN progress/findings.
- Accelerated identification of best practices for implementing policies (e.g. state legislation, local ordinances, organization rules and regulations) that may increase supports for breastfeeding and nutrition across the lifespan.
- Effective partnership of stakeholders for increased community based health promotion practice and research
- Sustainable collaborations that can advance research along the Knowledge to Action continuum for nutrition and obesity priorities of the CDC Division of Nutrition, Physical Activity and Obesity.

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

Public Health Priorities

Healthy People 2020 Objectives

Topic areas of Nutrition and Weight Status:

- Reductions in sugar and fat consumption: NWS-9, NWS-10.1, NWS-10.2, NWS-10.3
- Reductions in sugar and fat consumption: NWS-17.2, NWS-17.1
- Increases in whole grains: NWS-16

- Increases in fruit and vegetable consumption: NWS-14,NWS-15-1
- Nutrition standards for foods served to preschool-aged children: NWS-1
- Healthy food and beverages availability in schools: NWS-2.1.2
- Food retail outlets providing foods encouraged by Dietary Guidelines for Americans: NWS-3

NCCDPHP Domains

- Domain 2: "Environmental approaches that promote health and support and reinforce healthful behaviors" through building the evidence base for effective nutrition and obesity prevention policies that are scalable and relevant to public health practice.

This aligns with NCCDPHP/DNPAO programs: State Physical Activity and Nutrition program- SPAN; High Obesity Program- HOP; and Racial and Ethnic Approaches for Community Health- REACH.

Project Activities and Submission Requirements

Applications submitted in response to this SIP should present information that demonstrates the applicant's ability to effectively carry out the proposed research project and coordinate activities of the network and detailed methods and procedures to address the following requirements:

1. Conduct a Research Study and Plan for Dissemination

Identify and propose one project for nutrition and obesity policy research and evaluation addressing food insecurity. The project should focus on evaluation of system-level changes that impact nutrition through addressing food insecurity (e.g, screening and referral policies within a healthcare venue, nutrition standards or food service guidelines in food banks and/or food pantry policies.) The study design can draw on lessons from published literature on the topic, including a recent landscape assessment of healthcare entity-based programs that screen individuals for food insecurity and connect with food resources. [6, 7]

The proposed research study should seek to answer questions related to how food insecurity can be addressed through institutional policies or systems-level approaches. Projects should focus on policies within key anchor institutions with the ability to reach a large number of individuals and not on programmatic efforts such as individual cooking skills, nutrition literacy, direct client services or individual food relief packages. Examples of these key anchor institution include health care entities (e.g, hospitals, clinics, healthy systems, community health centers); food banking systems (e.g, food banks, food pantries); community center, or other similar groups involved in the hunger safety net systems. The study population can include any age group, but should prioritize populations at greatest risk of diet-related chronic diseases and other health related disparities.

2. Coordinate NOPREN

- Provide strategic leadership and guidance to NOPREN working groups and the NOPREN leadership group (i.e. CDC scientific collaborators, workgroup liaisons, workgroup co-leads, and Senior Advisors).
- Maintain the existing workgroups as appropriate. Work with CDC to help ensure NOPREN workgroups are (a) multi-disciplined, (b) address a set of activities that are practitioner informed, and (c) ensure products include translation products targeting public health practitioners and/or decision makers. This may include developing partnerships with public health departments (i.e., state, local, tribal, territorial), community based organizations, and/or health system professionals.
- Host a monthly network call on crosscutting workgroup topics, such as: methods for policy research, translational science, implementation science (e.g. acceptability, adoption, fidelity, and sustainability), costs analyses, measuring co-benefits, validity of pragmatic practitioner tools.
- Provide a virtual platform for NOPREN members to host and attend regular workgroup meetings, webinars, and teleconferences.
- Maintain a public facing clearinghouse for member materials (e.g. NOPREN website and workgroup calendar) and document monthly call and workgroup action steps.
- Coordinate strategic partnerships to ensure activities are not redundant and to prioritize the most needed efforts, e.g. facilitate partnerships with research networks such as the Physical Activity Policy Research and Evaluation Network (PAPREN), Robert Wood Johnson Foundation Healthy Eating Research (HER) Program, Council on Black Health, the Association of State Public Health Nutritionists (ASPHN), and National Collaborative on Childhood Obesity Research (NCCOR)
- Engage with other CDC-funded PRCs and thematic networks working on obesity prevention and nutrition-related research and/or health equity focused research and collaborate where applicable.
- Assist DNPAO program grantees in policy analysis, evaluation, and implementation strategies when appropriate
- Host an annual in-person meeting of the NOPREN leadership group to conduct strategic planning and review of network accomplishments Define performance expectations and objectives for NOPREN
- Represent and promote NOPREN's findings and accomplishments through a translation and dissemination plan that includes CDC's PRC Network
- Document plans for network sustainability, network health, impacts, and needed supports including surveying workgroup co-leads and members

Collaboration/Partnerships

- Collaborations with CDC program staff
- Collaborations with PRC core grantees that have projects that include the promotion of nutrition and obesity and other academic institutions funded or not funded by CDC that conduct nutrition and obesity policy research.
- Partnerships with state and local health departments and relevant NGOs.

- Collaborations with topic area workgroups aligned around policy and evaluation needs of DNPAO grantees and DNPAO priorities.
- Collaborations with State and/or local-level CDC funded program grantees for the State Physical Activity and Nutrition program- SPAN, High Obesity Program- HOP, and Racial and Ethnic Approaches for Community Health-REACH.

Annual Action Plan

The applicant should describe and provide a detailed 12 months actions plan with SMART goals and objectives for this project and provide description and timeline for key activities for entire 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. CDC will work collaboratively with awardee to develop an evaluation framework to guide evaluation of NOPREN.

Dissemination Plan

The awarded network coordinator is expected to create a plan for dissemination of key NOPREN outputs, including translation tools and resources, policy briefs, fact sheets, abstracts, presentations, white papers, and peer-reviewed manuscripts.

Translation plan

The awarded network coordinator is expected to provide guidance on methods to translate workgroup tools and findings for scientists, state and local public health practitioners, healthcare professionals, and other stakeholders.

Public Health Impact

This project will build the evidence base for effective policy implementation components to prevent obesity and improve nutrition for all Americans, inform high impact, scalable and cost-effective strategies for preventing obesity and improving nutrition and reducing health and societal costs associated with overweight and obesity. It will also provide a framework and platform to communicate and disseminate research findings related to nutrition and obesity 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.

Eligibility Criteria

The following criteria is necessary to enable the continued basic functioning of the NOPREN (network) that is specific to this SIP and will be used to determine the institution's eligibility:

- Previous or current relationship(s)/collaboration with at least one NOPREN network partner or member (i.e. other PRC, other academic institutions, state/local health departments and/or NGOs) as evidenced by a letter(s) of support from a NOPREN partner or workgroup member that clearly describes a previous/current relationship with NOPREN, including examples of participation and contribution to overall network strategies.

Additional Review Criteria

In addition to the standard review criteria 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.

The extent to which the applicant describes experience with:

- Coordinating and/or managing similar multi-site, collaborative research or evaluation initiatives with a clear description of growth and sustainability.
- Collaborating with non-traditional partners such as agriculture experts, health economists, psychologists, child health specialists, or administrators.
- Working with communities or public health departments on nutrition or obesity policy implementation or evaluation.
- Creating translation and dissemination products targeting public health practitioners, non-governmental organizations, and/or decision makers.
- Conducting nutrition and obesity policy research through peer reviewed publications that clearly depicts sole or join authorship on a paper that demonstrates expertise in nutrition and obesity policy implementation, practice, and evaluation.

The extent to which the applicant describes their ability to:

- Facilitate and coordinate strategic partnerships on behalf of the network.
- Host multi-site calls or events on policy research and evaluation methods.
- Provide a virtual IT platform to host webinars and teleconferences, document calls and multi-site action steps.
- Create and maintain a public facing, online clearinghouse for member materials and products.

The extent to which the applicant describes a plan to:

- Measure network performance, impact, and outputs.
- Represent and promote NOPREN to internal and external partners.

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 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 proposal.

Availability of Funds

It is anticipated that approximately $1,500,000 is available to fund one (1) Prevention Research Center(s) for a five (5)-year budget period. The average award is expected to be approximately $300,000 for year one. The year one ceiling is $300,000. Funding may vary and is subject to change.

Research Status

The applicant awarded under this SIP may conduct human subjects research, and therefore needs to seek appropriate IRB approval. The network coordinator may use funds for network coordination and strategic planning activities as described in this SIP proposal. Activities may include surveys of network members and of audience members of planned network resources. CDC staff will not have contact with human subjects or data collected from human subjects.

OMB/PRA

OMB/PRA is not expected to apply.

Award Administration

CDC project scientists will have substantial programmatic involvement that is beyond the normal stewardship role in awards.

CDC staff may provide consultation, as requested, on the design and administration of the network and provide guidance to individual NOPREN workgroups. CDC staff may be co-authors on manuscripts and/or provide subject matter expertise on specific elements of NOPREN workgroup products.

References

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SIP 19-011. Physical Activity Policy Research and Evaluation Network (PAPREN)

Background

The Division of Nutrition, Physical Activity, and Obesity (DNPAO) created the Physical Activity Policy Research Network (PAPRN), as a venue to exchange programmatic and scientific information as well as plan and implement collaborative research and evaluation activities to increase the quality and quantity of physical activity policy research and provide a framework to translate research into practice and policy. Since its inception, there have been two waves of the policy research network, PAPRN and PAPRN+.

An evaluation of the PAPRN found it to be effective, helping to build the field and increase the quality and quantity of physical activity policy research [1]. In the second wave, PAPRN was rebranded as PAPRN+ and shifted its focus to a more direct connection with public health and other practitioners. The primary focus of PAPRN+ was to conduct research that would serve as the basis for improved strategies for translation, dissemination, and implementation with an emphasis on non-health sectors. This emphasis included enhancing the ability of health departments to collaborate effectively with health and non-health partners [2]. PAPRN+ supported five funded research projects, carried out through a Coordinating Center PRC and four Collaborating Centers and included working directly with State or Local Health Departments or health care facilities. PAPRN+ also supports multi-disciplinary academics, state and local health practitioners, non-governmental organizations and community champions through six topical area working groups that are voluntary, and formed based on DNPAO priorities. Currently, the topical areas are: Complete Streets; Parks and Recreation; Rural Settings; Older Adults; Workplace Health Promotion; and School Wellness [3] .

This SIP will be referred to as PAPREN (Physical Activity Policy Research and Evaluation Network), the change in name emphasizing the importance of policy evaluation and implementation studies. PAPREN will build upon the successes of PAPRN and PAPRN+ and facilitate the conduct, translation, and implementation of applied policy research and evaluation that best address the needs of DNPAO grantees funded under State Physical Activity and Nutrition program SPAN [4] High Obesity Program HOP [5] , and Racial and Ethnic

Approaches for Community Health- REACH [6].

Purpose

The purpose of this SIP is to fund one PRC to serve as a network coordinator to coordinate actions and activities of the PAPREN (i.e. CDC program, network partners and workgroup and conduct physical activity policy research). The awarded applicant will guide the network through a collaborative model that engages key partners and also fosters coordination and collaboration with other PRC funded projects addressing physical activity. A key role of the funded PRC will be to maintain and support the PAPREN topical workgroups. The current number of six PAPREN working groups will not change, however, new working groups may be created if goals of an existing working group are accomplished, or other higher priority topics are identified. Limited funding may be provided for logistical, organizational and administrative support of the working groups. The recipient will not be involved in activities related to changing federal, state or local laws and must adhere to applicable anti-lobbying provisions.

This SIP aims to build the evidence for effective physical activity promotion policies and to ensure there is relevant public health practice. It also aims to cultivate leadership in policy research and evaluation within the national network, the local PAPREN members, and within their partners, including state and local public health practitioners.

Project Objectives/Outcomes

- Enhanced understanding of policy implementation and the effects of physical activity policy strategies as practiced in real world settings within the U.S.
- A process and platform for easy access and sharing of scientific information that widely and rapidly promotes PAPREN progress/findings
- Accelerated identification of best practices for implementing policies that can increase supports for regular physical activity
- Effective partnership of stakeholders for increased community based health promotion practice and research
- Sustainable collaborations that can advance physical activity priorities of the CDC Division of Nutrition, Physical Activity and Obesity.

Public Health Priorities

Healthy People 2020 Objective

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

- PA1 - Reduce the proportion of adults who engage in no leisure time physical activity
- PA2.1 - Increase the proportion of adults who engage in aerobic physical activity of at least moderate intensity for at least 150 minutes/week, or 75 minutes/week of vigorous intensity physical activity, or an equivalent combination.

NCCDPHP Domains

- Domain 2: Policy and environmental interventions.

Project Activities and Submission Requirements

Applications submitted in response to this SIP should present information that demonstrates the applicant's ability to effectively carry out the proposed research project and coordinate activities of the network and a plan that provides detailed methods and procedures to address the following requirements:

1. Conduct a Research Study and Plan for Dissemination

- Identify and propose one project for physical activity policy research addressing the effects of land use policies such as Pedestrian or Cycling Mater Plans, and Zoning Ordinances on physical activity. The proposal should include a description on how they will identify language in these policies that serves to promote physical activity, develop strategies for monitoring the prevalence of such policies and methods for evaluating their effects.
- The plan should also describe strategies for testing dissemination and implementation of the model policies in later years.

2. Coordinate PAPREN activities

- Facilitate and/or manage a productive, multidisciplinary physical activity policy research network.
- Facilitate, organize, maintain, and support voluntary topic specific working groups to develop useful products and tools relevant to the policy and evaluation needs of DNPAO grantees. Number of workgroups will be determined in consultation with CDC scientific collaborators.
- Maintain the existing workgroups as appropriate. Form new working groups as existing workgroups reach goals or additional priority topics identified. Topic areas should be selected based on factors including: DNPAO priorities, Community Guide recommendations, and feedback from DNPAO partners.
- Host an annual workshop where PAPREN members share their products and methods with one another and with public health practitioners
- Host monthly network call on cross-workgroup topics
- Develop a physical activity policy and evaluation agenda (in year one) with DNPAO funded states and other partners
- Assist DNPAO program grantees in policy analysis, evaluation, and implementation strategies
- Establish or maintain a public facing clearing house for PAPREN member materials (i.e. PAPREN website and workgroup calendar)

- Communicate progress and findings of the workgroups through policy briefs, an attractive and accessible web site, publications in peer reviewed journals, presentations, white papers, webinars and direct technical assistance to state and or local health departments to advance and inform public health practice
- Develop translation and dissemination products targeting public health practitioners and/or decision makers.
- Document plans for network sustainability and growth.
- Define strategies to provide technical assistance to states and communities on promoting physical activity through policy and environmental interventions.

Collaboration/Partnerships

- Collaborations with CDC program staff
- Collaborations with PRC core grantees that have projects that include the promotion of physical activity and other academic institutions funded or not funded by CDC that conduct physical activity policy research.
- Partnerships with state and local health departments and relevant NGOs.
- Collaborations with topic area workgroups aligned around policy and evaluation needs of DNPAO grantees, DNPAO priorities, and relevant Community Guide Recommendations
- Collaborations with State and/or local-level CDC funded program grantees for the State Physical Activity and Nutrition program-SPAN, High Obesity Program-HOP, and Racial and Ethnic Approaches for Community Health-REACH.

Annual Action Plan

The action plan integrates and delineates more specifically how the network coordinator PRC plans to carry out achieving the project objectives/outcomes, and accomplishing the following activities:

Evaluation Plan/Performance measurement

Applicants must provide an evaluation and performance measurement plan that demonstrates how the recipient will fulfill the requirements described. CDC will work collaboratively with recipient to develop an evaluation framework to guide evaluation of PAPREN.

Dissemination Plan

The network coordinator PRC is expected to create a plan for dissemination of key outputs including translation and implementation tools and resources, policy briefs and fact sheets, abstracts, presentations, white papers, and manuscripts.

Translation plan

The network coordinator PRC is expected to provide guidance to workgroups on methods to translate and implement workgroup tools and findings for state and local public health practitioners, scientists, decision makers, and other stakeholders.

Public Health Impact

This project will inform high impact, scalable and cost-effective strategies for increasing population levels of physical activity and reducing health and societal costs associated with inadequate levels of physical activity. it will also provide a framework and platform to communicate and disseminate research findings related to physical activity 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.

Eligibility Criteria

The following criteria necessary to enable the continued basic functioning of the PAPREN (network) that is specific to this SIP and will be used to determine the institution's eligibility:

- Previous or current relationship(s)/collaboration with at least one PAPRN or PAPRN+ network partner or member (i.e. other PRC, other academic institutions, state/local health departments and/or NGOs) as evidenced by a letter(s) of support from a PAPRN or PAPRN+ funded partner or workgroup member that describes a previous /current relationship with PAPRN or PAPRN+.

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:

- The extent to which the applicant describes experience in
    - coordinating and managing multi-site, collaborative, policy research and evaluation initiatives.
    - Working with state and local health departments.
    - Working with non-traditional public health partners such as planning departments, departments of transportation, public safety or education.
    - Conducting physical activity policy research as demonstrated in peer reviewed publications.
- The extent to which the applicant demonstrates ability to:
    - Facilitate and coordinate strategic partnerships on behalf of the network.
    - disseminate products that target public health practitioners and/or decision makers.
    - maintain a public facing clearinghouse to house member materials and platform to document monthly calls and workgroup action steps.

- Demonstration of experience and capacity to support physical activity policy research through peer reviewed publications that clearly depicts sole or joint authorship on a paper that addresses physical activity policy or programs.

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 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 is available to fund one (1) Prevention Research Center for the five (5) year project period. The average award is expected to be approximately $300,000 for year one. The year one ceiling is $300,000. Funding may vary and is subject to change.

Research Status

The applicant awarded under this SIP may conduct human subjects research and therefore needs to seek appropriate IRB approval. The network coordinator may use funds for network coordination and strategic planning activities as described in this SIP proposal. Activities may include surveys of network members and of audience members of planned network resources. CDC staff will not have contact with human subjects or data collected from human subjects.

OMB/PRA

OMB/PRA is not expected to apply.

Award Administration

CDC project scientists will have substantial programmatic involvement that is beyond the normal stewardship role in awards. CDC staff may provide consultation, as requested, on the design and administration of the network and provide guidance to individual PAPREN workgroups. CDC staff may be co-authors on manuscripts and/or provide subject matter expertise on specific elements of PAPREN workgroup products.

References

1. Manteiga AM, Eyler AA, Valko CR, Brownson RC, Evenson KR, Schmid, TL. (in press): The impact of the Physical Activity Policy Research Network. Am J Prev Med. (Epub Date 2017/02/22)
2. Pollack KM, Schmid TL, Wilson AL, Schulman E. Advancing Translation and Dissemination Research and Practice Through the Physical Activity Policy Research Network Plus. *Environment and behavior*. 2016;48(1):266-272. doi:10.1177/0013916515616990.
3. PAPRN+ https://www.jhsph.edu/research/centers-and-institutes/center-for-adolescent-health/academic-research/paprn/index.html
4. SPAN , https://www.cdc.gov/nccdphp/dnpao/state-local-programs/fundingopp/2018/span-1807.html
5. HOP, https://www.cdc.gov/nccdphp/dnpao/state-local-programs/fundingopp/2018/hop-1809.html
6. **REACH, https://www.cdc.gov/nccdphp/dnpao/state-local-programs/fundingopp/2018/reach-1813.html**

SIP 19-012. Supporting and Evaluating Initiatives to Prevent Overservice of Alcohol

Background

Excessive alcohol use accounts for over 88,000 deaths in the US each year, and was responsible for an estimated $249 billion ($2.05 per drink) in economic costs in 2010. [1,2] Binge drinking (4 or more drinks on an occasion for women, 5 or more for men) typically results in acute impairment, and is the most common, deadly, and costly pattern of excessive drinking. [1,3] Even so, in 2015, about 37 million U.S. adults reported binge drinking an average of once a week and consumed an average of seven drinks/binge, resulting in a total of 17.5 total billion drinks consumed in that year, or about 470 binge drinks per binge drinker. [4]

Over half of the binge drinking episodes among U.S. adults occur in a bar, club, or restaurant, and persons who binge drink in bars or clubs are known to binge drink at higher intensity (i.e., consume more drinks per binge) than those who binge drink in other settings. [5] Overservice is the provision of alcohol to someone who is already intoxicated. While overservice is illegal in most jurisdictions [1][1], overservice laws are rarely enforced. [6] A 2011 review of Overservice Enforcement by the Community Preventive Services Task Force determined that "further research is needed to evaluate the effectiveness of initiatives to enhance enforcement of overservice laws, to test new methods for conducting enforcement activities, and to assess the cost effectiveness of this intervention for reducing excessive alcohol consumption and related harms." [7]

Consistent with this recommendation, a recent study in one state found that enhanced enforcement of overservice laws reduced by nearly 50% the relative proportion of binge drinkers in licensed establishments who consumed 8 or more drinks during their most recent

binge drinking episode.[8] The challenge of convicting retailers for overservice [6] has also led some communities to deter overservice in other ways. For example, some public safety officials have been assessing the "place of last drink" among persons who have been stopped or are otherwise being investigated for alcohol-impaired driving or other offenses (e.g., domestic violence) that may be alcohol-related, in order identify alcohol retailers that may be violating overservice laws.

[1] As of 2009, overservice of alcohol to intoxicated patrons was not illegal in Nevada or Florida (http://www.nllea.org/documents/SIPLegalResearchReport.pdf).

Purpose

The purpose of this SIP is to evaluate overservice initiatives in states or communities. It is anticipated that this applied public health research project will be done in collaboration with other partners (e.g., public health and public safety agencies), and specifically assess the impact of overservice interventions (e.g., overservice enforcement) on binge drinking and related harms at the state or local levels.

Project Objectives/Outcomes

- Evaluate the effectiveness of population-based strategies for reducing the overservice of alcoholic beverages as a means of reducing binge drinking and related harms.
- Prepare publications, presentations, and other communications materials to support the dissemination of study findings to organizations involved in the prevention of binge drinking and related harms, including state and local public health agencies, public safety, community coalitions, and other organizations.

Public Health Priorities

Healthy People 2020 Objective

- SA-20 Reduce the number of deaths attributable to alcohol
- SA-14 Reduce the proportion of persons engaging in binge drinking of alcoholic beverages
- SA-14.3 Reduce the proportion of persons engaging in binge drinking during the past 30 days—adults aged 18 years and older (Leading Health Indicator)

NCCDPHP Domains

- Domain 2: Environmental Approaches

Project Activities and Submission Requirements

Applications submitted in response to this SIP should present a Research Plan that address the

following requirements:

- Describe the population-based (i.e., state- or community-level) intervention(s) that will be/are being used to reduce the overservice or alcoholic beverages in retail settings.
- Describe the methods that will be used to assess the implementation of the intervention in target areas (e.g., number of citations issued for overservice).
- Describe the data source and the measures that will be used to evaluate the impact of the overservice intervention on binge drinking and related harms (e.g., Behavioral Risk Factor Surveillance System (BRFSS) data on total binge drinks per binge drinker among adults drinking in on-premise retail alcohol outlets).
- Describe the role of partners that will be or are currently involved in the design, implementation, and evaluation of the overservice evaluation (e.g., public health and public safety organizations), and include letters of support from the key partners who will be involved in this project.
- Describe plans to disseminate the findings of this research project through publications, presentations, and active engagement with state and community partners.
- Describe plans to help sustain the overservice intervention(s) after the research project is completed.

Public Health Impact

The proposed research will improve our understanding of the effectiveness of various approaches to preventing overservice (e.g., overservice enforcement), and thus help inform state and local public health efforts to reduce binge drinking and related harms.

Eligibility Criteria

- 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 provide sufficient evidence that the intervention strategy(ies) they will be/are using are likely to have a sustained population-level impact on reducing overservice in retail settings, and consequently on binge drinking and related harms at the state or community level (i.e., does the intervention extend beyond the training of staff in a specific number of retail settings, and address serving practicing at the community level)?
- Are the methods the Applicant is proposing to use sufficient to assess the population-level impact of the intervention strategies they will be using to reduce overservice in

retail settings, as well as the population-level impact this intervention has on binge drinking and related harms in states and communities?
- Does the Applicant have experience partnering with public health, public safety, and other partner organizations that will be involved in this project to scientifically evaluate population-level interventions for reducing leading health risk behaviors, such as excessive alcohol use?
- Does the Applicant identify appropriate partners to achieve the goals/objectives of the study?

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 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 $1,000,000 is available to fund 1-2 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 is $500,000. Funding may vary and is subject to change.

Research Status

It is expected that this project will be non-exempt research. It is not anticipated that human subjects will be involved. 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 on activities such as study design and manuscript review.

References

1. Stahre M, Roeber J, Kanny D, Brewer RD, Zhang X. Contribution of excessive alcohol consumption to deaths and years of potential life lost in the United States. *Prev Chronic Dis* 2014. 11:130293. https://doi.org/10.5888/pcd11.130293.
2. Sacks JJ, Gonzales KR, Bouchery EE, Tomedi LE, Brewer RD. 2010 National and state costs of excessive alcohol consumption. *Am J Prev Med* 2015;49(5):e73–e79. https://doi.org/10.1016/j.amepre.2015.05.031.
3. Esser MB, Hedden SL, Kanny D, Brewer RD, Gfroerer JC, Naimi TS. Prevalence of Alcohol Dependence Among US Adult Drinkers, 2009–2011. *Prev Chronic Dis* 2014;11:140329.
4. Kanny D, Naimi TS, Liu Y, Lu H, Brewer RD. Annual Total Binge Drinks Consumed by U.S. Adults, 2015. *Am J Prev Med* 2018;54:486–496.
5. Naimi TS, Nelson DE, Brewer RD. Driving after binge drinking. *American Journal of Preventive Medicine*. 2009;37(4):314-320.
6. National Highway Traffic Safety Administration. *Legal Research Report: Laws Prohibiting Alcohol Sales to Intoxicated Persons*. Washington, DC: NHTSA, 2009.
7. Rammohan V, Hahn RA, Elder R, Brewer R, Fielding J, Naimi TS, et al. Effects of dram shop liability and enhanced overservice law enforcement initiatives on excessive alcohol consumption and related harms: two Community Guide systematic reviews. *Am J Prev Med* 2011;41(3):334-43.
8. Tomedi LE, Roeber J, Xuan Z, Kanny D, Brewer RD, Naimi TS. Enhanced Enforcement of Laws to reduce alcohol overservice among licensed establishments in New Mexico, 2004-2008. *P Chronic Dis* 2018 (In Press).

DP19-006 Questions and Answers

Question 1. The RFA states that using ASSIST is the preferred application platform. However, the RFA link directs me to Workspace. Can we use Workspace instead, we actually prefer it over ASSIST.

Answer 1. Submitting from Workspace, SYSTEM-To-SYSTEM, or ASSIST are acceptable. However, submitting electronic application via ASSIST is PREFERRED. Applicants are to follow the submission instructions in the NOFO to ensure proper submission. Do not use the multi-component option in ASSIST or workspace.

A separate application is required per SIP applied for.

Question 2. We have a question related to RFA-DP-19-006 (CFDA 93.135), Health Promotion and Disease Prevention Research Centers: 2019 Special Interest Project Competitive Supplements (SIPS).

On page 103, as it relates to SIP 19-010, the RFA states:

It is anticipated that approximately $300,000 is available to fund one (1) PRC for a one (1)-year budget period. The average award is expected to be approximately $300,000 for year one. The

year one ceiling is $300,000. Funding may vary and is subject to change. Approximately $1,500,000 is planned to fund one (1) Prevention Research Center for the five (5) year project period.

Could you please confirm whether one (1) PRC will be awarded for one (1) year? Or, because $1,500,000 is planned, is the one PRC awarded for (5) years? Or, perhaps five (5) PRCs will be funded for one (1) year?

Answer 2. Yes, it is anticipated that one PRC will be funded up to $300,000 per year for a 5-year project period (see SIP 19-010 "availability of funds" section of the NOFO on page 103). The year one ceiling is $300,000. In addition, approximately $1,500,000 is planned as total funding for the one (1) Prevention Research Center during the five (5) year project period.

Question 3. We have a question in regards to the system used to submit applications. The application method at our institution is Cayuse. On page 2 of your application it notes above in the first paragraph that the application must be submitted using the ASSIST Module but below under required application instructions it is only noted as preferred. Can our institution use Cayuse for these applications?

Answer 3 Although the NOFO states "electronic submissions via ASSIST is preferred" (see "application due date" on page 2 of the NOFO), www.grants.gov has three methods for applicants to submit their applications (Workspace, SYSTEM-TO-SYSTEM, and ASSIST). An applicant may use any of the 3 method to submit an application.

Question 4A. The RFA states that the applications must be submitted as a Revision. Per the requirements of revision applications, the PI listed on the application should match the PI on the prime grant. Because we are proposing different PIs for each SIP, how should this be handled? As you may recall, this created huge problems with rejections of applications in the last round of SIP submissions in March 2018 because, in following the directions of the RFA, the applications would not validate through eRA Commons.

Answer 4A. The applications should be submitted as revisions. The PI may be different from the prime grant (DP19-001) as long as the PI is registered in eRA Commons.

Question 4B. Please clarify the proposed project period for SIP 19-010 Nutrition and Obesity Policy Research and Evaluation Network (NOPREN). On pg. 103, it states that "approximately $300,000 is available…for a **one (1)-year** budget period." Then it goes on to state, "Approximately $1,500,000 is planned to fund (1) PRC for the **five (5) year** project period." Is this SIP to be proposed as a one year or a five year project?

Answer 4B. This SIP has a 5-year project period. It is anticipated that one PRC will be funded up to $300,000 per year for a 5-year project period (see "availability of funds" section of the NOFO on page 103). The year one ceiling is $300,000. In addition, approximately $1,500,000 is planned as total funding for the one (1) Prevention Research Center during the five (5) year project period.

This section of the NOFO was updated to clarify the language.

Question 4C. Please confirm that the research strategy is limited to 12 pages for both the Coordinating Center SIPs and the Collaborating Center SIPs. Since the Coordinating Center application includes a description of program activities for both the Coordinating Center and the Collaborating Center, we want to verify that the research strategy is still limited to 12 pages.

Answer 4C. Yes, under Part 1. Overview Information, on page 2 of the NOFO, it states the research strategy is limited to 12 pages. The 12 page limit applies to each individual SIP and each SIP requires a separate application.

Question 5. Do you have any guidance on what to say to a colleague who might want to apply for a sip but who says: 'we need to have a prc on campus...do we?' our prc also includes [name of university]. as co-i's on the project,...are they are eligible (or are only [name of university] people eligible b/c we are the pi institution?...if they are eligible then our announcement before the announcement issue is compounded...so any guidance would be helpful. My other question is: do colleagues from our collaborating university [name of institution] qualify for submitting a sip?

Answer 5: In Section III. "Eligibility Information", under "Special Eligibility Requirements" it states only "applicants currently funded under CDC PRC Program Notice of Funding Opportunity RFA-DP-19-001 are eligible to apply to compete for SIP supplemental funding", thus the potential applicant must be a funded PRC under DP19-001 to apply to DP19-006. Eligible applicants may include collaborators or consultants.

Question 6. [We] have several questions regarding SIP 19-001 involving the KERA tool. We appreciate any feedback you feel you are able to provide relevant to our planned response.

Question 6A. The RFA suggests that activities are not likely to include human subjects research and thus not require IRB approval. However, review criteria suggest that successful projects will train physicians and engage patients in KERA protocols. If KERA protocols are not usual care wouldn't project activities - both with respect to physicians and patients - be considered experimental?

Answer 6A. For this SIP CDC anticipates that Human subjects would not be required. The applicant institution makes the final determination. This is referenced in section IV-Application and Submission Information section, under Research Plan (page 23), the NOFO states:

"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."

Question 6B. If applicants are expected to widely implement the KERA model within a health care system, does a proposal require commitments regarding the number of practices to be included or a recruitment plan for engaging practices in this effort?

Answer 6B.The NOFO does not specify any requirements regarding the number of practices to be included. In section VIII-Other Information, SIP19-001 under enrollment plan, the SIP recruitment plan, further states, “The applicant should describe the manner in which they plan to recruit healthcare providers within their healthcare system to adopt the KAER model within their practice with older adults.”

Question 6C. Can CDC provide any guidance about the level of effort a successful project should devote to tailoring the KERA model to a specific health system vs training and implementation of the model in that system?

Answer 6C. The applicant is expected to describe their approach for accomplishing the purpose, goals and objectives of the SIP. In Section VIII-Other Information, SIP-19-001, the NOFO states the purpose of the SIP is to review and refine the KAER toolkit for application and use within a healthcare system as it was developed for primary care settings.

The NOFO further states, the objective of this SIP is to review the KAER toolkit and if necessary, refine and adapt the materials for use by its primary care providers. Successful applicants will describe how they will integrate the KAER model into their standard protocol for older adult encounters within the healthcare system as well as other materials to encourage people with memory loss to consult with their healthcare provider for an assessment. The applicant will provide evaluation of the KAER model for its ease of use and prepare a report ready for dissemination that details their evaluation findings.

Question 7. We had a question regarding who needs to be PI of the SIP proposal based on some differing recent experiences with this type of application. [Previously], when we applied for SIP funding our local site investigator was PI and [we] submitted the documents to era commons through our [name of institution]. [Recently], when we tried to do the same thing, we got an error message on NIH commons and after a lot of last-minute work finally managed to get the SIP submitted with our PRC director as PI. We got funded but the SIP grant never showed up on my ERA commons account and only the PRC PI could access it.

Now I am planning to submit a PRC SIP in collaboration with the team at the [name of institution]. The local PIs would be myself and [name of PI]. The SIP PI there is [name of PI]. What I am trying to figure out now is if [name of PI] needs to be the proposal PI since she is the SIP Director and we are submitting through [name of institution]. Or can [name of PI] and I be the PIs and submit this ourselves through the [name of institution] grants office.

Answer 7. In Section III. “Eligibility Information”, under “Special Eligibility Requirements” it states only “applicants currently funded under CDC PRC Program Notice of Funding Opportunity RFA-DP-19-001 are eligible to apply to compete for SIP supplemental funding”, thus the potential applicant must be a funded PRC under DP19-001 to apply to DP19-006. Eligible applicants may include collaborators or consultants.

The PI may be different from the prime grant (DP19-001) as long as the PI is registered in eRA Commons, and the application is submitted by an eligible institution (normally identified by a unique DUNS number).

Question 8. We are interested in submitting a proposal in response to SIP 19-008: Feasibility Testing of a Model Cancer Surveillance Report Using Electronic Health Record Data.

The RFA mentioned that each database must meet the criteria that "the proposed project research activity would be exempt under 45 CFR 46.101(b)(4), where human subjects can't be identified, directly or through identifiers linked to the subjects".

However, we are proposing to implement customized CDM model using hospital EHR data, which can be used for a cancer registry report. Towards that goal, we need identifiable information to determine whether the patient is an incidence case (e.g. the cancer diagnosis has to be new for the patient), so we have to use PHI data to look at historical data in the hospital registry to confirm it. Could we get IRB approval to access to the data and keep PHI information in a HIPPA-compliant server? All the machine learning related computation will be conducted on that server too. Once the cancer registry data is populated it is easy to get it de-identified and prepared for data submission or surveillance reporting purpose.

Another advantage of this plan is that it includes the CDM implementation step which is easier to be scaled to another hospital registry for unified surveillance reporting.

We would really appreciate clarification, and to know if our plan is compliant with the RFA requirement.

Answer 8. Yes, although the NOFO states "the proposed project research activity would be exempt…" in SIP19-008 under "Project Activities", "study designs and methods" the NOFO also states that "the methods that will be used to prepare the de-identified data file for project activities; the number of records, years of data, and variables that would be included in the de-identified file for project activities…" and "the applicant should include a statement no one having access to the project data will attempt to learn the identity of any persons in these data and/or their physicians or treating hospitals."

Question 9. One of our PIs would like to apply for the SIP (CDC: RFA-DP-19-006) and we would like to know whether a *clinical trial proposal* is allowed when responding to RFA-DP-19-006.

Answer 9. The applicant determines the approach to achieve the SIP goals and objectives. The NOFO does not restrict clinical trials nor specify, so a clinical trial is permissible. The focus should be on evaluating public health interventions aimed at linking women in communities to clinical services for screening.

Question 10. Where can I obtain the Federal Identifier number for the SIP Application since we do not have the official notice of award yet.

Answer 10. The NOAs will be provided next month in February prior to the application due date. The NOA will contain the Federal Identifier number.

Question 11. We have a few questions about the PRC SIP Applications for RFA-DP-19-006. Is there a timeline for obtaining answers to questions in this NOFO?

Question 11A. NOFO page 15 says to select Revision on the SF 424 Research and Related Face Page Form, Field B. ASSIST then asks us to indicate whether the application is A. Increase Award; B. Decrease Award; C. Increase Duration; or D. Other (please specify). Which of these options should we select? If D. Other, what should we type in?

Answer 11A. The applications should be submitted as revisions. The PI may be different from the prime grant (DP19-001) as long as the PI is registered in eRA Commons.

Question 11B. The NOFO requires a Research Plan which, for most SIPs, includes study design and methods, target population, collaboration/partnerships, recruitment and retention Plan, Annual Action Plan, and Evaluation Plan/Performance measurement, Dissemination Plan, and Translation Plan. However, the NOFO states that the research Strategy Component of the Research Plan narrative is limited to 12 pages and that support materials for the Research Plan narrative can be included as an Appendix not to exceed 10 PDF files. 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. Can any of the following be included in the Appendix: Annual Action Plan, and Evaluation Plan/Performance measurement/Dissemination Plan, and Translation Plan?

Answer 11B. Support materials maybe included in the Appendix.

Question 11C. The current PRC funding cycle utilizes a detailed Action Plan template. Is there a template for the Action Plan for this SIP submission?

Answer 11C. An Action Plan template was not provided as part of this NOFO. However, the template included in the DP19-001, PRC Core NOFO is appropriate for the DP19-006 – the 2019 SIP NOFO.

Question 11D. In some cases, the period of the Action Plan is specified (i.e. 2 years for SIP 19-001 and 12 months for SIPs 19-004 and 19-005, 19-006, and 19-007). However for SIPs 19-002 and 19-003, and 19-011, the NOFO does not specify how many years the Action Plan should include. Should the Action Plans for SIPs 19-002, 19-003, and 19-011 be for a 12 month period, or some other period?

Answer 11D. Please follow the instructions included in Section Project Activities and Submission Requirements for the specific SIP. In the case of SIP 19-001, a 2-year Action Plan is requested.

Question 12. Our team is working on a proposal in response to SIP RFA DP-19-006. Our proposal includes a clinical trial.

We had a question about some of the additional attachments.

Do you know if we need to include the Form E attachments if our proposal includes a clinical trial?

Other attachments “Form E” from NIH instructions

- Timeline & milestones
- Recruitment & retention
- Overall study team organization
- Study dissemination
- Statistical design and plan
- Study synopsis
- Resource sharing plan

We were a little confused because the body of the SIP says our science can’t be more than 12 pages. But some of what we have in that 12 pages would also fit under the above separate attachment categories. How should we handle putting text in the 12-page scientific text vs. in the Form E documents? For example, if we use Form E we can put the milestones, dissemination plan and stats all in a separate document rather than in the 12 pages of science.

Answer 12. The FORMS-E application package for this NOFO is attached on Grants.gov. The clinical trial forms is attached to the PHS Human Subjects and Clinical Trials Information form. If you have additional documents that need to be submitted with application, we recommend uploading them under the RESEARCH & RELATED Other Project Information on Line 12.

We also recommend that you refer to things briefly in the 12 page science section of the form and attach specific documents in the Form E attachments.