


**Centers for Disease Control**

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

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

RFA-DP-17-005

Application Due Date: 02/22/2017

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

RFA-DP-17-005

TABLE OF CONTENTS


Part 1. Overview Information
- Key Dates
- Required Application Instructions
- Executive Summary

Part 2. Full Text
- Section I. Funding Opportunity Description
- Section II. Award Information
- Section III. Eligibility Information
- Section IV. Application and Submission Information
- Section V. Application Review Information
- Section VI. Award Administration Information
- Section VII. Agency Contacts
- Section VIII. Other Information

## 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)

### Funding Opportunity Announcement (FOA) Title

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

### Activity Code

Amendment 1. February 10, 2017

Appendix A: "Questions from Potential Applicants and CDC Responses" added to Section VIII. "Other Information"

Applications in reponse to this FOA will be funded using the U48 activity code.

### Funding Opportunity Announcement Type

New

### Funding Opportunity Announcement Number

RFA-DP-17-005

### Catalog of Federal Domestic Assistance (CFDA) Number(s)

93.135

### Category of Funding Activity:

Health

### FOA Purpose

This RFA will provide supplemental funding to Prevention Research Centers (PRCs) to design, test, and disseminate effective applied public health prevention research strategies to include behavioral interventions, environmental or system-wide solutions, and strategies that address major causes of disease and disability. Research strategies align with public health priorities such as the Healthy People 2020 topic areas: Arthritis; Cancer; HIV/STD and Sexual Health; and School-based Health.

### Key Dates

**Publication Date:** **To receive notification of any changes to RFA-DP-17-005, 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: 01/23/2017**

December 9, 2016 To receive notification of any changes to RFA-DP-17-005, 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.

**Application Due Date:** **02/22/2017**

On-time submission requires that electronic applications be error-free and made available to CDC for processing from eRA Commons on or before the deadline date. Applications must be submitted to and validated successfully by Grants.gov/eRA Commons no later than 5:00 PM U.S. Eastern Time. Note: HHS/CDC grant submission procedures do not provide a period of time beyond the application due date to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e., error correction window).

**Scientific Merit Review:** **04/01/2017**

**Secondary Review:** **05/01/2017**

**Estimated Start Date:** **09/30/2017**

**Expiration Date:** **02/23/2017**

**Due Dates for E.O. 12372: Executive Order 12372 does not apply to this program.**

## Required Application Instructions

It is critical that applicants follow the instructions in the SF 424 (R&R) Application Guide except where instructed to do otherwise in this FOA. Conformance to all requirements (both in the Application Guide and the FOA) 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

## Executive Summary

- **Purpose.** This RFA will provide supplemental funding to Prevention Research Centers (PRCs) to design, test, and disseminate effective applied public health prevention research strategies to include behavioral interventions, environmental or system-wide solutions, and strategies that address major causes of disease and disability.
- **Mechanism of Support.** Cooperative Agreement
- **Funds Available and Anticipated Number of Awards.** The CDC intends to commit a total of approximately $3,914,800 (direct and indirect) for the entire project period. It is anticipated that up to 6 awards will be made. Awards issued under this FOA are contigent upon aibility 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 budget period, 09/30/2017 – 09/29/2018, is $2,064,800. The estimated total funding (direct and indirect) for the entire project period, 09/30/2017 – 09/29/2019, is $3,914,800.
- **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 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, but 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.
- **Number of Applications.** A PRC may apply for multiple SIPs; however, a separate application must be submitted for each SIP. A PRC may submit only one application per SIP.
- **Application Type.** New
- **Special Date(s).** A summary of the questions and answers received from applicants will be published as an FOA amendment prior to the application receipt date. Questions and answers will be shared via e-mail with the PRC PI and any additional e-mail contacts.
- **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/funding/424/index.htm #inst

  **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY: (770) 488-2783.

## Part 2. Full Text

## Section I. Funding Opportunity Description

### Statutory Authority

Awards for this FOA 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 .

### 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. [7] 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. [8] 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 SIP mechanism, created in 1993, allows the PRCs to compete for research projects sponsored by CDC organizational units and other HHS agencies. A SIP is a health promotion and disease prevention research project that focuses on a topic of interest or a gap in knowledge or research. It can also support the development of effective state and local public health strategies.

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**

The US Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC), National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) seeks competitive supplement cooperative agreement applications for the Health Promotion and Disease Prevention Research Centers Program. This FOA aligns with the following public health priorities:

1. Healthy People 2020 Objectives
2. The National Prevention Strategy
3. CDC's Winnable Battles
4. NCCDPHP's Domains of Chronic Disease Prevention

This FOA 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 FOA includes the Healthy People 2020 topic areas of Arthritis; Cancer; HIV/STD and Sexual Health; and School-based Health. The following are the current SIPs and associated topic areas:

Arthritis: SIP 17-001;

School-based Health: SIP 17-002;

Cancer: SIP 17-003, and SIP 17-004;

HIV and Sexual Health: SIP 17-005 and SIP 17-006.

**Public Health Impact**

**Public Health Impact of this Opportunity**

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

**SIP 17-001 Community-based Short and Longer Term Evaluation of the Chronic Pain Self-Management Program (CPSMP)**

US adults living with chronic pain have a limited choice of affordable, evidence-based, pain self-management programs in their community. Study results will be used to assess whether CPSMP is a promising practice for chronic pain self-management and whether there is sufficient evidence for development of public health infrastructure to support wide-scale dissemination of CPSMP.

**SIP 17--002 Evaluation of the Effectiveness of School-based Health Services Interventions on Student Outcomes**

This proposed evaluation will help identify the barriers, facilitators to implementation of school health services policies, protocols, and practices; identify staffing and training needs of school health services' staff within a large school district; and identify strategies that can be used to create and foster external partnerships as well as referral networks for students. The intended long term impact of this evaluation can contribute to understanding best practices in improving health status, providing clinical linkages to care and improving academic performance for students with chronic health conditions through school-based health services.

**SIP 17-003 Formative Study of Patient Navigators with the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) and the Colorectal Cancer Control Program (CRCCP)**

Patient navigation has been shown to increase cancer screening completion, including for breast, cervical, and colorectal (CRC) cancers. Patient navigation can help to increase cancer screening among disparate populations so that breast, cervical, and CRC will be either avoided completely or detected early, leading to better health outcomes. This project will provide critical information about the current delivery of this evidence-based intervention in CDC's NBCCEDP and CRCCP programs.

**SIP 17-004 Assessing the Lifetime Economic Burden in Younger, Midlife, and Older Women with Metastatic Breast Cancer**

Economic costs identified from this project will address the knowledge base for breast cancer in women in different life stages; inform public health decisions on strategies to reduce the impact of mBC on patient's well-being; inform health care system and society about how economic factors influence the welfare of mBC patients; and provide data to inform development of effective interventions. In addition, the outcomes from this project could be used to generate new economic knowledge that will promote the optimal design of cancer control strategies to improve the quality of a woman's life if her breast cancer progresses to a metastatic stage.

**SIP 17-005 Understanding Provision of Confidential Sexual Health Services to Adolescents**

Understanding provider, parent, and adolescent perspectives on provision of confidential SHS will yield a comprehensive assessment that can inform intervention to enhance confidentiality and adolescents' receipt of SHS. Increasing receipt of preventive services, including behavioral counseling, can reduce risk behavior and improve sexual and reproductive health outcomes.

**SIP 17-006 Communicating With Youth to Prevent HIV, Other STIs, and Pregnancy: Identifying Key Messages, Messengers, and Communication Channels**

Understanding the communication messages, messengers, and channels that can be used to encourage key protective behaviors for reducing pregnancy and the transmission of HIV and other STIs among youth will allow public health professionals to better provide critical information to youth in order to improve sexual and reproductive health outcomes.

**References:**

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

**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.

**Objectives/Outcomes**

**Target Population**

**Collaboration/Partnerships**

**Evaluation/Performance Measurement**

**Translation Plan**

## 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:** $3,914,800

The estimated total funding (direct and indirect) for the first budget period, 09/30/2017 – 09/29/2018, is $2,064,800. The estimated total funding (direct and indirect) for the entire project period, 09/30/2017 – 09/29/2019, is $3,914,800.

**Anticipated Number of Awards:** 6

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

**Award Ceiling:** $600,000 Per Project Period

**Award Floor:** $0 Per Project Period

**Total Project Period Length:** 2 year(s)

Throughout the project period, 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 FOA.

## Section III. Eligibility Information

### 1. Eligible Applicants

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

Additional Eligibility Category:

### 2. Foreign Organizations

Foreign Organizations are not eligible to apply.

Foreign components of U.S. Organizations are 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

Others (see text field entitle "Special Eligibility Requiements" for clarification.

Competition is limited to Prevention Research Centers (PRCs) institutions funded under DP-14-001.

Special eligibility requirement(s) may apply to each SIP (see Section IX Special Interests Project Description).

### 4. Justification for Less than Maximum Competition

Competition is limited to Prevention Research Centers under CDC Program Announcement DP14-001 because they are uniquely positioned to perform, oversee, and coordinate applied public health research that promotes the field of health promotion and chronic disease prevention research due to their established relationships with multidisciplinary faculty and 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 budget for the application's Year 1 costs does not exceed the Year 1 ceiling amount for the specific SIP (see Section II. Award Information).

Unresponsive applications will not be entered into the review process. Applicants will be notified that their application did not meet the submission requirements.

### 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/#1.
- 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 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 registration process at least four (4) weeks prior to the application due date.

## 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 grantee 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 grantee 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,(http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf), 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 FOA that is essentially the same as one currently pending initial peer review unless the applicant withdraws the pending application.

Only applicants affiliated with institutions funded as PRCs under CDC Program Announcement Funding Opportunity Announcement (FOA) DP14-001 are eligible to compete for Special Interest Project (SIP) supplemental funding. A Prevention Research Center may apply for multiple SIPs; however, a separate application must be submitted for each SIP. A PRC may submit only one application per SIP.

Although the financial plans of the CDC provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications. Continuation of awards will be conditioned on 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.

All page limitions described in this indivicual FOA must be followed. For this specific FOA, the Research Strategy component of the Research Plan narriative is limited to 12 pages. Supporting materials for the Research Plan narrative included as appendices may not eendices.xceed 10 PDF files with a maxium of 30 pages for all appendices. Any pages in excess of these limits will be discarded and will not be considered in the review process. Other criteria may also be provided for each SIP in Section IX Special Interest Project Descriptions.

If your application is incomplete or non-responsice to the special requirements listed in this section, it will not enter into the review process. An applicant will be notified of this determination.

## Section IV. Application and Submission Information

### 1. Address to Request Application Package

Applicants must download the SF424 (R&R) application package associated with this funding opportunity from www.Grants.gov.
If access to the Internet is not available or if the applicant encounters difficulty accessing the forms on-line, contact the HHS/CDC Office of Grants Services (OGS) Technical Information Management Section (TIMS) staff at (770) 488-2700 or ogstims@cdc.gov for further instructions. Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Time. CDC Telecommunications for the hearing impaired or disabled is available at: TTY 1-888-232-6348.

### 2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide http://grants.nih.gov/grants/how-to-apply-application-guide.htm and here: http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general-forms-d.pdf, except where instructed in this Funding Opportunity Announcement 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 forms package associated with this FOA includes all applicable components, mandatory and optional. Please note that some components marked optional in the application package are required for submission of applications for this FOA. Follow the instructions in the SF 424 (R&R) Application Guide to ensure you complete all appropriate "optional" components.
In conjunction with the SF424 (R&R) components, CDC grants applicants should also complete and submit additional components titled "PHS398." Note the PHS398 should include assurances and certifications, additional data required by the agency for a complete application. While these are not identical to the PHS398 application form pages, the PHS398 reference is used to distinguish these additional data requirements from the data collected in the SF424 (R&R) components. A complete application to CDC will include SF424 (R&R) and PHS398 components. These forms can be downloaded from http://grants.nih.gov/grants/forms.htm

**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.

**SF424 Research and 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 11-040) 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.
- Field # 11 (Descriptive Title of Applicant's Project): Applicants must enter the exact project title as used in their original PRC application (including spacing and punctuation). The original PRC title can be found on the Notice of Award.

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.

## 3. Letter of Intent

Due Date for Letter of Intent: **01/23/2017**

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

Descriptive title of proposed research

Name, address, and telephone number of the PD(s)/PI(s)

Names of other key personnel

Participating institutions

SIP number and title of SIP proposal

The letter of intent should be sent to:

**Scientific/Research Contact(s)**

Michael A. Brown, M.P.H.

Scientific Program Official

Extramural Research Program Operations and Services

Centers for Disease Control and Prevention

4770 Buford Hwy, NE

Mailstop F-80

Atlanta, GA 30342

Telephone: (770) 488-5118

E-mail: mab5@cdc.gov

## 4. Required and Optional Components

A complete application has many components, both required and optional. The forms package associated with this FOA in Grants.gov includes all applicable components for this FOA, required and optional.

## 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 16 components. Not all 16 components of the Research Plan apply to all Funding Opportunity Announcements (FOAs). Specifically, some of the following 16 components are for Resubmissions or Revisions only. See the SF 424 (R&R) Application Guide http://grants.nih.gov/grants/how-to-apply-application-guide.htm and here: http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general-forms-d.pdf for additional information. Please attach applicable sections of the following Research Plan components as directed in Part 2, Section 1 (Funding Opportunity Announcement Description).

Follow the page limits stated in the SF 424 (R&R) unless otherwise specified in the FOA. As applicable to and specified in the FOA, 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 FOA.

**2. Specific Aims** – state the problem the proposed research addresses and how it will result in public health impact and improvements in population health.

**3. Research Strategy** – the research strategy should be organized under 3 headings: Significance, Innovation and Approach. Describe the proposed research plan, including staffing and timeline.

**4. Inclusion Enrollment Report** (Renewal and Revision applications ONLY)

**5. Progress Report Publication List** (for Continuation ONLY)

Human Subjects Section

**6. Protection of Human Subjects**

**7. Inclusion of Women and Minorities**

**8. Targeted/Planned Enrollment Table** (for New Application ONLY)

**9. Inclusion of Children**

Other Research Plan Sections

**10. Vertebrate Animals**

**11. Select Agent Research**

**12. Multiple PD/PI Leadership Plan.**

**13. Consortium/Contractual Arrangements**

**14. Letters of Support**

**15. Resource Sharing Plan(s)**

**16. Appendix**

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

## 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 FOA must be followed. For this specific FOA, 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** http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general-forms-d.pdf.

## 9. Submission Dates & Times

Part I. Overview Information contains information about Key Dates. Applicants are encouraged to submit in advance of the deadline to ensure they have time to make any application corrections that might be necessary for successful submission.
Organizations must submit applications via Grants.gov (http://www.grants.gov), the online portal to find and apply for grants across all Federal agencies. The eRA Commons systems retrieve the application from Grants.gov and check the application against CDC business rules. If no errors are found, the application will be assembled in the eRA Commons for viewing by the applicant before moving on for further CDC processing.
If errors are found, the applicant will be notified in the eRA Commons. They must make required changes to the local copy of their application and submit again through Grants.gov.
**Applicants are responsible for viewing their application in the eRA Commons to ensure accurate and successful submission.**

Once you can see your application in the Commons, be sure to review it carefully as this is what the reviewer will see. Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (http:// grants.nih. gov/grants /guide/url_redirect .htm? id=11123).
Information on the submission process is provided in the SF424 (R&R) Application Guide.
**Note:** HHS/CDC grant submission procedures do not provide a period of time beyond the grant application due date 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).
The application package is not complete until it has passed the Grants.gov/eRA Commons validation process. This process and email notifications of receipt, validation or rejection may take two (2) business days.
Applicants are strongly encouraged to allocate additional time prior to the submission deadline to submit their applications and to correct errors identified in the validation process. Applicants are encouraged also to check the status of their application submission to determine if the application packages are complete and error-free. Applicants who encounter system errors when submitting their applications must attempt to resolve them by contacting the Grants.gov Contact Center ( 1-800-518-4726; support@grants.gov). If the system errors cannot be resolved, applicants must contact TIMS at 770-488-2700; ogstims@cdc.gov for guidance at least 3 calendar days before the deadline date.
**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. This validation process may take as long as two (2) business days. A third and final e-mail message is generated once the applicant's application package has passed validation and the grantor has confirmed receipt of the application.**

**Unsuccessful Submissions:** If an application submission was unsuccessful, ***the applicant*** must:
1. Track his/her 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 his/her emails from both Grants.gov and eRA Commons for rejection notices.
    a. If the deadline has passed, he/she should email the Grant Management Specialist listed in the FOA (pgotim@cdc.gov) explaining why the submission failed. b. If there is time before the deadline, he/she should correct the problem(s) and resubmit as soon as possible.

Due Date for Applications: **02/22/2017**

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.
For more information on expanded authority and pre-award costs, go to:
http://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).
Awardees 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: http://www.cdc.gov/grants/additionalrequirements/index.html for revised AR-25.

**General FY 15 Appropriations Act Provisions**

HHS recipients must comply with all terms and conditions outlined in their grant award, including grant policy terms and conditions contained in applicable Department of Health and Human Services (HHS) Grant Policy Statements, requirements imposed by program statutes and regulations, and HHS grant administration regulations, as applicable; as well as any requirements or limitations in any applicable appropriations acts.

## 12. Other Submission Requirements and Information

**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/ Electronic Receipt /avoiding_ errors.htm or http:// grants. nih.gov/grants/ Electronic Receipt/submit_ app.htm
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 and/or globally?
- Will the work be influential in that it will lead others to investigate the problem, open new areas of research, or change the scientific approach or public health practice, and 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 large 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 FOA requires an evaluation plan, are outputs identified and are measures/metric to assess outcomes included?
- If the FOA requires a translation plan, does the application describe how the results from the research will be disseminated and ultimately used?

### 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 utilize 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 (http://www.cdc.gov/grants/additionalrequirements/index.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 (http:// www.cdc.gov /maso Policy /Policy_women.pdf and http:// www.gpo.gov /fdsys /pkg /FR-1995-09-15 /pdf/95-22950.pdf #page=1) and the policy on the Inclusion of Persons Under 21 in Research (http:// 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 (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11150).

**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.

**Individual SIP Project'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 FOA. Does the applicant adequately address the additional review criteria detailed in the Special Interest Project they are applying for?

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: http://www.cdc.gov/grants/additionalrequirements/index.html

New additional requirement: CDC requires awardees 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 funding opportunity announcement 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

## 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 FOA. 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.

As part of the scientific peer review, all applications:

- Will receive a second level of review (Secondary Review) by HHS/CDC/NCCDPHP/ERPOS

Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review. The following will be considered in making funding decisions:

- Additional criteria and funding preferences for each SIP as detailed in the individual project descriptions contained in Section IX Special Interest Project Descriptions of this announcement.

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.

**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 Awardee 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 funding opportunity announcement.

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 FOA 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 (http://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.

Awardees 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**
All HHS/CDC grant and cooperative agreement awards include the HHS Grants Policy Statement as part of the NoA. For these terms of award, see the HHS Grants Policy Statement Part II: Terms and Conditions of Award (http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).
Awardees must comply with the administrative requirements (AR) outlined in 45 Code of Federal Regulations (CFR) Part 75, as appropriate, as well as any additional requirements included in the FOA. Specific requirements that apply to this FOA are the following:

Specific requirements that apply to this FOA are the following:

**Generally applicable ARs:**

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-21: Small, Minority, And Women-owned Business

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

**ARs applicable to HIV/AIDS Awards:**

AR-4: HIV/AIDS Confidentiality Provisions

AR-5: HIV Program Review Panel Requirements

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

AR-25: Data Management and Access

CDC requires awardees for projects that involve the collection or generation of data with federal funds to develop, submit and comply with a Data Management Plan (DMP) for each collection or generation of public health data undertaken as part of the award and, to the extent appropriate, provide access to and archiving/long-term preservation of collected or generated data.

Data Management Plan

Consistent with the terms of and activities expected under the funding opportunity announcement (FOA),

awardees must develop and submit a DMP generally during the project planning phase, but in any event, prior to the initiation of generating or collecting public health data. Accordingly, the DMP may be evaluated during the application, study proposal, or project review process or during other times in the project period. For FOAs that involve already defined projects which include data collection or generation at the time of application, applications submitted without the required DMP may be deemed non-responsive for award. For FOAs where CDC specifies that submission of the DMP is deferred to a later period, funding restrictions may be imposed pending submission and evaluation of the DMP. For awards where data collection or generation activities may become necessary during the project period, DMPs will be required to be submitted and evaluated during the project period of the award. These DMPs also will be required to comply with this AR. In all instances described above, the reviewing officials have to approve an acceptable DMP. Costs associated with developing and implementing a DMP, including costs of sharing, archiving and long-term preservation, may be included in the budget submissions for grants and cooperative agreements.

A DMP for each collection and/or generation of public health data funded by this award should include the following information:

- A description of the data to be collected or generated in the proposed project;
- Standards to be used for the collected or generated data;
- Mechanisms for or limitations to providing access to and sharing of the data (include a description of provisions for the protection of privacy, confidentiality,

  security, intellectual property, or other rights). This section should address access to identifiable and de-identified data (see below for additional information

  about access);
- Statement of the use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data

  represent, and potential limitations for use; and
- Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified. This section should address

  archiving and preservation of identifiable and de-identified data (see below for additional information regarding archiving).

Access to and Archiving of the Data

Awardees whose terms of award do not include submitting data to CDC are expected to plan and prepare for access to and archiving/long-term preservation of collected and/or generated data within the funding period, as set forth below. The final version of a collected and/or generated data set intended for release or sharing should be made available within thirty (30) months after the end of the data collection or generation, except surveillance data which should be made accessible within a year of the end of a collection cycle. In addition, awardees should ensure the quality of data they make accessible and seek to provide the data in a nonproprietary format. Awardees who fail to release public health data in a timely fashion may be subject to procedures normally used to address lack of compliance consistent with applicable authorities, regulations, policies or terms of their award.

For public use de-identified (removal of sensitive identifiable or potentially identifiable information) datasets, an accompanying data dictionary, and other documentation relevant to use of the data set should be deposited in a sustainable repository to provide access to the data. Data that cannot be de-identified can be

provided on request under a data-use agreement.

Awardees will be required to inform the appropriate CDC point-of-contact identified in the award via an update to their DMP of the location of the deposited data. The DMP is a living document that should be updated throughout the life cycle of data.

For data underlying scientific publication, awardee should make the data available coincident with publication of the paper, unless the data set is already available via a release or sharing mechanism. At a minimum, release of the data set should consist of a machine-readable version of the data tables shown in the paper.

Requirements set forth in this policy are not intended to conflict with or supersede applicable grants regulations related to agency access to awardee data and records.

For more information on the Code of Federal Regulations, visit the National Archives and Records Administration at: http://www.archives.gov/.

To view brief descriptions of relevant CDC requirements visit: http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm

Either refer to the current Releasing and Sharing Data Policy AR-25 here (http://www.cdc.gov/grants/additionalrequirements/index.html#ar25) and/or replace it on the PGO website with the Data Access and Management policy and add the link above as an AR.

## 3. Additional Policy Requirements

The following are additional policy requirements relevant to this FOA:

**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:http://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 http://www.cdc.gov/grants/additionalrequirements/index.html outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.

## 4. Cooperative Agreement Terms and Conditions

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR, and other HHS, PHS, and CDC grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial CDC programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the HHS/CDC purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; CDC Project Scientist and Project Officer are not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and HHS/CDC as defined below.

**Recipient Rights and Responsibilities**

**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 announcement.
- Recipient Organization will obtain appropriate Institutional Review Board approvals for research involving human subjects for all participating sites.
- Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and CDC policies.
- Coordination of all prior approval requests and submission of report requirements with the PRC PI.

**HHS/CDC Responsibilities**

An HHS/CDC Project Scientist will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described in each of the special interest project descriptions contained in Section IX of this announcement. Each SIP has specific requirements and applicants should refer to Section IX Special Interest Project Descriptions of this announcement for details.

Additionally, ERPOS will provide overall oversight to the research portfolio for NCCDPHP. The Prevention Research Centers Program will provide day to day administrative and technical assistance to the PRCs, CDC

SIP sponsors, and SIP awardees.

The ERPOS Scientific Program Official (SPO) will:

- Be named in the Notice of Grant Award as the Scientific Program Official;
- Provide oversight and assure overall scientific and programmatic stewardship of the award;
- Monitor performance against approved project objectives; and
- Assure assessment of the public health impact of the research conducted under this funding opportunity announcement and promote translation of promising practices, programs, interventions, and other results from the research.

The PRC Program Project Officer will:

- Be named in the Notice of Grant Award as the Project Officer;
- Monitor performance against approved project objectives;
- Provide administrative and technical assistance to the CDC SIP sponsors and awardees.
- Assess the public health impact of the research and assure translation of promising practices, programs, interventions, and other results from the research; and
- Make recommendations on requests for changes in scope, objectives, and/or budgets that deviate from the approved peer-reviewed application.
- Promote translation of promising practices, programs, interventions, and other results from the research.

The CDC SIP sponsor will:

- Be identified as the CDC Project Scientist/Scientific Collaborator or Subject Matter Expert;
- Monitor performance against approved project objectives;
- Provide technical assistance and consultation at awardee's request on research design and methodology, program implementation, measurement selection, and dissemination of study findings.
- Promote translation of promising practices, programs, interventions, and other results from the research.

## 5. Reporting

Awardees will be required to submit the Non-Competing Continuation Grant Progress Report (PHS 2590) annually 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 awardees 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 awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees 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 (http://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**, (use form PHS 2590, posted on the HHS/CDC website, www.grants.gov and at http:// grants.nih.gov/grants/ funding/2590/ 2590.htm, **is due 90 to 120 days prior to the end of the current budget period.** 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 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 project period.**

**B. Content of Reports**

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

- Description of Progress during Annual Budget Period: Current Budget Period Progress reported on the PHS 2590 (http:// grants1.nih.gov/ grants/funding/ 2590/2590.htm) http:// grants.nih.gov/grants/ funding/2590/2590.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:

- Human Subjects Education Requirement: Provide certification, for any new key personnel or other significant contributors involved in the design or conduct of research involving human subjects, that they have completed an educational program in the protection of human subjects.

**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. **All CDC Financial Expenditure data due on/after October 1, 2012 must be submitted using the FFR via the eFSR/FFR system in the eRA Commons.** All Federal Reporting in the Payment Management System is unchanged. All new submissions should be prepared and submitted as FFRs.
CDC's implementation of the FFR retains a financial reporting period that coincides with the budget period of a particular project. However, **the due date for annual FFRs will be 90 days after the end of the calendar quarter in which the budget period ends**. Note that this is a change in due dates of annual FFRs and may provide up to 60 additional days to report, depending upon when the budget period end date falls within a calendar quarter. For example, if the budget period ends 1/30/2012, the annual FFR is due 6/30/2012 (90 days after the end of the calendar quarter of 3/31/2012). Due dates of final reports will remain unchanged. The due date for final FFRs will continue to be 90 days after the project period end date.
Grantees must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, grantees 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 grantees are now available at http:// grants.nih.gov/ grants/forms.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://era.nih.gov/registration_accounts.cfm
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/ registration/ registration Instructions. jsp 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: http:// era.nih.gov/ commons /index.cfm.
**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 project period. 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 Time

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

**Scientific/Research Contact**

Michael A. Brown, M.P.H.

Scientific Program Official

Extramural Research Program Operations and Services

Centers for Disease Control and Prevention

4770 Buford Hwy, NE

Mailstop F-80

Atlanta, GA 30342

770-488-5118

mab5@cdc.gov

**Peer Review Contact**

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

**Financial/Grants Management Contact(s)**

Patricia French, Grants Management Specialist/Officer

Office of Grants Services (OGS)

Office of Financial Resources (OFR)

Office of the Chief Operating Officer (OCOO)

Centers for Disease Control and Prevention (CDC)
Telephone: 770-488-2849

Email: pff6@cdc.gov

## Section VIII. Other Information

Other CDC funding opportunity announcements 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.

**Authority and Regulations**

Awards 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 17-001 Community-based Short and Longer Term Evaluation of the Chronic Pain Self-Management Program**

**Project Description**

One in 10 (25.3 million) US adults experience chronic, or daily, pain (1). Multiple recent public health reports have recommended greater use of self-management strategies in chronic pain management (2-4) and highlight the need for further development of evidence-based self-management strategies such as self-management education programs (3). US adults living with chronic pain have a limited choice of affordable, evidence-based, pain self-management programs in their community. Currently, programs include the Chronic Pain Self-Management Program (CPSMP) which is offered by community based organizations throughout the United States. The CPSMP is a standardized, community based workshop that teaches people with chronic pain how to manage their symptoms. To date, CPSMP's effectiveness has been evaluated in only one short term (3 month) study (5). Although this randomized controlled trial demonstrated numerous benefits (e.g., reduced pain severity, improvements in self-efficacy, physical function, and depression), additional rigorous evaluation studies examining both the short and longer term effects of CPSMP are needed to ensure that this program has a sufficiently strong evidence-base to support its wide-scale implementation

Pain can have a profound effect on physical and psychosocial function such as reduced physical function and sleep and increased fatigue, depression, need for prescription opioids, medical expenditures, and work loss (2, 3, 5). CPSMP was developed for all people with chronic pain, regardless of the underlying condition causing the pain. CPSMP uses the behavioral principles that originated in the Arthritis Self-Management Program (ASMP) (5, 6), which is a community based self-management education program developed at Stanford University. Both ASMP and CPSMP are part of a suite of Stanford-developed self-management education programs, all of which use the same behavioral principles. ASMP and CDSMP have a strong evidence-base (7, 8). Like ASMP and CDSMP, CPSMP was designed to build self-efficacy and encourage adoption of cognitive behavioral techniques to address the numerous and frequent physical and psychosocial challenges of chronic conditions. CPSMP's ultimate goal is to improve the quality of life of those living with ongoing pain. While higher self-efficacy may be associated with better glycemic control and lower A1C values (9), the potential physiological benefits (e.g., decreases in A1C, hypertension, and blood cholesterol) of ASMP and CDSMP have not been studied. Because the Stanford self-management programs show consistent and substantial improvements in self-efficacy, participants may experience physiological benefits. Because physiologic improvements would provide additional justification for self-management education program participation, future evaluations of the Stanford self-management education programs will ideally include assessment of physiologic measures.

Previous Stanford program evaluation studies have examined potential changes in health care utilization resulting from program participation. A meta-analysis of ASMP and CDSMP evaluations found no meaningful statistically significant changes in health care utilization following program participation (7, 8). The lack of findings may be because health care utilization was measured through self-report at 6 month intervals. Evaluation of health care utilization in future studies would ideally be based on direct utilization measures (e.g., health care claims data) or at least improved measures of self-reported health care utilization (e.g., collected at more frequent intervals such as monthly). Although chronic conditions are associated with missed work days (10), to date there is no published evidence that Stanford program participants have fewer missed work days and reduced productivity loss. Ideally, studies examining work related outcomes would measure work days lost directly or if self-reported, at more frequent intervals.

**Project Objectives/Outcomes**

The objective of this SIP is to fund an eligible institution to evaluate CPSMP's short term and longer term post-intervention effectiveness. A secondary objective of the study is to evaluate whether changes produced by CPSMP also influence physiological health indicators. The successful applicant will prepare a report presenting the evaluation study findings, and disseminate results to appropriate community-based organizations, public health practitioners, and health care providers.

**Public Health Priorities**

**Healthy People 2020**

Arthritis Objectives:

- AOCBC-1 Reduce the mean level of joint pain among adults with doctor-diagnosed arthritis
- AOCBC-8 Increase the proportion of adults with doctor-diagnosed arthritis who have had effective, evidence-based arthritis education as an integral part of the management of their condition
- AOCBC-15 (Developmental) Increase self-management of high impact chronic pain

Diabetes Objectives:

- D-16 Increase prevention behaviors in person at high risk for diabetes with pre-diabetes
- D-16.1 Increase the proportion of persons at high risk for diabetes with pre-diabetes who report increasing their levels of physical activity

Heart Disease Objective:

- HDS -10.4 Increase the proportion of adults with hypertension who meet the recommended guidelines for physical activity

**National Prevention Strategy**

N/A

**CDC Winnable Battles**

N/A

**NCCDPHP Domain**

Community programs linked to clinical services

**Other**

**National Pain Strategy**

Prevention and Care Recommendation #2: Develop nationwide pain self-management programs

**CDC Guideline for Prescribing Opioids for Chronic Pain – 2016, United States**

Recommendation #1: Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain.

**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 Research Plan will describe a proposed study to evaluate CPSMP program outcomes. This study should examine both short (e.g., 6 month) and longer (e.g., 12 month) term outcomes. Description should include:

- Inclusion and exclusion criteria,

- Participant recruitment and retention,
- Outcomes and how they will be measured,
- Sample size estimation and justification,
- Power calculations, and
- Statistical methods.

Examples of outcomes to be considered include: measures of pain, health status (e.g., self-rated health, mental health), functional status, health-related quality of life, physiological status (e.g., A1C, blood pressure, body mass index, blood cholesterol), physical activity levels, work outcomes, and health care utilization. Chronic disease status (e.g., diagnosis of arthritis, diabetes, heart disease, etc.) and health outcomes should be collected.

Ideally the study design and analytic methods will be sufficiently rigorous to ensure that characteristics (for example, age, sex) that may influence the association between the intervention and the outcomes of interest are considered. The proposed study may use an observational design.

**Target population**

The target population is adults with chronic pain; the Research Plan will describe the proposed study population and how chronic pain will be defined in the proposed study.

**Collaboration/Partnerships**

Applicants are expected to partner with one or more organizations to accomplish the SIP objectives. Because this SIP is limited to 2 years, applicants are expected to partner with community based organizations that are either delivering CPSMP or are currently delivering CDMSP and can deliver CPSMP within 4 months of the award; these organizations must agree to collect data from the program enrollees to evaluate CPSMP's short term and longer term post-intervention effectiveness.

**Recruitment Plan**

The Research Plan will include a description of how the community-based partner organization(s) will recruit and retain a socio-demographically diverse population of adults with chronic pain.

**Annual Action Plan**

Provide a 12 month action plan, using SMART goals and objectives that includes a timeline and milestones. Applicant is also to describe and provide timeline for key activities for entire project period. Progress in achieving these milestones should be reported in progress reports and conference calls with CDC.

**Evaluation Plan/Performance measurement**

Evaluation plan should identify specific internal evaluation measures and research measures (e.g., pain scale, psychosocial characteristics, health care utilization, work loss, physiologic measures) that will be assessed. Applicant may categorize measures as primary (e.g., pain, psychosocial characteristics) and secondary. Ideally, the evaluation will be designed to detect moderate differences in effects for primary outcomes with statistical power of 80% and statistical significance of 5%.

**Dissemination and Translation plans**

Applicants are expected to prepare a detailed report of findings and/or a publication ready manuscript. Disseminate the SIP study results to relevant community-based organizations, public health practitioners, and health care providers. The Research Plan will identify appropriate target audiences and describe recommended dissemination methods.

**Public Health Impact**

US adults living with chronic pain have a limited choice of affordable, evidence-based, pain

self-management programs in their community. Study results will be used to assess whether CPSMP is a promising practice for chronic pain self-management and whether there is sufficient evidence for development of public health infrastructure to support wide-scale dissemination of CPSMP.

**Eligibility Criteria**

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

- The institution must show evidence, in the form of Letters of Support, of a partnership with a community-based organization(s) that has access to an appropriate study population. This Letter of Support from the community-based organization(s) must explicitly state the number of study participants that could be recruited during the study period.

**Additional Review**

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 determining the scientific merit and priority score:

- Does the applicant have Letters of Support from community-based organizations that indicate their experience with CPSMP delivery or experience with CDSMP delivery and willingness to provide CPSMP?
- Does the applicant demonstrate that each organization will be able to attain the projected sample size and that this study population will be socio-demographically diverse?
- Does this community-based organization demonstrate a commitment to collaborating with the applicant which includes ensuring that the applicant is able to collect data needed to evaluate the intervention?
- Does the applicant demonstrate experience in evaluation of community-delivered interventions among adults with chronic pain or other chronic conditions?
- Does the applicant demonstrate evidence of the successful completion of rigorous evaluation projects (e.g., publications, reports, etc.)?
- Does the applicant propose a rigorous study design to address the study questions?
- Does the applicant plan to evaluate outcomes for multiple chronic conditions (e.g., arthritis, diabetes, heart disease)?
- Does the applicant identify study investigators and demonstrate the qualifications of all individuals who will be involved in the design and execution of the project (including recruitment, training, data collection, data analysis, and report writing)?
- Does the applicant identify any anticipated barriers to conducting the Research Plan and how these will be addressed?

**Funding Preferences**

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

- Socio-demographic diversity of the proposed study population

**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 $600,000 is available to fund 1 Prevention Research Center(s) for a

2-year project period. The average award for each recipient is expected to be approximately $264,800 for year one. 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 site included in the project. Year 1 funds will be restricted until local IRB approval is received.

**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. CDC staff will not be involved in any data collection activity and will not receive any personally identified data.

**References**

[1] Nahin RL. Estimates of pain prevalence and severity in adults: United States, 2012. The journal of pain : official journal of the American Pain Society. 2015;16(8):769-80.

[2] Institute of Medicine Committee on Advancing Pain Research C, and Education,. Relieving Pain in America. Washington DC: National Academies Press; 2011.

[3] The Interagency Pain Research Coordinating Committee. National Pain Strategy 2016. Available from: https://iprcc.nih.gov/docs/HHSNational_Pain_Strategy.pdf.

[4 Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain - United States, 2016. MMWR Recomm Rep. 2016;65(1):1-49.

[5] LeFort SM, Gray-Donald K, Rowat KM, Jeans ME. Randomized controlled trial of a community-based psychoeducation program for the self-management of chronic pain. Pain. 1998;74(2-3):297-306.

[6] Stanford Patient Education Research Center. Chronic Pain Self-Management Program 2016 [Available from: http://patienteducation.stanford.edu/programs/cpsmp.html.

[7] Brady TJ, Murphy L, Beauchesne D, Bhalakia A, Chervin D, Daniels B, et al. Sorting through the evidence for the Arthritis Self-Management Program and the Chronic Disease Self-Management Program2011. Available from: http://www.cdc.gov/arthritis/docs/asmp-executive-summary.pdf.

[8] Brady TJ, Murphy L, O'Colmain BJ, Beauchesne D, Daniels B, Greenberg M, et al. A meta-analysis of health status, health behaviors, and healthcare utilization outcomes of the Chronic Disease Self-Management Program. Prev Chronic Dis. 2013;10:120112.

[9] Wykes TL, Lee AA, McKibbin CL, Laurent SM. Self-Efficacy and Hemoglobin A1C Among Adults With Serious Mental Illness and Type 2 Diabetes: The Roles of Cognitive Functioning and Psychiatric Symptom Severity. Psychosom Med. 2016;78(3):263-70.

[10] Trogdon JG, Murphy LB, Khavjou OA, Li R, Maylahn CM, Tangka FK, et al. Costs of Chronic Diseases at the State Level: The Chronic Disease Cost Calculator. Prev Chronic Dis. 2015;12:E140.

**SIP 17-002 Evaluation of School-based Health Services on Student Outcomes in Students with Chronic Health Conditions**

**Project Description**

CDC proposes to evaluate the process of initiating or expanding school health services policies, protocols, and practices to address management of chronic health conditions among middle school students in a local education agency (e.g. school district). The school-based health services will focus on chronic health conditions such as obesity, type 2 diabetes, food allergies, seizure disorders, poor oral health, or asthma.

The proposed evaluation seeks to understand the following in a school-based health services setting:

1) The process for managing students with chronic health conditions, such as type 2 diabetes, food allergies, seizure disorders, poor oral health, obesity, asthma in a school-setting,

2) The process of collaboration between schools and community-based medical services to manage students with chronic health conditions;

3) The process of implementing a referral system to link those students identified as having a chronic health condition or being at risk for these conditions with medical services that can provide further evaluation (e.g., cholesterol testing, behavior assessments) and counseling on management of their condition; and

4) The relationship between referrals for chronic health conditions and student health outcomes and/or academic performance.

**Project Objectives/Outcomes**

The evaluation is to focus on process and implementation of school health services policies, protocols, and practices to manage chronic health conditions among middle school students, focusing on a single, large school district. Applicants will propose evaluation design, methods, and analytic plans aimed at evaluating the implementation or expansion of school-based health services for students with chronic health conditions

**Project objectives/outcomes include:**

1) Identification and details of strategies used to identify and track students with chronic health conditions, as well as possible barriers and facilitators to identification and tracking of these students,

2) A description of the availability and type of school health services staffing and training that focuses on management of chronic health conditions,

3) Identification and description of school health services staff needs related to training and support to identify and track students with chronic health conditions, establish collaborative relationships with external partners, and create referral networks for students with chronic health conditions,and

4) Identification and details of the strategies used for collaboration with external partners in the local community and for creating referral networks for students with chronic health conditions.

5) Additionally, the relationship between referral care networks and student level outcomes may include documentation of clinical measurements, if appropriate for the health condition, health care utilization, and academic measures such as attendance, grades or test scores.

**Public Health Priorities**

**Healthy People 2020 Objective**

This project will address the following topic areas and objectives:

- ECBP-5: Increase the proportion of elementary, middle, and senior high schools that have a full-time registered school nurse-to-student ratio of at least 1:750
- MICH-30: Increase the proportion of children, including those with special health care needs, who have access to a medical home
- MICH-31: Increase the proportion of children with special health care needs who receive their care in family-centered, comprehensive, and coordinated systems

**National Prevention Strategy Key Direction/Priority**

N/A

**CDC Winnable Battle**

Nutrition, Physical Activity and Obesity

**NCCDPHP Domain**

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**

Applicant should describe evaluation design and methods based on capacity and availability of resources to achieve expected outcomes in project description above. Start up or scale up activities should be described, and process and implementation evaluation methods are strongly encouraged.

**Target population**

Applicant should describe target population including chronic disease burden data (e.g. asthma, diabetes, seizure disorders, poor oral health), including disparities by race, ethnicity, gender identity, sexual orientation, geography, socioeconomic status, disability status, primary language, health literacy, and other relevant dimensions (e.g., tribal communities).

**Collaboration/Partnerships**

Applicant should describe how they will evaluate the activities of organizations including school health services NGOs or initiatives, community organizations, hospitals, health insurance plans, non-profit agencies, health departments, education departments, or others that focus on managing chronic condition within schools to accomplish the SIP objectives. Memorandum of Understanding/Memorandum of Agreement (MOUs/MOAs) and Letters of Support (LOS) are strongly encouraged.

**Recruitment Plan**

Applicant should describe how they will work with the educational institution (i.e., school district) to identify and recruit students to participate in the evaluation plan. This includes descriptors of the overall population or sub-populations of interest, and how student data will be protected as per Family Educational Rights and Privacy Act (FERPA) requirements.

**Annual Action Plan**

Applicant to provide a 12 month action plan using SMART goals and objectives to include a progressive timeline for completion of activities. Applicant is also to provide description and timeline for key activities for entire project period.

**Evaluation Plan/Performance measurement**

Applicant to describe a comprehensive internal evaluation plan and research plan to monitor and document the implementation of the school-based health services policies, protocols, and practices. The evaluation plan should include both qualitative and quantitative methods to determine how the policies, protocols, and practices were implemented, identify barriers and facilitators related to implementation, and determine what strategies are used for improvement. To the extent feasible, the plan should also address the relationship to student-level health and academic outcomes and the implementation of policies, protocols, and practices.

**Dissemination and Translation plans**

Applicant to describe a plan to broadly disseminate, using a diverse set of dissemination strategies (e.g., scientific abstracts or publications, presentations, e-newsletters, list servs, webinars, virtual trainings,

e-learning, meetings), the results of the evaluation to decision makers and key stakeholders (e.g., school administrators, superintendents, school health services professionals, and teachers).

**Public Health Impact**

This proposed evaluation will help identify the barriers, facilitators to implementation of school health services policies, protocols, and practices; identify staffing and training needs of school health services' staff within a large school district; and identify strategies that can be used to create and foster external partnerships as well as referral networks for students. The intended long term impact of this evaluation can contribute to understanding best practices in improving health status, providing clinical linkages to care and improving academic performance for students with chronic health conditions through school-based health services.

**Eligibility Criteria**

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

1) The institution must show evidence of access to the study population (e.g. districts, schools, students) in the form of Letters of Support or Memorandums of Understanding.

2) The institution must provide evidence that the project team includes experts in school health services or evaluation research as evidenced in the Research & Related Senior/Key Person Section of the SF424 (R&R).

**Additional Review**

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:**

- Prior experience with school-based research?
- Expertise in process and implementation evaluation?
- Capacity to used mixed method study designs?

**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.

- Applicants may include items such as survey instruments or data collection tools

**Availability of Funds**

It is anticipated that approximately $1,000,000 is available to fund 1 Prevention Research Center for a 2-year project period. The average award is expected to be approximately $400,000 for year one. The year one ceiling is $600,000. Funding may vary and is subject to change.

**Research Status**

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

**OMB/PRA**

OMB/PRA is not expected to apply.

**Award Administration**

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

**SIP 17-003 Formative Study of Patient Navigators with the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) and the Colorectal Cancer Control Program (CRCCP)**

**Project Description**

Disparities in cancer screening persist, based on race, ethnicity, and health care access and use, among other factors [1]. Several types of barriers contribute to the perpetuation of disparities in cancer screening including those related to the health system (e.g., lack of insurance, lack of provider reminders), the individual (e.g., knowledge, transportation), and culture (e.g., language, distrust of the medical system) [2-6].

Patient navigation (PN) is an intervention to increase cancer screening by addressing barriers. Developed in the early 1990s [7], PN has been applied to multiple cancers including breast, cervical, colorectal, and prostate [8]. Navigators help participants overcome practical barriers to cancer screening, diagnosis, and treatment; provide culturally appropriate patient education; offer peer counseling, and provide linkages to financial and community resources [7]. These activities align with the evidence-based strategies to increase cancer screening recommended by the Community Preventive Services Task Force, including offering client reminders and outreach, providing one-on-one education, and reducing structural barriers [9]. Many studies support the effectiveness of PN in improving breast, cervical, and colorectal cancer screening and reducing cancer disparities [8]. Consequently, PN is an important evidence-based strategy for dissemination and scale-up.

The backgrounds of those delivering navigation vary. Navigators may be lay (i.e., non-clinical) members of the community they serve or healthcare professionals (e.g., nurses, social workers, health educators) [8]. Navigator background likely influences the range of services they are able to deliver (e.g., psycho-social assessment). While some studies have systematically examined patient navigator activities within cancer treatment settings, we are aware of only one study among navigators addressing cancer screening. In that study of breast cancer screening and treatment navigation, researchers found that although individual-level tasks, such as eliminating barriers, providing patient-centric care, and integrating care were similar across health care sites, the scope of PN practice varied greatly [10].

No study has been conducted among navigators working with CDC's National Breast and Cervical Cancer Early Detection Program (NBCCEDP) and the Colorectal Cancer Control Program (CRCCP). These two important public health programs represent nearly $165 million in Federal funding. There are currently 67 NBCCEDP and 30 CRCCP grantees. In fact, there has not been any study conducted in the U.S. to characterize the background, training, roles and responsibilities, and working conditions of patient navigators who address cancer screening. Information is also lacking about the organizational and professional context where navigators work, such as where navigators are physically located (e.g., clinic, health department), how they deliver navigation (e.g., by phone), whether a specific protocol is followed, their case load, how much they are paid, and if they conduct other work aside from navigation. Another gap in the literature involves collaborations and networks: whether navigators work closely with community outreach workers and whether they work as part of larger health care teams. The challenges navigators face or the training and technical assistance they desire have never been assessed and reported in the literature. Finally, it is not known what data are typically collected by navigators and what processes and outcomes are monitored as part of their practice. Conducting a formative study among navigators who are part of the NBCCEDP and CRCCP would provide valuable information regarding the professional and organizational settings navigators operate in, their work, and their training and technical assistance needs. Study results would

advance the field of navigation for cancer screening in general.

**Project Objectives/Outcomes**

The purpose of this special interest project is to conduct a formative study of navigators from NBCCEDP and CRCCP programs. This study should characterize the background, training, roles and responsibilities, and working conditions of patient navigators who address cancer screening. Results from this study should inform efforts to implement and scale up patient navigation interventions for cancer screening.

**Public Health Priorities**

**Healthy People 2020 Objective**

- C-15. Increase the proportion of adults who receive a cervical cancer screening based on the most recent guidelines
- C-16. Increase the proportion of adults who receive a colorectal cancer screening based on the most recent guidelines
- C-17. Increase the proportion of adults who receive a breast cancer screening based on the most recent guidelines

**National Prevention Strategy Key Direction/Priority**

Elimiation of Health Disparities: Patient navigation has been shown to reduce cancer disparities by reducing barriers to screening.

**CDC Winnable Battle**

N/A

**NCCDPHP Domain**

- Health care system interventions
- 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**

Applicants should describe the research design and methodology. Include research questions and information about recruitment, sampling, instrument development, data collection, analysis, and data dissemination. Include a study timeline.

**Target population**

The target population for the research study is patient navigators working on behalf of the NBCCEDP and CRCCP. Describe this target population.

**Collaboration/Partnerships**

Applicants will need to collaborate with NBCCED and CRCCP grantees to reach the target population and develop a sampling frame. Applicants should describe strategies for collaborating with these grantees.

**Recruitment Plan**

Applicants will need to recruit navigators to participate in the research study. Applicants should describe plans to recruit research participants.

**Annual Action Plan**

Applicants should provide a 12 month action plan using SMART goals and objectives to include a

progressive timeline for completion of activities. Applicant is also to provide description and timeline for key activities for entire project period.

**Evaluation Plan**

Provide an evaluation plan to assess project performance and progress. Provide a detailed

timeline for completing the proposal activities.

**Dissemination and Translation plans**

Applicants should describe activities to disseminate findings of the research to study participants, public health practicitioners, and CDC.

**Public Health Impact**

Patient navigation has been shown to increase cancer screening completion, including for breast, cervical, and colorectal (CRC) cancers. Patient navigation can help to increase cancer screening among disparate populations so that breast, cervical, and CRC will be either avoided completely or detected early, leading to better health outcomes. This project will provide critical information about the current delivery of this evidence-based intervention in CDC's NBCCEDP and CRCCP programs.

**Eligibility Criteria**

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

- The institution must show evidence that the project team includes experts in the research of patient navigation and cancer screening as evidenced in the Research & Related Senior/Key Person Section of the SF424 (R&R).

**Additional Review**

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

- Prior experience in conducting formative research, including surveys.
- Experience working with NBCCEDP or CRCCP grantees.

**Funding Preferences**

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

None

**Research Plan Length and Supporting Material**

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

Applicants should include an example of a previous data collection instrument for cancer screening.

**Availability of Funds**

It is anticipated that approximately $250,000 is available to fund 1 Prevention Research Center for a 1-year project period. The award for the recipient 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.

**References**

[1] Centers for Disease Control and Prevention (CDC). *Cancer Screening Test Use. MMWR Morb Mortal Wkly Rep.2015;64(17);464-468.* https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6417a4.htm

[2] Lasser KE, Ayanian JZ, Fletcher RH, Good MJ. Barriers to colorectal cancer screening in community health centers: a qualitative study. *BMC Fam Pract*. 2008;9:15.

[3] Sly JR, Edwards T, Shelton RC, Jandorf L. Identifying barriers to colonoscopy screening for nonadherent african american participants in a patient navigation intervention. *Health Educ Behav.* 2012;40(4):449-457.

[4] Hendren S, Chin N, Fisher S, et al. Patients' barriers to receipt of cancer care, and factors associated with needing more assistance from a patient navigator. *J Natl Med Assoc*. 2011;103(8):701-10.

[5] Guessous I, Dash C, Lapin P, et al. Colorectal cancer screenings barriers and facilitators in older persons. *Prev Med*. 2010;50(1-2):3-10.

[6] Jones R., Woolf S, Cunningham T, Johnson R, Krist A, Rothemich S, et al. Patient-reported barriers to colorectal cancer screening. *Am J Prev Med*. 2010;38(5):508–16.

[7] Freeman HP, Rodriguez RL. History and principles of patient navigation. *Cancer*. 2011;117(SUPPL. 15):3539-3542.

[8] Paskett ED, Harrop JP, Wells KJ. Patient navigation: An update on the state of the science. *CA Cancer J Clin.* 2011;61(4):237-249.

[9] Community Preventive Services Task Force. Updated Reviews and Findings added to The Community Guide: Increasing breast, cervical, & colorectal cancer screening. The Community Guide 2012,. http://www.thecommunityguide.org/news/2012/CancerClientOrientedUpdate.html. Accessed July 14, 2016.

[10] Gunn CM, Clark JA, Battaglia TA, Freund KM, Parker VA. An assessment of patient navigator activities in breast cancer patient navigation programs using a nine-principle framework. *Health services research.* Oct 2014;49(5):1555-1577.

**SIP 17-004 Assessing the Lifetime Economic Burden in Younger, Midlife, and Older Women with Metastatic Breast Cancer**

**Project Description**

Female breast cancer remains one of the leading causes of death in the United States (US), as well as the most common non-skin cancer among US women. CDC remains committed to reducing health disparities in female breast cancer patients who are at increased risk for getting breast cancer at a younger age [1]. More specifically, the Education and Awareness Requires Learning Young (EARLY) Act [2] authorized CDC to develop initiatives to increase knowledge of breast health and breast cancer among women under the age of 45 and those at heightened risk for developing the disease. CDC has employed a multi-pronged approach to

addressing breast cancer in young women, including determining economic impact as demonstrated in recent studies on the economic burden of breast cancer in younger women in the US [3-9].

Younger women are generally diagnosed with breast cancers that are more aggressive, harder to treat, and may metastasize [10-12]. In the US, nearly 30 percent of women diagnosed with early stage breast cancer will eventually develop metastatic breast cancer (mBC) [13]. In these women, the expected median survival is between two to four years [14]. Among younger women, the incidence of mBC has increased by 2% per year from 1976 to 2009 [14]. The intensity of care for mBC is significant and can be expensive [16-19] at different life stages.

Compared to women with early stage breast cancer, those living with mBC encounter distinct challenges such as undergoing continual treatment and living with a pervasive sense of limited time, which greatly affects their family, physical and mental health, and economic well-being [20-21]. While mBC currently remains incurable [22], there have been recent developments of targeted and combination therapies [23-25] and advances in supportive care that may prolong a woman's life [26]. To date, no study has estimated the cost-benefit and return on investment of their use in treating mBC patients. Understanding the full economic impact of mBC in different life stages on the society, health care system, patient, and their family will be important for decision-making. Further, economic data would also provide information to decision makers on costs related to palliative care, psychological support, other forms of symptom management, and therapeutic interventions to treat mBC

This cost information will be invaluable in developing new and effective interventions to reduce the impacts of mBC in younger, midlife, and older women. The age range for younger women (aged 18-44 years) was based on the statutory authority from the US Congress [1], the range for midlife women (aged 45-64 years) was based on a recent study documenting the impact of cancer in this specific age-group [27], and the range for older women (aged 65+ years) was based on studies reporting different impact of cancer burden in this group [28-29].

**Project Objectives/Outcomes:**

The objectives of this project are to:

1) Estimate the lifetime direct treatment costs, indirect productivity costs, and life-years lost due to mBC in three different life stages: younger, midlife, and older women;

2) Project the estimated economic burden costs to 2030; and

3) Estimate the cost-effectiveness, cost-benefit, and return on investment in the use of combinations of systemic versus targeted therapies in treating mBC in younger, midlife, and older women.

**The outcomes from this project are:**

1) Economic cost data that could help decision makers better allocate public health resources (e.g., program support, health promotion, etc.) to mBC patients.

2) Data that can serve as a "ready-to-use" resource available to public health practitioners and program managers for use in support of decision making to improve the lives of women living with mBC.

3) Identification of effective interventions to improve health-related quality of life of mBC patients.

4) Better understanding of the cost drivers of mBC treatment in order to optimize healthcare expenditure and to help inform appropriate prevention strategies and policies.

5) Evaluation of the overall survival for the use of combinations of systemic versus targeted therapies in treating mBC patients.

**Public Health Priorities**

**Healthy People 2020 Objective**

- (C-3). Breast cancer mortality and
- (C-11). Late-stage disease.

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

**National Prevention Strategy**

NA

**CDC Winnable Battles**

NA

**NCCDPHP Domain**

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**

- Describe study rationale, design and methods to be used in this project.
- Describe detailed proposed approach(es), which will include modeling strategies that will be used to achieve the objectives and outcomes of this project.

**Target population**

- Describe and provide evidence of access to existing population-based cancer data with mBC patients for the target populations of this project (i.e., younger, midlife, and older women) and a non-mBC comparison group of similar age-group.
- Describe and provide evidence of access to all relevant datasets including economic costs to be used in this project.

**Collaboration/Partnerships**

- 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.
- Describe applicant's 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**

Describe and provide a detailed 12 months action plan with SMART goals and objectives for this project. Provide description and timeline for key activities for entire project period.

**Evaluation Plan /Performance measurement**

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.

**Dissemination and Translation plans**

Describe a detailed dissemination and translation plan to be used in disseminating the outcomes of this project to the potential stakeholders, such as CDC, breast cancer survivorship organizations, the US Congress, public health decision-makers, medical organizations (e.g., American Society for Clinical Oncology), and other partners. The plan should also include potential manuscripts to be published from this project.

**Public Health Impact:**

Economic costs identified from this project will address the knowledge base for breast cancer in women in different life stages; inform public health decisions on strategies to reduce the impact of mBC on patient's well-being; inform health care system and society about how economic factors influence the welfare of mBC patients; and provide data to inform development of effective interventions. In addition, the outcomes from this project could be used to generate new economic knowledge that will promote the optimal design of cancer control strategies to improve the quality of a woman's life if her breast cancer progresses to a metastatic stage.

**Eligibility Criteria**

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

- Show evidence of access to population-based data on mBC to conduct this study as evidenced by a letter of support or memorandum of agreement.
- Show evidence that the research team includes a health economist with expertise in health economic research and modelling as evidenced in the Research & Related Senior/Key Person Section of the SF424 (R&R).

**Additional Review**

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:

- Evidence that the project team will include staff with experience in economic evaluation modeling?
- Experience conducting recent or ongoing studies in breast cancer?
- Experience in conducting research in clinical settings?
- Strategies for how findings from this study could advance scientific knowledge that would facilitate the effective interventions and health care policy related to preventing the progression of mBC?

**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 award for the recipient is expected to be approximately $350,000 for year one and $150,000 in year two. The year one ceiling is $350,000. Funding may vary and is subject to change.

**Research Status**

It is expected that this project will be exempt research; the project will involve analysis of previously collected treatment and cost data without identifiers.

**OMB/PRA:**

OMB/PRA is not expected to apply because CDC will have no input into the design, analysis, or interpretation of the project beyond providing technical consultation and advice at the request of the awardee.

**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.] http://www.cdc.gov/cancer/breast/young_women/index.htm

[2.] Breast Cancer Education and Awareness Requires Learning Young (EARLY) Act of 2009 (H.R. 1740, S. 994). (http://www.hhs.gov/sites/default/files/iv-amendments).

[3.] Ekwueme DU, Guy Jr, Rim SH, et al (2014). Health and economic impact of breast cancer mortality in young women, 1970-2008. Am J Prev Med;46(1):71–79.

[4.] Ekwueme DU, Trogdon JG (2016). The Economics of Breast Cancer in Younger Women in the U.S. The Present and Future. Am J Prev Med;50(2):249–254.

[5.] Brown DS, Trogdon JG, Ekwueme DU, et al (2016). Health-state utility impact of breast cancer in U.S. women aged 18–44. Am J Prev Med;50(2):255–261.

[6.] Trogdon JG, Ekwueme DU, Chamiec-Case L, Guy GP (2016). Breast cancer in young women: health state utility impacts by race/ethnicity. Am J Prev Med;50(2):262–269.

[7.] Allaire BT, Ekwueme DU, Guy GP, et al (2016). Medical care costs of breast cancer in privately insured women aged 18-44 years. Am J Prev Med;50(2):270–277.

[8.] Ekwueme DU, Allaire BT, Arnold SE, Guy GP, Trogdon JG (2016). Treatment costs of breast cancer among younger women aged 19 to 44 years enrolled in Medicaid. Am J Prev Med;50(2):278–285.

[9.] Ekwueme DU, Trogdon JG, Khavjou OA, Guy GP (2016). Productivity costs associated with breast cancer among survivors aged 18–44 years. Am J Prev Med;50(2):286–294.

[10.] Herdman R, Norton L (eds) (2005) Saving Women s Lives: Strategies for Improving Breast Cancer Detection and Diagnosis: A Breast Cancer Research Foundation and Institute of Medicine Symposium. Washington, DC: National Academies Press.

[11.] Klauber-DeMore N (2005). Tumor biology of breast cancer in young women. Breast Disease, 6;23:9-15.

[12.] Zabicki K, Colbert JA, Dominguez FJ, et al (2006). Breast cancer diagnosis in women < or = 40 versus 50 to 60 years: increasing size and stage disparity compared with older women over time. Ann Surg Oncol,13(8):1072-1077.

[13.] O'Shaughnessy J. (2005). Extending survival with chemotherapy in metastatic breast cancer. The Oncologist,10,20,20-29.

[14.] Mosher, CE, Johnson C, Dickler M, Norton L, Massie MJ, DuHamel K. (2013). Living with metastatic breast cancer: A qualitative analysis of physical, psychological, and social sequelae. Breast J, 19, 3, 285-92.

[15.] Johnson RH, Chien FL, Bleyer A (2013). Incidence of breast cancer with distant involvement among women in the United States, 1976 to 2009. JAMA;309(8):800-5

[16.] Campbell JD, Ramsey SD (2009). The costs of treating breast cancer in the US. Pharmacoeconomics. 27: 199-209. 10.2165/00019053-200927030-00003.

[17.] Max W, Sung HY, Stark B (2009). The economic burden of breast cancer in California. Breast Cancer Res Treat; 116: 201-207. 10.1007/s10549-008-0149-4.

[18.] Barron JJ, Quimbo R, Nikam PT, Amonkar MM (2008). Assessing the economic burden of breast cancer in a US managed care population. Breast Cancer Res Treat, 109: 367-377. 10.1007/s10549-007-9650-4.

[19.] Ekwueme DU, Yabroff KR, Guy Jr GP, et al (2014). Medical costs and productivity losses of cancer survivors - United States, 2008–2011. MMWR Morb Mortal Wkly Rep,63(23):505–510.

[20.] Canadian Breast Cancer Network. (2012). Metastatic Breast Cancer in Canada. Cbcn.ca. Accessed on September 8, 2014 at http://www.cbcn.ca/documents/cbcn_special_reports/MBCIC-Report.pdf.

[21.] Mayer M, Grober SE. (2014). Silent voices: Women with advanced (metastatic) breast cancer share their needs and preferences. For information, support, and practical resources. Living Beyond Breast Cancer. Available at: www.lbbc.org/content/download/2220/20076/version/1/file/LBBCsilentvoices.pdf. Accessed on May 13, 2016.

[22.] American Cancer Society. (2013). Detailed Guide: Breast cancer. American Cancer Society. Accessed on September 6, 2014 at http://www.cancer.org/acs/groups/cid/documents/webcon-tent/003090-pdf.pdf.

[23.] American Cancer Society. (2013). Breast cancer facts & figures 2013-2014. American Cancer Society. Accessed on September 8, 2014 at http://www.cancer.org/acs/groups/content/@research/documents/document/acspc-042725.pdf.

[24.] Romond EH, Perez EA, Bryant J., et al. (2005). Trastuzumab plus adjuvant chemotherapy for operable HER2-Positive breast cancer. N Engl J Med, 353,16,1673-84.

[25.] Sandoval C, Rahal R, Forte T, Klein-Geltink J, He D, Bryant H. (2013). Indicator measures ER/PR and HER2 testing among women with invasive breast cancer. Curr Oncol. 20,1,62-3.

[26.] Metastatic Breast Cancer Alliance project. Changing the Landscape for People Living with Metastatic Breast Cancer. MBCA report 2014: Available at: www.avonfoundation.org/assets/images/2014/mbca_full-report.pdf. Accessed on May 13, 2016.

[27.] Gehlert S, Holman DM, White MC, Henley J, Peipins LA, Ekwueme DU (2014). Opportunities for Cancer Prevention during Midlife. Am J Prev Med 2014;46(3):S1-S110.

[28.] Smith BD, Jiang J, McLaughlin SS, Hurria A, Smith GL, Giordano HS, Buchholz TA (2011). Improvement in Breast Cancer Outcomes Over Time: Are Older Women Missing Out? J Clin Oncol 29:4647-4653.

[29.] uss HB, Busby-Whitehead J (2011). Older Women With Breast Cancer: Slow Progress, Great Opportunity, Now Is the Time. J Clin Oncol. 2011 Dec 10;29(35):4608-10.

**SIP 17-005 Understanding Provision of Confidential Sexual Health Services to Adolescents**

**Project Description**

Preventing HIV, other sexually transmitted infections (STIs), and unintended pregnancy among adolescents are public health priorities. Sexual health-related services (SHS) (e.g., sexual behavior risk assessment, STI/HIV testing) are important components of prevention efforts and have been shown to decrease risky behaviors and improve health outcomes [1-3]. However, adolescents are medically underserved and may not

seek SHS because of unique barriers, including concerns about confidentiality [4-6]. These concerns, coupled with provider and parent attitudes and behaviors related to confidential care, could limit adolescent access to currently available services.

To date, there is limited research on the quality of and attitudes surrounding confidential SHS care for adolescents. In order to fully understand the complexity of providing confidential SHS to teens, we must understand the barriers and facilitators encountered by providers and teens as well as attitudes among these groups surrounding confidential care; parental perspectives are also essential.

**Project Objectives/Outcomes**

The purpose of this project is to better understand provision of confidential sexual health services by pediatricians and family medicine providers to female and male adolescents 11-17 years of age. Specifically, the project will describe perspectives from three key populations—adolescents, providers, and parents. Potential topics of interest may include:

- Adolescent report of time alone with providers and performance of SHS-related risk assessment, perspectives on quality of confidential care, and barriers / facilitators to accessing confidential SHS.
- Provider knowledge about relevant state laws/policies, comfort providing confidential SHS (including attitudes and knowledge surrounding PrEP), barriers and facilitators to confidential care, including time alone with adolescents, and attitudes about and communication with parents.
- Parent knowledge of and attitudes about adolescents accessing confidential sexual health services, receiving sexual health information, and having time alone with providers.

**Public Health Priorities**

**Healthy People 2020 Objective**

This project address the following topic areas and objectives:

- FP-7 Increase the proportion of sexually experienced persons who received reproductive health services
- FP-8 Reduce pregnancies among adolescent females
- HIV-2 Reduce the number of new HIV infections among adolescents and adults
- HIV-14 Increase the proportion of adolescents and adults who have been tested for HIV in the past 12 months
- STD-1 Reduce the proportion of adolescents and young adults with Chlamydia trachomatis infections
- STD-3 Increase the proportion of sexually active females aged 24 years and under enrolled in Medicaid plans who are screened for genital Chlamydia infections during the measurement year
- STD-4 Increase the proportion of sexually active females aged 24 years and under enrolled in commercial health insurance plans who are screened for genital Chlamydia infections during the measurement year

**National Prevention Strategy Key Direction/Priority**

Sexual and Reproductive Health: 1) improving confidential care has the potential to enhance uptake of preventive services and early detection of HIV, viral hepatitis, and other STIs.

**CDC Winnable Battle**

Teen Pregnancy Prevention and HIV prevention.

**NCCDPHP Domains**

Health care system interventions

**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**

Describe and justify an approach to addressing the study objectives. It is anticipated that mixed methods (i.e. both qualitative and quantitative methods) may be used. For each study population--parents, providers, and adolescents--indicate the specific research questions to be addressed and method(s) of data collection (quantitative and/or qualitative). It is likely that both quantitative and qualitative data collection components with providers will be used. Please justify the selection of data collection methods based on the proposed research questions.

Provide details on each data collection component, including sampling and recruitment plans, target sample size with justification, survey modes (e.g., paper and pencil, web-based), preliminary domains for interview questions/survey items, and potential analyses.

**Target populations**

Describe and provide evidence of access to clinic-based populations, including each of the following:

- Pediatric and family medicine providers
- Female and male adolescents 11-17 years of age
- Parents of female and male adolescents 11-17 years of age

It is anticipated that sample sizes will vary depending on the proposed data collection methods. For example, a quantitative data collection component would likely occur with a relatively large sample (e.g., >300) in order to meet study objectives. Similarly, it is expected that a qualitative component could be conducted with a sufficient sample (e.g., approximately 30 individuals) to meet stated objectives.

**Collaboration/Partnerships**

Describe and provide evidence of collaboration/partnerships with organizations that will facilitate recruitment of providers, adolescents, and parents, including national professional organizations or other organizations/networks able to reach a diverse sample of pediatric and family practice providers and clinics that will yield diverse samples for each of the three target populations.

**Recruitment Plan**

Describe plans to recruit research participants as part of the study design and methods section. Recruitment plans for each data collection component should be addressed and ensure guardian consent is discussed when conducting research with minors (e.g., https://humansubjects.nih.gov/children1).

**Annual Action Plan**

Provide a 12-month action plan using SMART objectives. Identify key staff who will be devoted to the project. For each person, describe their demonstrated knowledge and experience relevant to the proposed study.

Applicant is also to provide description and timeline for key activities for entire project period.

**Evaluation Plan/Performance measurement**

Provide an evaluation plan to assess project performance and progress. Provide a detailed

timeline for completing the proposal activities.

**Dissemination and Translation plans**

Describe a plan for disseminating the results of this project to relevant stakeholders, including researchers, providers, parents and adolescents.

**Public Health Impact**

Understanding provider, parent, and adolescent perspectives on provision of confidential SHS will yield a comprehensive assessment that can inform intervention to enhance confidentiality and adolescents' receipt of SHS. Increasing receipt of preventive services, including behavioral counseling, can reduce risk behavior and improve sexual and reproductive health outcomes.

**Eligibility Criteria**

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

- Provides letters of support demonstrating access to proposed clinical settings where adolescents seek care, including with parents.
- Provides a letter of support from at least one proposed organization/network demonstrating access to the intended diverse sample of pediatric and family practice providers.

**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 appropriate experience conducting research related to sexual and reproductive health with providers, parents, and adolescents?
- Does the applicant demonstrate experience conducting quantitative surveys and qualitative interviews?
- Do the data collection methods proposed with adolescents and parents optimally address the specific research questions outlined for these populations?
- Does the applicant demonstrate evidence of access to a diverse provider population in terms of geography, practitioner type (i.e. pediatric and family medicine), age, and sex?
- Does the applicant demonstrate evidence of access to a diverse clinic-based adolescent population in terms of race/ethnicity, socioeconomic status (SES), age, and sex?
- Does the applicant demonstrate evidence of access to a diverse clinic-based parent population in terms of race/ethnicity and SES?
- Do the data collection methods proposed with adolescents and parents optimally address the specific research questions outlined for these populations? Are the proposed sample sizes for each data collection component sufficient?

**Funding Preferences**

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

- Diverse provider population in terms of geography, practitioner type (i.e. pediatric and family medicine), age, and sex
- Diverse adolescent population in terms of race/ethnicity, SES, age, and sex
- Diverse parent population in terms of race/ethnicity and SES

**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 is available to fund 1 Prevention Research Center for a 2-year

project period. The average award 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. 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.

**References**

[1.] O'Connor EA, Lin JS, Burda BU, Henderson JT, Walsh ES, Whitlock EP. Behavioral sexual risk-reduction counseling in primary care to prevent sexually transmitted infections: a systematic review for the U.S. Preventive Services Task Force. Ann Intern Med 2014; 161(12): 874-83.

[2.] Hofstetter AM, Ompad DC, Stockwell MS, Rosenthal SL, Soren K. Human papillomavirus vaccination and cervical cytology outcomes among urban low-income minority females. JAMA Pediatr 2016.

[3.] Ozer EM, Adams SH, Orrell-Valente JK, et al. Does delivering preventive services in primary care reduce adolescent risky behavior? J Adolesc Health 2011; 49(5): 476-82.

[4.] Cuffe KM, Newton-Levinson A, Gift TL, McFarlane M, Leichliter JS. (2016). Sexually transmitted infection testing among adolescents and young adults in the United States. J Adol Health; 58 (5):512-519

[5.] Ford CA, Best D, Miller WC. Confidentiality and adolescents' willingness to consent to sexually transmitted infection testing. Arch Pediatr Adolesc Med 2001;155:1072e3.

[6.] Ford CA, Millstein SG, Halpern-Felsher BL, et al. Influence of physician confidentiality assurances on adolescents' willingness to disclose information and seek future health care. A randomized controlled trial. JAMA 1997;278:1029e34.

[7.] Hagan JF, Shaw JS, Duncan PM, eds. Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents. 3rd Edition ed. Elk Grove, IL: American Academy of Pediatrics 2008.

**SIP 17-006 Communicating With Youth to Prevent HIV, Other STIs, and Pregnancy: Identifying Key Messages, Messengers, and Communication Channels**

**Project Description**

Risk behaviors that can lead to HIV, other sexually transmitted infections (STIs), and unintended pregnancy often begin in adolescence. Nationally representative data from U.S. high school students revealed that in 2015, 41.2% reported having ever had sex, and 11.5% of students reported having had sex with four or more partners.[1] Approximately 30.1% of U.S. high school students reported being currently sexually active (i.e., "having had sexual intercourse with at least one person during the 3 months before the survey"), and among those students, 43.1% reported they did not use a condom during last sexual intercourse.[1] In addition, youth and young adults report relatively low levels of HIV and STD testing. In 2013, only 22% of sexually experienced U.S. high school students reported having ever been tested for HIV.[2] A recent online survey conducted with a national sample of individuals ages 15-25 revealed that only 6.7% of 15-19 year old respondents had been tested for STDs in the last 12 months.[3]

In light of the prevalence of sexual risk behaviors reported among youth, the purpose of this project is to gain a better understanding of the communication messages, messengers, and channels that can be used to encourage behaviors that prevent HIV, other STIs, and pregnancy among youth and to develop specific messages addressing targeted behaviors. The specific target protective behaviors include:

- Abstinence (including delaying initiation of sex and practicing abstinence after sexual initiation)
- Using condoms consistently and correctly
- Seeking sexual health services such as HIV or STI testing

The intended outcome of the project is (1) a draft set of messages that are expected to resonate with youth and would likely lead to an increase in the target protective behaviors and (2) a set of recommendations for who should deliver those messages and through what channels messages should be delivered. Messages might be appropriate for delivery through communication campaigns (electronic or print) or embedded in other intervention approaches such as school or community-based curriculum, clinic-based programs, and/or health care provider or counselor communication. The draft set of messages should include specific concepts (e.g., peer norms around sex, services are confidential and low-cost or free) that are important for youth, and allow for messages to be further defined and tailored in future work through specific language, images, and/or other design features to appeal to specific geographic or cultural subpopulations of youth.

**Project Objectives/Outcomes**

The specific objectives of this project are to:

- Identify known barriers and facilitators for the target protective behaviors that are currently found in peer-reviewed literature.
- Describe youth perspectives on (1) the most influential barriers and facilitators for the target protective behaviors, (2) what type of content they would find most effective in promoting these behaviors, (3) who should deliver such messages, and (4) through what communication channels they would prefer to receive those messages.
- Provide a draft set of messages expected to resonate with youth that would feasibly lead to an increase in the target protective behaviors, and provide a companion set of recommendations for who should deliver those messages and through what channels.

**Public Health Priorities**

**Healthy People 2020 Objective**

The project will address the following topic areas and objectives:

- FP-7 Increase the proportion of sexually experienced persons who received reproductive health services
- FP-9 Increase the proportion of adolescents aged 17 years and under who have never had sexual intercourse
- FP-10 Increase the proportion of sexually active persons aged 15 to 19 years who use condoms to both prevent pregnancy and provide barrier protection against disease
- HIV-14 Increase the proportion of adolescents and adults who have been tested for HIV in the past 12 months
- HIV-17 Increase the proportion of sexually active persons who use condoms

**National Prevention Strategy Key Direction/Priority**

Sexual and Reproductive Health: (1) provide effective sexual health education, especially for adolescents, and (2) enhance early detection of HIV, viral hepatitis, and other STIs and improve linkage to care

**CDC Winnable Battle**

Teen pregnancy prevention and HIV prevention

**NCCDPHP Domains**

Environmental approaches

**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**

Describe the proposed study design that addresses the SIP objectives and desired outcomes.

The study design should describe an approach to synthesizing the current state of the literature on known barriers and facilitators for the identified protective behaviors that can serve as a foundation for both message development and the qualitative research. The application is expected to include a description of suggested search terms, databases, coding and synthesis processes, and specific research questions to be addressed.

The study design should also reflect how it will build on the factors identified in the literature to provide an in-depth description of youth perspectives on (1) the most influential barriers and facilitators for the target protective behaviors (allowing youth to reflect on barriers and facilitators that emerged in the literature as well as additional barriers and facilitators that may be important), (2) what type of content they want and/or need in messages related to the most influential barriers and facilitators, (3) who (e.g., teachers, parents, health care providers, other trusted adults, peers, celebrities) should deliver such messages, and (4) through what communication channels (e.g., in-person conversations or teaching; specific social media channels such as Facebook, SnapChat, Instagram, or other websites or applications; text messaging or other electronic forms of communication) they would prefer to receive those messages.

The design is expected to include individual interviews or focus groups with youth. The applicant may propose including participants other than youth (e.g., parents, adults working in youth-serving organizations), but the study should be heavily grounded in the perceptions of youth themselves. Methods should be selected based on appropriateness for each study question of interest and considerations of participant comfort and convenience. The application is expected to include a discussion of the basis for the selected data collection methods, the proposed number of participants, and study design based on the proposed study questions. The application is also expected to include a description of proposed plans for data collection including proposed approach and plans for consent processes and incentives (if applicable).

The study design selected may include quantitative approaches. For example, the applicant may propose quantitative processes to have a larger and diverse set of youth rank or weight identified barriers and facilitators or provide feedback to create or refine draft messages. If the applicant proposes an additional quantitative component to the study, the application should include a description of the rationale for the component and the proposed plans for data collection and analysis.

Finally, the application should include a description of how the applicant plans to develop (1) a draft set of messages expected to resonate with youth that would feasibly lead to an increase in the target protective behaviors, and (2) a companion set of recommendations for who should deliver those messages (who are the recommended messengers?) and through what channels those messages should be delivered. The draft set of messages should include specific concepts (e.g., peer norms around sex, services are confidential and low-cost or free) that are important for youth, and allow for messages to be further defined and tailored in future work through specific language, images, and/or other design features to appeal to specific geographic or cultural subpopulations of youth. Recommendations about how to tailor messages for subpopulations of youth (e.g., language that might have been heard most commonly from specific groups of youth; preferences of certain groups of youth for specific delivery channels) should also be included in the companion recommendations if data to support such recommendations emerged in the study. Messages might be

appropriate for delivery through communication campaigns (electronic or print) or embedded in other intervention approaches such as school or community-based curriculum, clinic-based programs, and/or health care provider or counselor communication.

The application should include a description of plans for engaging a diverse group of youth in the creation of draft messages and in engaging youth in creating recommendations for messengers and communication channels. The application should also provide a few examples of the type of messages, messengers, and channels that might be considered.

**Target population**

The target population for this SIP is youth 13-18 years of age who are diverse in terms of age, racial and ethnic backgrounds, geographic location, urban/suburban/rural settings, sexual and/or gender identity, and extent of connection to sexual health services.

**Collaboration/Partnerships**

Applicants are expected to describe and provide evidence of collaboration/partnerships that will support the accomplishment of study goals and objectives. These include:

- Organizations that have access to or serve diverse groups of youth
- Organizations or individuals with substantial experience in communication research and communication message development and delivery

**Recruitment Plan**

Applicants are expected to describe plans to recruit youth for the study who are diverse in terms of age, racial and ethnic backgrounds, geographic location, urban/suburban/rural settings, sexual and/or gender identity, and extent of connection to sexual health services. Plans should reflect the ability to gather information from each segment of the target population in a manner that will provide sufficient information for representation from all groups. Plans should ensure guardian consent is discussed when conducting research with minors (e.g., https://humansubjects.nih.gov/children1).

**Annual Action Plan**

Provide a 12 month action plan, using SMART goals and objectives that includes a timeline and milestones. Applicant is also to provide description and timeline for key activities for entire project period. Identify key staff who will work on the project. For each person, describe their demonstrated knowledge, experience, and ability in planning and conducting the activities that are proposed.

**Evaluation Plan/Performance measurement**

Provide an evaluation plan to assess project performance and progress. Provide a detailed

timeline for completing the proposal activities.

**Dissemination and Translation plans**

Describe a plan for disseminating the results of this project to relevant stakeholders.

**Public Health Impact**

Understanding the communication messages, messengers, and channels that can be used to encourage key protective behaviors for reducing pregnancy and the transmission of HIV and other STIs among youth will allow public health professionals to better provide critical information to youth in order to improve sexual and reproductive health outcomes.

**Eligibility Criteria**

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

- Demonstrate access to proposed study population as described in "target population" section by providing

letters of support from youth-serving organizations, clinics, or education agencies that will partner on 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 proposed study design is appropriate for accomplishing the required objectives?
- That the project team includes experts in conducting research using the methods proposed and with the proposed target population?
- That at least one member of the project team has substantial experience in communications research and communication message development and delivery for the target population?
- The proposed project team has expertise in adolescent sexual and reproductive health?
- A clear understanding of each of the major project components (identifying barriers/facilitators from the literature, the study involving data collection from youth, and message development and related recommendations)?
- That the proposed design includes a clear and appropriate approach for ensuring a diverse group of youth will be represented in the study? (Youth should be diverse in age, racial and ethnic backgrounds, geographic location, urban/suburban/rural settings, sexual and/or gender identity, and extent of connection to sexual health services.)
- That the proposed study will be built from the barriers/facilitators identified in the literature and is designed to elicit the type of youth feedback that can provide valuable basis for shaping messages and selecting messengers and dissemination channels?

**Funding Preferences**

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

- Diversity of the study population.

**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 is available to fund 1 Prevention Research Center for a 2-year project period. The average award 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 involving human subjects. It is anticipated that this project will require local IRB approval. Applicants should provide a federal-wide assurance number for each performance site included in the project.

**OMB/PRA**

OMB/PRA is not expected to apply

**Award Administration**

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

**References**

[1.] Centers for Disease Control and Prevention. Youth Risk Behavior Surveillance--United States, 2015. MMWR 2016;65(SS-6):1-174.

[2.] Centers for Disease Control and Prevention. Sexual risk behaviors: HIV, STD, & teen pregnancy prevention. http://www.cdc.gov/healthyyouth/sexualbehaviors/index.htm Published 2015. Accessed July 20, 2016.

[3.] Cuffe KM, Newton-Levinson A, Gift TL, McFarlane M, Leichliter JS. (2016). Sexually transmitted infection testing among adolescents and youth adults in the United States. J Adolesc Health. 2016;58(5):512-519.

## APPENDIX A

## FY17 SIPs DP17-005

## Amendment 1 2/10/2017

## Questions from Potential Applicants and CDC Responses

A text modification has been made in Executive summary to change form C to form D. https://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general-forms-d.pdf

**Answers are in red.**

**Question 1**

**SIP 17-002 – Q1:** We would need to work with all schools within a given school district or if it is ok that the project focuses on multiple schools within a given school district.

**Answer:** The FOA does not specify how many schools must participate. The FOA under **Project Description** indicates "… in a local education agency (e.g. school district)." Applicants can determine the number of schools within a district to target for the evaluation.

**Question 2**

**SIP 17-002 - Q2:** If we currently operate school based health centers are we expected to improve outcomes for addressing chronic health conditions by expanding the services that we provide in a given area or by strengthening the services that we provide and the collaboration between Nurse Practitioners in the school based health centers with the primary care providers for the patients. We want to apply with two PI's versus a PI and Co-PI and want to make sure this is a permissible with CDC.

**Answer:** The FOA **Project Objectives** indicate the focus to be onevaluating the implementation or expansion of school-based health services for students with chronic health conditions.

**Question 3**

**SIP 17-002 - Q3:** "It is a question of "services policies, protocols,…" or did you mean "services, policies, protocol s…"

**Answer:** The FOA states in the Project Objectives: The evaluation is to focus on process and implementation of school health services, policies, protocols, and practices to manage chronic health conditions among middle school students, focusing on a single, large school district. The school-based health

services will focus on chronic health conditions such as obesity, type 2 diabetes, food allergies, seizure disorders, poor oral health, or asthma.

**Question 4**

**SIP 17-002 – Q4: "**Can you please clarify how the CDC defines "middle school" as there can be variations in the grades included in this definition?"

**Answer:** The FOA does not define what grades are included in a middle school, thus, applicants may use the definition of middle school within the school district selected for study.

**Question 5**

**SIP 17-004 – Q5:** "On p. 18 of RFP-DP-17-005, it states that "CDC requires awardees 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." If our proposed study relies on existing data, and thus would not collect or generate any data, would a DMP still be required?"

**Answer:** The question doesn't distinguish if you plan on using existing data that you already have, or if you plan on acquiring existing data from another source. In either case, the FOA outlines the new policy regarding data management plans (DMPs) and specifies what should be included in a DMP. The application should include a DMP or an explanation of why one is not needed. If the proposed study involves non-federally funded data that you already possess, then the DMP could consist of statements indicating that the requirements for a DMP are not met and why. However, if federal money were used to acquire a data set, even if it were a pre-existing data set, then a DMP would be required. The 'owner' of the data in question might have a pre-existing DMP; if so, it would help you in drafting your own DMP.

**Question 6**

**SIP 17-003 – Q6:** Is there a rapid way to contact all grantees in the NBCCED and CRCCP network? (e.g. a listserves)

**Answer:** Yes, CDC maintains a listing of all program directors (and their emails) for the NBCCEDP and CRCCP grantees. As a part of CDC's technical assistance for this award, CDC may provide, upon request, the contact listing or otherwise assist in communications with NBCCEDP and CRCCP grantees.

**Question 7**

**SIP 17-003 – Q7:** Is there an easy way to know which grantees were funded to do navigation as part of their award? Similarly, which were funded to provide free screening to eligible patients (Cx, mammography, or FIT)?

**Answer:** Yes, CDC collects data from NBCCEDP and CRCCP that can help identify which grantees are conducting patient navigation. All NBCCEDP grantees receive funding to support delivery of clinical services (e.g., mammography). Six CRCCP grantees receive funding to support delivery of clinical services (e.g., FIT, colonoscopy). As a part of CDC's technical assistance for this award, CDC may provide, upon request, contact information or otherwise assist in communications with NBCCEDP and CRCCP grantees.

**Question 8**

**SIP 17-003 – Q8:** Were grantees required to collect a standard set of outcome or process data?

**Answer**: CDC does not require NBCCEDP grantees to collect a standard set of outcome or process data related to patient navigation, but CDC does collect this information in aggregate where available. For the CRCCP, CDC collects the number of persons navigated at each partner health system clinic. In the FOA under **Project Description** it indicates "Finally, it is not known what data are typically collected by navigators and what processes and outcomes are monitored as part of their practice."

**Question 9**

**SIP 17-003 – Q9:** Is there a time limit on which grantees experience should be included, e.g. only those

grantees conducting navigation as part of their projects since 2012?

**Answer:** The FOA does not specify a limit on grantee experience. This information is not specified in the FOA.

**Question 10**

**SIP 17-003 – Q10:** Is there a way to know which grantees adopted the New Hampshire model CRC navigation program made available in October 2016.

**Answer:** This information is not specified in the FOA. As a part of CDC's technical assistance for this award, CDC may provide, upon request, contact information or otherwise assist in communications with NBCCEDP and CRCCP grantees.

**Question 11**

**SIP 17-003 – Q11:** Is there an interest in gathering cost and sustainability information?

**Answer:** There is no requirement in the FOA to collect cost and sustainability information; however, the FOA does indicate "Results from this study should inform efforts to implement and scale up patient navigation interventions for cancer screening." Thus, the applicant can include elements of costs and sustainability if desired.

**Question 12;**

**SIP 17-003 – Q12:** Is there a clearinghouse on screening navigation protocols within the NBCCED and CRCCP networks that could serve as a baseline?

**Answer:** No, there is not a clearinghouse on screening navigation protocols within the NBCCED and CRCCP networks.

**Question 13**

**SIP 17-003 – Q13:** Is there a desire to align screening navigation variables with screening completion? Would completion data by site be made available?

**Answer:** There is no requirement in the FOA to align screening navigation variables with screening completion. The FOA does state, "it is not known what data are typically collected by navigators and what processes and outcomes are monitored as part of their practice."

**Question 14**

**SIP 17-005 – Q14:** Whereas on page #52 of the SIP announcement for availability of funds is a reference to $800,000 for the 2-year project period with a year one ceiling of $400,000. I'm trying to figure out the $600,000 project period and $800,000 project period references. Is it possible that $800,000 is the ceiling for the full 2 year period while maybe the $600,000 reference is for an individual year total (maybe year 2) instead of the full 2 year period?

**Answer:** In Section II. Award Information (page 6), the award ceiling and floor shown represent the range across all SIPs, not a SIP-specific funding amount. Within the specific SIP descriptions (in Section IX) are the SIP-specific funding and ceiling levels. The ceiling for year one for SIP 17-005 is $400,000, and the proposed funding for two years is $800,000.

**Question 15**

**SIP 17-002 – Q15**: The RFA states "The school-based health services will focus on chronic health conditions such as obesity, type 2 diabetes, food allergies, seizure disorders, poor oral health, or asthma." Is the expectation that the services would focus on ONE of these conditions, a few, or all of them?

**Answer:** The FOA does not specify how many conditions to focus on, thus, applicants are expected to address at least one of the chronic conditions listed, but may address additional conditions.

**Question 16**

**SIP 17-002 – Q16:** The RFA also states that the project should focus on "a single, large school district." We have a unique ongoing partnership with 5 local school districts of varying size and we could potentially work with any number of them. For the purposes of this grant, what is the definition of a "large" school district, and would other configurations be considered (for example, multiple smaller districts or one medium and one small district)?

**Answer:** The FOA does not specify how many schools makes up a large school district. The FOA does state: "The evaluation is to focus on process and implementation of school health services policies, protocols, and practices to manage chronic health conditions among middle school students, focusing on a single, large school district." However, applicants determine their desired approach for responding to this announcement, which can include defining the target population.

**Question 17**

**SIP 17-001 – Q17:** Is a health department considered a community-based organization?

**Answer:** For this funding opportunity announcements, health departments are not considered community-based organizations. They are categorized as government or governmental organizations.

**Question 18**

**SIP 17-006 – Q18:** Is it expected that this project would cover all types of diversity listed in the target population?

**Answer:** Yes, the FOA under **Recruitment Plan** indicates "Applicants are expected to describe plans to recruit youth for the study who are diverse in terms of age, racial and ethnic backgrounds, geographic location, urban/suburban/rural settings, sexual and/or gender identity, and extent of connection to sexual health services. Plans should reflect the ability to gather information from each segment of the target population in a manner that will provide sufficient information for representation from all groups."

**Question 19**

**SIP 17-004 – Q19:** On page 45 of the RFA, the 2nd objective/outcome of this project is stated to "Provide the estimated economic burden costs to 2030". My question is:

1. Does this mean we need to convert our cost estimates into 2030 constant dollars using the consumer price index?
2. Or, does this mean we need to forecast the cost burden till year 2030 by using projecting the mBC incidence and mortality rates till 2030?

**Answer:** The FOA does not specify the approach but indicates the objectives are to:

1) Estimate the lifetime direct treatment costs, indirect productivity costs, and life-years lost due to mBC in three different life stages: younger, midlife, and older women;

2) Project the estimated economic burden costs to 2030; and

3) Estimate the cost-effectiveness, cost-benefit, and return on investment in the use of combinations of systemic versus targeted therapies in treating mBC in younger, midlife, and older women.

The intent of objective 2 is to project the estimated economic burden costs out to the year 2030.

**Question 20**

**SIP 17-003 – Q20:** Is the intent of the RFA to develop a study that examines the NBCCEDP and CRCCP nationwide? Or, is it sufficient to examine the programs (as administered in a respective state)?

**Answer:** In the FOA under **Project Objectives/Outcomes** it states "The purpose of this special interest project is to conduct a formative study of navigators from NBCCEDP and CRCCP programs" in order to

"characterize the background, training, roles and responsibilities, and working conditions of patient navigators who address cancer screening." The FOA does not require a nationwide study. The target population outlined in the FOA is patient navigators working on behalf of the NBCCEDP and CRCCP programs.

**Question 21**

**SIP 17-005 – Q21:** In regards to the required 12 Month action plan, evaluation plan and dissemination plan are these to be included in the Appendices?

**Answer:** Yes, the action plan, evaluation plan and dissemination plan can be submitted as Appendices but must stay within the 30 page limit for all appendices and not exceed 10 PDF files.

**Question 22**

**SIP 17-005 – Q22:** Are their page limits for each of these items?

**Answer:** The FOA does not specify a page limit foreach item**:** action plan, evaluation plan and dissemination plan. However, appendices may not exceed 10 PDF files and a maximum of 30 pages for all appendices.

**Question 23**

**SIP 17-005 – Q23**: If these items are indeed meant to be included in the Appendices do they contribute to the overall page limit (30) and are included in the 10 pdf limit?

**Answer:** Yes, appendices may not exceed 10 PDF files and a maximum of 30 pages for all appendices.

**Question 24**

**SIP 17-002 – Q24**: The FOA indicates that a 12-month Action Plan should be included in the Research Strategy section. The Research Strategy has a page limit of 12 pages. The CDC Annual Action Plan guidelines for SIPs indicate that the Action Plan should not exceed 20 pages. Is it expected that this will be a short Action Plan of just one or two pages that will fit within the Research Strategy section? Or should it be included as an appendix?

**Answer:** The FOA indicates that the action plan is among the items included in the Research Plan vs the Research Strategy. The FOA does not specify a page limit for theaction plan. However, the action plan may be included as an appendix. Appendices may not exceed 10 PDF files and a maximum of 30 pages for all appendices.

**Question 25**

SIP 17-001 Q25: Is the Action Plan supposed to be included in the 12-page research strategy limit? (these are usually several pages long). I searched the RFA and the SF424 and there is no mention of this.

**Answer:** The FOA indicates that the action plan is among the items included in the Research Plan vs the Research Strategy. The FOA does not specify a page limit for theaction plan. However, the action plan may be included as an appendix. Appendices may not exceed 10 PDF files and a maximum of 30 pages for all appendices.

**Question 26**

**SIP 17-001 Q26:** Was a list of FAQs published somewhere? Could not find it.

**Answer:** The FAQs will be posted as an amendment to the FOA the week of 02/6/2017.