

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-18-002
Application Due Date: 03/06/2018

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

RFA-DP-18-002

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)

Notice of Funding Opportunity (NOFO) Title

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

Activity Code

U48

Amendment 1 - 2/14/18

- Additional instructions for submitting revision applications, in Section IV- Application and Submission Information, under PHS 398 Research Plan elements.
- Questions from Potential Applicants and CDC Responses added to Section VIII - Other Information.

Notice of Funding Opportunity Type

Reissue of RFA-DP-14-001

Agency Notice of Funding Opportunity Number

RFA-DP-18-002

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

93.135

Category of Funding Activity:

Health

NOFO 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: Epilepsy, Cancer, and Oral Health.

Key Dates

Publication Date:

To receive notification of any changes to RFA-DP-18-002, 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:	**01/22/2018**
Application Due Date:	**03/06/2018**

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:	**05/01/2018**
Secondary Review:	**06/01/2018**
Estimated Start Date:	**09/30/2018**
Expiration Date:	**03/07/2018**
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 NOFO. Conformance to all requirements (both in the Application Guide and the NOFO) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

Note: The Research Strategy component of the Research Plan is limited to 12 pages.

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

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

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 $1,028,000 (direct and indirect) for the entire project period. It is anticipated that up to 5 awards will be made. Awards issued under this FOA are contingent upon availibility 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, 09/30/2018 ? 09/29/2019, is $1,028,000 The estimated total funding (direct and indirect) for the entire project period, 09/30/2018 ? 09/29/2019, is $1,028,000.

Application Research Strategy Length: Page limits for the Research Strategy are clearly specified in Section IV. Application and Submission Information of this announcement.

Eligible Institutions/Organizations. Institutions 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. Additional PIs are permitted, but would be referred to as Co-PIs.

Number of Applications. Only one application per institution (normally identified by a unique DUNS number) per SIP is permitted. Applicants may apply to more than one SIP; however, a separate application is required for each SIP.

Application Type. Revision

Special Date(s). None

Application Materials. See Section IV.1 for application materials. **Please note that Form E 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 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. The PRCs also serve as demonstration sites for the use of new and innovative applied public research and activities for disease prevention and health promotion. CDC administers the PRC Program and provides leadership, technical assistance, and oversight. Funded PRCs are able to compete for SIPs, research projects sponsored by CDC, HHS, and other federal agencies, to conduct research and other activities in priority areas. Funded PRCs are encouraged to apply for SIPs that expand and strengthen their PRC?s mission and increase their applied public health research activities.

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

Prevention research includes applied public health research that develops and evaluates health promotion and disease prevention and control strategies that are community- and population-based. It can involve testing interventions for efficacy, effectiveness, or translational power; may focus on primary, secondary, or tertiary prevention; or may improve health and prevent disease through approaches that involve changes to individual behavior, policy or environmental structure, health systems, or socio-economic factors. Prevention research may provide initial evidence of the efficacy or effectiveness of a health promotion or prevention strategy, raise current evidence to a higher level, or provide evidence of the effectiveness of a practice-based strategy.

Healthy People 2020 and other National Strategic Priorities

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
2. The National Prevention Strategy
3. CDC?s Winnable Battles

4. NCCDPHP?s Four 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 Epilepsy; Cancer; Oral Health. The following are the current SIPs and associated topic areas:

Epilepsy: SIP 18-001;

Cancer: SIP 18-002;

Oral Health: SIP 18-003.

Public Health Impact

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

SIP 18-001 Targeting Treatment Gaps: Describing When, How Quickly, And Why Persons with Epilepsy Are Referred For Specialty Care

Findings from this study can inform health system interventions that can facilitate more appropriate and timely diagnosis and treatment to optimize health outcomes in people with epilepsy. Health system interventions based on the findings from this project may reduce barriers and speed up the diagnosis and the appropriate treatment of epilepsy so that patients with epilepsy receive the best available care.

SIP 18-002 Effect of Survivorship Care Plans on Cancer Survival

This project will help improve care for cancer survivors by determining the health impact of survivorship care plans.

SIP 18-003 Enhancing Surveillance of Fluorosis

This project can improve the measurement of dental fluorosis. In addition, findings could guide development of new examination protocols and innovative or new technology that may be more valid and reliable.

Relevant Work

As appropriate, this information will be provided for each SIP in the individual descriptions contained in **Section IX. Special Interests Project Descriptions** of this announcement.

2. Approach

As appropriate, the information that follows (up to Section II. Award Information) will be

provided for each SIP in the individual descriptions contained in **Section IX. Special Interests Project Descriptions** of this announcement to include:

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

References:

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

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:

Revision (formerly Competing Supplement) - Request for additional funds for a current award

to expand the scope of work. Applicants should contact the awarding agency for advice on submitting any revision/supplement application.

Estimated Total Funding: $1,028,000

The estimated total funding (direct and indirect costs) for the first budget period and project period, 09/30/2018 – 09/29/2019, is $1,028,000.

Anticipated Number of Awards: 5

SIP 18-001 Targeting Treatment Gaps: Describing When, How Quickly, And Why Persons with Epilepsy Are Referred For Specialty Care - It is anticipated that approximately $278,000 is available to fund 2 Prevention Research Centers for a 1-year project period. The average award for each recipient is expected to be approximately $139,000 for year one. The year one ceiling is $139,000. Funding may vary and is subject to change.

SIP 18-002 Effect of Survivorship Care Plans on Cancer Survival - It is anticipated that approximately $450,000 is available to fund 2 Prevention Research Centers for a 1-year project period. The average award for each recipient is expected to be approximately $225,000 for year one. The year one ceiling is $450,000. Funding may vary and is subject to change.

SIP 18-003 Enhancing Surveillance of Fluorosis - It is anticipated that approximately $300,000 is available to fund 1 Prevention Research Center(s) for a 1-year project period. Funding may vary and is subject to change. The year one ceiling is $300,000.

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

Award Ceiling: $450,000 Per Project Period
Award Floor: $0 Per Project Period
Total Period of Performance Length: 1 year(s)

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

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

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:

Public and State controlled institutions of higher education
Private institutions of higher education

Additional Eligibility Category:

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

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

2. Foreign Organizations

Foreign Organizations are not eligible to apply.

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

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

3. Special Eligibility Requirements

Competition is limited to investigators at Prevention Research Center (PRC) institutions funded under DP-14-001.

Special eligibility requirements may apply to each SIP. For SIP 18-001 “Targeting Treatment Gaps: Describing When, How Quickly, And Why Persons with Epilepsy Are Referred For Specialty Care”, the specific eligibility criteria can be found under “Eligibility Requirements” in Section IX Special Interests Project Description.

4. Justification for Less than Maximum Competition

Competition is limited to PRCs 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 project period costs does not exceed the project period ceiling amount for the specific SIP (see Section II. Award Information).

Non-responsive 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 recipient organization **must** notify potential sub-recipients that no organization may receive a subaward under the grant unless the organization has provided its DUNS number to the recipient organization.

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

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

9. Cost Sharing

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

10. Number of Applications

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

Only applicants affiliated with institutions funded as PRCs under CDC Notice of Funding Opportunity (NOFO) DP14-001 are eligible to compete for Special Interest Project (SIP) supplemental funding. Only one SIP application is permitted per PRC institution (normally identified by a unique DUNS number). A Prevention Research Center institution may apply for more than one SIP; however, a separate application is required for each 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 limitations described in this individual NOFO must be followed. For this specific NOFO, the Research Strategy component of the Research Plan narrative is limited to 12 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed10 PDF files with a maximum 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-responsive 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 https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf and here: https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf, except where instructed in this Notice of Funding Opportunity to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.
The forms package associated with this NOFO 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 NOFO. 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/funding/424/index.htm.

Duplication of Efforts

Applicants are responsible for reporting if this application will result in programmatic, budgetary, or commitment overlap with another application or award (i.e. grant, cooperative

agreement, or contract) submitted to another funding source in the same fiscal year. Programmatic overlap occurs when (1) substantially the same project is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific objective and the project design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source. Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source. Commitment overlap occurs when an individual's time commitment exceeds 100 percent, whether or not salary support is requested in the application. Overlap, whether programmatic, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. Any overlap will be resolved by the CDC with the applicant and the PD/PI prior to award. Report Submission: The applicant must upload the report in Grants.gov under "Other Attachment Forms." The document should be labeled: "Report on Programmatic, Budgetary, and Commitment Overlap."

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 "Revision" only for each submission. NOTE: The application is identified as a Revision. An introduction is required.

- Field # 11 (Descriptive Title of Applicant's Project): Applicants must enter the title of their SIP application.

These responses are necessary for SIP applications to be submitted and processed electronically. If your application is incomplete or non-responsive to these four requirements, it will not be processed. NOTE: These special instructions have been changed for this announcement. Please read carefully and include these required changes in your application.

If an applicant selects Revision on #8 (Type of Application) of the RR SF424 Cover Page, then the applicant **MUST** attach a file to the Introduction field in the Research Plan form. The field is mandatory. If the applicant does not follow these rules, then the application will fail

submission to **Grants.gov**.

3. Letter of Intent

Due Date for Letter of Intent: **01/22/2018**

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 institution(s)

SIP number and title of SIP proposal

The letter of intent should be sent electronically to:

Natalie J. Darling, Scientific Program Official

Extramural Research Program Operations and Services

Centers for Disease Control and Prevention

4770 Buford Highway, NE

Mailstop F-80

Atlanta, GA 30342

Telephone: (770)-488-5740

Email: ndh6@cdc.gov

4. Required and Optional Components

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

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 Notices of Funding Opportunities(NOFOs). Specifically, some of the following 16 components are for Resubmissions or Revisions only. See the SF 424 (R&R) Application Guidehttps://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf and here: https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf for additional

information. Please attach applicable sections of the following Research Plan components as directed in Part 2, Section 1 (Notice of Funding Opportunity Description).
Follow the page limits stated in the SF 424 (R&R) unless otherwise specified in the NOFO. As applicable to and specified in the NOFO, the application should include the bolded headers in this section and should address activities to be conducted over the course of the entire project, including but not limited to:

1. Introduction to Application (for Resubmission and Revision ONLY) - provide a clear description about the purpose of the proposed research and how it addresses the specific requirements of the NOFO.
2. Specific Aims – state the problem the proposed research addresses and how it will result in public health impact and improvements in population health.
3. Research Strategy – the research strategy should be organized under 3 headings: Significance, Innovation and Approach. Describe the proposed research plan, including staffing and timeline.
4. 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 NOFO. All instructions in the SF424 (R&R) Application Guide https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf and here: https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf must be followed along with any additional instructions provided in the NOFO.

Applicants that plan to collect public health data must submit a Data Management Plan (DMP) in the Resource Sharing Plan section of the PHS 398 Research Plan Component of the application. A DMP is required for each collection of public health data proposed. Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds.
The DMP may be outlined in a narrative format or as a checklist but, at a minimum, should include:
• Descriptions of the data to be produced in the proposed project
• How access will be provided to the data (including provisions for protection of privacy, confidentiality, security, intellectual property, or other rights)
• Use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use
• Plans for archival and long-term preservation of the data, or explaining why long-term preservation and access cannot be justified
Examples of DMPs may be found here: University of California https://dmp.cdlib.org/, or USGS, http://www.usgs.gov/datamanagement/plan/dmplans.php

Research Plan

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

To see details of the research plan requirements for each SIP, see **Section IX. Special Interest Project Descriptions** of this announcement.

6. Appendix

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

7. Page Limitations

All page limitations described in this individual NOFO must be followed. For this specific NOFO, the Research Strategy component of the Research Plan narrative is limited to 12 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 30 pages for all appendices.

8. Format for Attachments

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

and agency staff. Applicants should ensure that all attachments are uploaded to the system. **CDC requires all text attachments to the Adobe application forms be submitted as PDFs and that all text attachments conform to the agency-specific formatting requirements noted in the SF424 (R&R) Application Guide** https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf and here: https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf.

9. Submission Dates & Times

Part I. Overview Information contains information about Key Dates. Applicants are 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 (https://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 NOFO (ogstims@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: **03/01/2018**

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

10. Intergovernmental Review (E.O. 12372)

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

11. Funding Restrictions

All HHS/CDC awards are subject to the federal regulations, 45 CFR 75, terms and conditions,and other requirements described in the HHS Grants Policy Statement. Pre-award costs may be allowable as an expanded authority, but only if authorized by CDC.
In accordance with the United States Protecting Life in Global Health Assistance policy, all non-governmental organization (NGO) applicants acknowledge that foreign NGOs that receive funds provided through this award, either as a prime recipient or subrecipient, are strictly prohibited, regardless of the source of funds, from performing abortions as a method of family planning or engaging in any activity that promotes abortion as a method of family planning, or to provide financial support to any other foreign non-governmental organization that conducts such activities. See Additional Requirement (AR) 35 for applicability (https://www.cdc.gov/grants/additionalrequirements/ar-35.html).
For more information on expanded authority and pre-award costs, go to: https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf.
CDC requires that mechanisms for, and cost of, public health data sharing be included in grants, cooperative agreements, and contracts. The cost of sharing or archiving public health data may also be included as part of the total budget requested for first-time or continuation awards. Fulfilling the data-sharing requirement must be documented in a Data Management Plan (DMP) that is developed during the project planning phase prior to the initiation of generating or collecting public health data and must be included in the Resource Sharing Plan(s) section of the PHS398 Research Plan Component of the application.
Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds

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

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

If an applicant requests a funding amount greater than the ceiling for the first year of the SIP, HHS/CDC will consider the application non-responsive and it will not enter into the review process. HHS/CDC will notify the applicant that the application did not meet the submission requirements.

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 NOFO requires an evaluation plan, are outputs identified and are measures/metric to assess outcomes included?

- If the NOFO requires a dissemination plan, does the application describe how the research results will be shared with academic and practice audiences?
- If the NOFO requires a translation plan, does the application describe how the results from the research will be translated 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 (https://www.cdc.gov/maso/Policy/Policy_women.pdf and the policy on the Inclusion of Persons Under 21 in Research(https://www.cdc.gov/maso/Policy/policy496.pdf).

Vertebrate Animals
The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section (https://grants.nih.gov/grants/olaw/VASchecklist.pdf).

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

Dual Use Research of Concern
Reviewers will identify whether the project involves one of the agents or toxins described in the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern, and, if so, whether the applicant has identified an IRE to assess the project for DURC potential and develop mitigation strategies if needed.
For more information about this Policy and other policies regarding dual use research of concern, visit the U.S. Government Science, Safety, Security (S3) website at: http://www.phe.gov/s3/dualuse. Tools and guidance for assessing DURC potential may be found at: http://www.phe.gov/s3/dualuse/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: https://www.cdc.gov/grants/additionalrequirements/ar-25.html
New additional requirement: CDC requires recipients for projects and programs that involve data collection or generation of data with federal funds to develop and submit a Data Management Plan (DMP) for each collection of public health data.
Investigators responding to this notice of funding opportunity should include a detailed DMP in the Resource Sharing Plan(s) section of the PHS 398 Research Plan Component of the application. The AR-25 outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.
The DMP should be developed during the project planning phase prior to the initiation of collecting or generating public health data and will be submitted with the application. The submitted DMP will be evaluated for completeness and quality at the time of submission.
The DMP should include, at a minimum, a description of the following:
• Type of data to be produced in the proposed project;
• Mechanisms for providing access to and sharing of the data (including provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights);
• Use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use; and
• Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified.
Applications submitted without the required DMP may be deemed ineligible for award unless submission of DMP is deferred to a later period depending on the type of award, in which case, funding restrictions may be imposed pending submission and evaluation.

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research. The applicant can obtain guidance for completing a detailed justified budget on the CDC website, at the following Internet address: http://www.cdc.gov/grants/interestedinapplying/applicationresources.html

The budget can include both direct costs and indirect costs as allowed.
Indirect costs could include the cost of collecting, managing, sharing and preserving data.
Indirect costs on grants awarded to foreign organizations and foreign public entities and performed fully outside of the territorial limits of the U.S. may be paid to support the costs of compliance with federal requirements at a fixed rate of eight percent of modified total direct costs exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000. Negotiated indirect costs may be paid to the American University, Beirut, and the World Health Organization.
Indirect costs on training grants are limited to a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and sub-awards in excess of $25,000.
If requesting indirect costs in the budget, a copy of the indirect cost rate agreement is required. Include a copy of the current negotiated federal indirect cost rate agreement or cost allocation plan approval letter.
The applicant can obtain guidance for completing a detailed justified budget on the CDC website, at the following Internet address: https://www.cdc.gov/grants/documents/Budget-Preparation-Guidance.docx

4. Review and Selection Process

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

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

- Will receive a written critique.

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

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

As part of the scientific peer review, all applications:

- Will receive a second level of review (Secondary Review) by

HHS/CDC/NCCDPHP/ERPOS.

Following initial peer review, recommended applications will receive a third 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.

Review of risk posed by applicants.
Prior to making a Federal award, CDC is required by 31 U.S.C. 3321 and 41 U.S.C. 2313 to review information available through any OMB-designated repositories of government-wide eligibility qualification or financial integrity information as appropriate. See also suspension and debarment requirements at 2 CFR parts 180 and 376.
In accordance 41 U.S.C. 2313, CDC is required to review the non-public segment of the OMB-designated integrity and performance system accessible through SAM (currently the Federal Recipient Performance and Integrity Information System (FAPIIS)) prior to making a Federal award where the Federal share is expected to exceed the simplified acquisition threshold, defined in 41 U.S.C. 134, over the period of performance. At a minimum, the information in the system for a prior Federal award recipient must demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics. CDC may make a Federal award to a recipient who does not fully meet these standards, if it is determined that the information is not relevant to the current Federal award under consideration or there are specific conditions that can appropriately mitigate the effects of the non-Federal entity's risk in accordance with 45 CFR §75.207.
CDC's framework for evaluating the risks posed by an applicant may incorporate results of the evaluation of the applicant's eligibility or the quality of its application. If it is determined that a Federal award will be made, special conditions that correspond to the degree of risk assessed may be applied to the Federal award. The evaluation criteria is described in this notice of funding opportunity.
In evaluating risks posed by applicants, CDC will use a risk-based approach and may consider any items such as the following:
(1) Financial stability;
(2) Quality of management systems and ability to meet the management standards prescribed in this part;
(3) History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;
(4) Reports and findings from audits performed under subpart F 45 CFR 75 or the reports and findings of any other available audits; and
(5) The applicant's ability to effectively implement statutory, regulatory, or other requirements

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

5. Anticipated Announcement and Award Dates

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

Section VI. Award Administration Information

1. Award Notices

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

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

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

2. CDC Administrative Requirements

Overview of Terms and Conditions of Award and Requirements for Specific Types of Grants

Administrative and National Policy Requirements, Additional Requirements (ARs) outline the administrative requirements found in 45 CFR Part 75 and the HHS Grants Policy Statement and other requirements as mandated by statute or CDC policy. CDC programs must indicate which ARs are relevant to the NOFO. All NOFOs from the Center for Global Health must include AR-35. Recipients must then comply with the ARs listed in the NOFO. Do not include any ARs that do not apply to this NOFO. NOFO Recipients must comply with administrative and national policy requirements as appropriate. For more information on the Code of Federal Regulations, visit the National Archives and Records Administration: http://www. access.gpo.gov/ nara/cfr/cfr-table- search.html.

Specific requirements that apply to this NOFO are the following:

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

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 NOFO:

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

Federal Funding Accountability and Transparency Act of 2006 Federal Funding Accountability and Transparency Act of 2006 (FFATA), P.L. 109–282, as amended by section 6202 of P.L. 110–252, requires full disclosure of all entities and organizations receiving Federal funds including grants, contracts, loans and other assistance and payments through a single, publicly accessible website, www.usaspending.gov. For the full text of the requirements, please review the following website: https://www.fsrs.gov/.

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

manner. For more information on this law, go to: http://www.plainlanguage.gov/plLaw/index.cfm.

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

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. Recipients (foreign and domestic) receiving CDC funding on or after September 24, 2015 are subject to this policy. Research funded by CDC involving the agents or toxins named in the policy, must be reviewed to determine if it involves one or more of the listed experimental effects and if so, whether it meets the definition of DURC. This review must be completed by an Institutional

Review Entity (IRE) identified by the funded institution.
Recipients also must establish an Institutional Contact for Dual Use Research (ICDUR). The award recipient must maintain records of institutional DURC reviews and completed risk mitigation plans for the term of the research grant, cooperative agreement or contract plus three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation.
If a project is determined to be DURC, a risk/benefit analysis must be completed. CDC will work collaboratively with the award recipient to develop a risk mitigation plan that the CDC must approve. The USG policy can be found at http://www.phe.gov/s3/dualuse.
Non-compliance with this Policy may result in suspension, limitation, restriction or termination of USG funding, or loss of future USG funding opportunities for the non-compliant USG-funded research project and of USG funds for other life sciences research at the institution, consistent with existing regulations and policies governing USG funded research, and may subject the institution to other potential penalties under applicable laws and regulations.

Data Management Plan(s)
CDC requires that all new collections of public health data include a Data Management Plan (DMP). For purposes of this announcement, "public health data" means digitally recorded factual material commonly accepted in the scientific community as a basis for public health findings, conclusions, and implementation.
This new requirement ensures that CDC is in compliance with the following; Office of Management and Budget (OMB) memorandum titled "Open Data Policy–Managing Information as an Asset" (OMB M-13-13); Executive Order 13642 titled "Making Open and Machine Readable the New Default for Government Information"; and the Office of Science and Technology Policy (OSTP) memorandum titled "Increasing Access to the Results of Federally Funded Scientific Research" (OSTP Memo).
The AR-25 https://www.cdc.gov/grants/additionalrequirements/ar-25.html outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.

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.

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.

PRC Program Project Officer (PO) 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.

CDC SIP sponsor (Project Scientist) 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

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

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

Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity depend upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.

The **Federal Funding Accountability and Transparency Act of 2006 (Transparency Act),** includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later.

Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by recipients:

1) **Information on executive compensation when not already reported through the SAM Registration; and**

2) **Similar information on all sub-awards/ subcontracts/ consortiums over $25,000.** It is a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later.

All recipients of applicable CDC grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over $25,000. See the HHS Grants Policy Statement (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

A. Submission of Reports

The Recipient Organization must provide HHS/CDC with an original, plus one hard copy of the following reports:

1. **Yearly Non-Competing Grant Progress Report** is due 90 to 120 days before the end of the current budget period. The RPPR form (https://grants.nih.gov/grants/rppr/index.htm; https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf) is to be completed on

the eRA Commons website. The progress report will serve as the non-competing continuation application. Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.

2. **Annual Federal Financial Report (FFR)** SF 425 https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.htm required and must be submitted through eRA Commons **within 90 days after the end of the calendar quarter in which the budget period ends.**

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

B. Content of Reports

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

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

- Research Aims: list each research aim/project

a) Research Aim/Project: purpose, status (met, ongoing, and unmet), challenges, successes, and lessons learned
b) Leadership/Partnership: list project collaborations and describe the role of external partners.

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

in preparing this section include:

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

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

- How will this project lead to improvements in public health?
- How will the findings, results, or recommendations been used to influence practices, procedures, methodologies, etc.?
- How will the findings, results, or recommendations contributed to documented or projected reductions in morbidity, mortality, injury, disability, or disease?

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

- New Budget Period Proposal:

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

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

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

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

narrative.

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

- Additional Reporting Requirements:

- 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.
The due date for final FFRs will continue to be 90 days after the Period of Performance end date. Recipients must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, recipients must submit a final FFR, final progress report, and Final Invention Statement and Certification within 90 days of the end of grant period. Failure to submit timely and accurate final reports may affect future funding to the organization or awards under the direction of the same Project Director/Principal Investigator (PD/PI).
FFR (SF 425) instructions for CDC recipients are now available at https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.htm. For further information, contact GrantsInfo@nih.gov. Additional resources concerning the eFSR/FFR system, including a User Guide and an on-line demonstration, can be found on the eRA Commons Support Page: https://grants.nih.gov/support/index.html
FFR Submission: The submission of FFRs to CDC will require organizations to register with

eRA Commons (Commons) (https://commons.era.nih.gov/commons/). CDC recommends that this one time registration process be completed at least 2 weeks prior to the submittal date of a FFR submission.
Organizations may verify their current registration status by running the "List of Commons Registered Organizations" query found at: https://era.nih.gov/registration_accounts.cfm.
Organizations not yet registered can go to https://commons.era.nih.gov/commons/ for instructions. It generally takes several days to complete this registration process. This registration is independent of Grants.gov and may be done at any time.
The individual designated as the PI on the application must also be registered in the Commons. The PI must hold a PI account and be affiliated with the applicant organization. This registration must be done by an organizational official or their delegate who is already registered in the Commons. To register PIs in the Commons, refer to the eRA Commons User Guide found at: https://era.nih.gov/docs/Commons_UserGuide.pdf.
3. Final Reports: Final reports should provide sufficient detail for CDC to determine if the stated outcomes for the funded research have been achieved and if the research findings resulted in public health impact based on the investment. The recipient's final report should include:

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

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

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

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

- Final Data Management Plan: Applicants must include an updated final Data Management Plan that describes the data collected, the location of where the data is stored (example: a

repository), accessibility restrictions (if applicable), and the plans for long term preservation of the data.

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

Scientific/Research Contact

Natalie J. Darling, MPH, Scientific Program Official

Extramural Research Program Operations and Services

Centers for Disease Control and Prevention

4770 Buford Highway, NE

Mailstop F-80

Atlanta, GA 30342

Telephone: (770)-488-5740

Email: ndh6@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 Notices of Funding Opportunities can be found at www.grants.gov.
All awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement.

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

Awards 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 18-001 Targeting Treatment Gaps: Describing When, How Quickly, And Why Persons with Epilepsy Are Referred For Specialty Care

Project Description

Epilepsy is a brain disorder leading to recurrent seizures, and it affects up to 3.4 million Americans [1]. It has more recently received increased public health attention because persons with epilepsy experience pronounced and persistent health and socioeconomic disparities

despite treatment advances, public awareness programs, and expanded rights for persons with disabilities [1,2,3]. About 150,000 persons in the United States are newly diagnosed each year with epilepsy. Concerns have been raised about the length of time (e.g., between 7-15 years) that some individuals, especially those with uncontrolled seizures, must wait for referrals to specialty care for additional evaluation [3].

Because epilepsy may be difficult to accurately diagnose and to appropriately treat, more information is needed to determine when, how quickly, and why persons with epilepsy are referred for neurological specialty care (for example, to a neurologist). A diagnosis of epilepsy requires the occurrence of either two unprovoked seizures occurring at least 24 hours apart; one unprovoked seizure with at least a 60% probability of further seizures over 10 years; or a diagnosis of an epilepsy syndrome [4]. Moreover, many different anti?seizure medications are available in the United States to reduce seizure occurrence. Appropriate treatment for persons diagnosed with epilepsy may therefore be difficult for non-specialist physicians to prescribe without referral for specialty care.

All persons with epilepsy who have uncontrolled seizures should receive appropriate medical care as operationalized in the Healthy People 2020 Disability and Health--Barriers to Care objective DH-6 [see below] by having visited a neurologist or epilepsy specialist in the past year. However, practice guidelines and published informal recommendations have advised different options for when a person with epilepsy should be referred to a neurologist for treatment, either at epilepsy onset or if early treatment after diagnosis fails to reduce seizures [3,5,6,7]. These guidelines aim to clarify decision points regarding under what circumstances people with epilepsy should obtain referrals to specialists (e.g., seizure control is not achieved after two anti-seizure drugs) and which type of specialist (e.g., neurologist, epileptologist) they should see [3]. For example, some guidelines stipulate referral to a specialist/neurologist only if a primary care provider's treatment approach does not reduce seizures within 6 months to a year; and referral to a neurologist within a few weeks of a primary care provider's initial diagnosis for definitive diagnosis and appropriate treatment. Because of high rates of impaired physical and mental health, comorbidity, and disability, and because of the variability in types and quality of care trajectories among people with epilepsy, the 2012 Institute of Medicine Report on the Public Health Dimensions of the Epilepsies prioritized the need to assess differences in the utilization of epilepsy health care services, particularly for underserved populations, in order to identify best practices and improve quality of care [3].

The purpose of this special interest project is to use existing data (e.g., claims data; electronic records in a health care system, or a registry of epilepsy cases) to describe when, how quickly, and why persons with epilepsy are referred for specialty care (neurologist). Findings from this study can inform health system interventions that can facilitate more appropriate and timely diagnosis and treatment to optimize health outcomes in people with epilepsy.

Project Objectives/Outcomes

1. Design a study using existing data to ascertain a sample of epilepsy cases, representative of the U.S. population distribution (e.g., age, sex, race/ethnicity) whose sociodemographic, medical characteristics, and access to specialty care can be described and that had already been followed, up to five-years after their first documented seizure (at epilepsy onset), or during their subsequent treatment after epilepsy diagnosis (the course of epilepsy).

2. Use existing data to answer these and related research questions:
3. Are there sociodemographic characteristics of epilepsy patients that are associated with referrals to neurologists?
4. Are there medical characteristics of epilepsy patients that are associated with referrals to neurologists?
5. Do referrals of epilepsy patients to neurologists result in changes in epilepsy diagnosis or treatment?
6. Do referrals of epilepsy patients to neurologists result in changes in diagnoses of comorbidity and associated treatment?
7. Develop a dissemination plan to describe study findings at a national conference or through publication(s) in a peer-reviewed medical journal.

Public Health Priorities

Healthy People 2020 Topic and Objective: Disability and Health - Objective 6: Increase the proportion of people with epilepsy and uncontrolled seizures who receive appropriate medical care.

National Prevention Strategy Key Direction/Priority: Reduce disparities in access to quality health care.

NCCDPHP Domains: Determines baseline epidemiologic information in a representative population of the characteristics of referrals of persons with epilepsy to specialty care (for example, a neurologist) for the definitive diagnosis and the effective treatment of epilepsy. Health system interventions based on these determinations may reduce barriers and speed up the diagnosis and the appropriate treatment of epilepsy so that patients with epilepsy receive the best available care.

Project Activities and Submission Requirements

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

Study design and methods

Provide the study rationale, methods, and an analytical plan to describe when and how quickly specialty referrals occurred, why these referrals occurred, and whether such referrals led to changes in the epilepsy diagnosis or in epilepsy treatment after the referral, and associations, if any, with patient characteristics.

Target population

Persons with epilepsy of all ages from a representative sample of the U.S. population (e.g., age; sex, race/ethnicity, etc.) that had already been followed up to five years either after their first documented seizure (at epilepsy onset) or during their subsequent treatment after epilepsy diagnosis (the course of epilepsy).

Collaboration/Partnership

Collaborations with health care system(s) or groups who have access to a sample of U.S. epilepsy cases that had already been followed, up to five years either after their first documented seizure or during their subsequent treatment after diagnosis to determine referral patterns. Investigators are encouraged to collaborate with technical advisors or other subject

matter experts from national organizations that address epilepsy (e.g., National Epilepsy Foundation; American Epilepsy Society; National Association of Epilepsy Centers; Epilepsy Leadership Council).

Describe and provide evidence of sufficient institutional and other necessary support for carrying out this project. Identify key staff who will be involved in the project. For each person, describe their demonstrated knowledge, experience, and ability in planning and carrying out this project.

Annual Action Plan

Provide a detailed timeline with milestones for completing the proposed activities to accomplish this project within the 12-month project period. Develop a timeline to provide monthly reports on the activities completed and a final report summarizing the project accomplishments.

Evaluation Plan/Performance measurement

The applicant should provide a timeline with measurable objectives and outcomes. Outcomes should include:

1. A written overview of all U.S. practice guidelines and recommendations for referrals to specialty care within the past 10 years, and selection of one or more guidelines that will guide the study design.

2. Participation in monthly conference calls with CDC scientific collaborator to describe project progress and to discuss technical assistance needs;

3. A report describing the results of the analyses associating patient sociodemographic and medical characteristics to the observed referral patterns and characteristics

Dissemination Plan

Describe how the project applicant will disseminate findings from the review of the medical literature and from the results of the analyses on referral patterns of persons with epilepsy to neurological specialty care (for example, through a presentation at a national conference or a publication in a peer-reviewed medical journal).

Public Health Impact

Health system interventions based on the findings from this project may reduce barriers and speed up the diagnosis and the appropriate treatment of epilepsy so that patients with epilepsy receive the best available care.

Eligibility Criteria

The following criteria is specific to SIP 18-001 and will be used to determine the institution's eligibility:

Demonstrated access to the target population through availability of existing data (e.g., claims data; electronic records in a health care system, or a registry of epilepsy cases) with appropriate records that had already followed persons with epilepsy up to five years either after their first documented seizure or during their subsequent treatment after diagnosis to determine referral patterns. The documentation (e.g., MOU, collaborator letter) must include confirmation of access to data at time of application or within 60 days of award.

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:

- Include a research team with documented expertise in epilepsy or neurology?
- Include a research team with documented expertise in epidemiology?
- Describe the socio-demographic characteristics and size of the study population?
- Describe the methods of case ascertainment and data variables to be examined?
- Does the applicant ensure access to a study population at time of application or within 60 days of award?
- Does the applicant provide evidence of a study population with sufficient size to provide reasonable precision in statistical estimates of critical importance?
- Provide evidence of a feasible analytical plan in place?
- Describe the representativeness of study population (i.e., how well the study sample generalizes to the U.S. population distribution)?
- Describe the representativeness of the epilepsy population (i.e., how well the study sample generalizes to people with different types of epilepsy)?

Funding Preferences

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

1. Size of study population
2. Generalizability of study population to the US population by age, sex, race/ethnicity, socioeconomic status

Research Plan Length and Supporting Material

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

Availability of Funds

It is anticipated that approximately $278,000 is available to fund 2 Prevention Research Center(s) for a 1-year project period. The average award for each recipient is expected to be approximately $139,000 for year one. The year one ceiling is $139,000. 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. Zack MM, Kobau R. National and State Estimates of the Numbers of Adults and Children with Active Epilepsy — United States, 2015. MMWR Morb Mortal Wkly Rep 2017;66:821–825.
2. Koh HK, Kobau R, Whittemore VH, et al. Toward an integrated public health approach for epilepsy in the 21st century. Prev Chronic Dis 2014;11:E146. https://doi.org/10.5888/pcd11.140270.
3. Institute of Medicine. Epilepsy across the spectrum: promoting health and understanding. Washington, DC: The National Academy Press; 2012. http://www.nationalacademies.org/hmd/Reports/2012/Epilepsy- Across-the-Spectrum/Report-Brief.aspx.
4. Fisher RS, Acevido C, Arzimanoglou A, et al. A practical clinical definition of epilepsy. Epilepsia 2014;55:475–82.
5. Smith MC, Bulow JM. Epilepsy. Disease-A-Month 1996;42:1-100.
6. Labiner DM, Ahern GL (2002) Neurologic consultation for seizures. Postgraduate Medicine 2002;111:53-64.
7. The National Institute of Health and Clinical Excellence. National Clinical Guideline Centre. The epilepsies: The diagnosis and management of the epilepsies in adults and children in primary and secondary care. Pharmacological Update of Clinical Guideline 20. Methods, evidence, and recommendations. January 2012. https://www.nice.org.uk/guidance/cg137/evidence/full-guideline-pdf-6664855034.

SIP 18-002 Effect of Survivorship Care Plans on Cancer Survival

Project Description

A priority of the National Comprehensive Cancer Control Program (NCCCP) is to address the public health needs of cancer survivors. Survivorship care plans provide a record of cancer history and treatment, outline future need for follow up, tests, possible long-term effects of cancer treatment, and identify health care providers responsible for care. Accrediting organizations, such as the Commission on Cancer, have also included the use of survivorship care plans as a mandatory requirement for hospital accreditation. While there has been increased implementation of survivorship care plans, there is limited evidence that survivorship care plans increase survival among cancer survivors (1). This project will evaluate the effectiveness of

survivor care plans on cancer survival. CDC plans to disseminate the results widely within the NCCCP as well as to others who care for cancer survivors.

Project Objectives/Outcomes

In 2006, the Institute of Medicine recommended that every cancer patient receive a survivorship care plan. However, there is limited evidence that survivorship care plans increase survival among cancer survivors. The objective of this project is to determine whether survivorship care plans increase survival among cancer survivors.

Public Health Priorities

Healthy People 2020 Topic and Objective: Cancer Objective C13: Increase the proportion of cancer survivors who are living 5 years or longer after diagnosis. The results of this project will guide recommendations to CDC-funded National Comprehensive Cancer Control programs and others on the use of survivorship care plans to increase survival among cancer survivors.

National Prevention Strategy Key Direction/Priority: Clinical and Community Preventive Services: This project will evaluate whether survivorship care plans are effective in increasing survival among cancer survivors.

NCCDPHP Domains: Health Care system interventions . This project aims to measure the effectiveness of survivorship care plans, which are widely disseminated by health care systems. Improving understanding of the utility of survivorship care plans will improve health care system interventions for cancer survivors.

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 design of the research study and analytic methodology capable of:

- Determining whether survivorship care plans increase survival among cancer survivors
- Utilizing existing data- either public use or another data set approved by local IRB for this project
- Examining survival outcomes by survivorship care plan status for the top 5 leading causes of cancer death and by clinical and sociodemographic characteristics such as age, sex, race, ethnicity, poverty, cancer type, cancer stage, comorbidities, treatment modality, and year of treatment
- Providing 5-year and 10-year survival data by cancer survivorship plan status

Collaboration/Partnerships

The applicant is expected to consult or partner with other institutions or experts in the field as needed to accomplish the project's aims and objectives. Identify key staff who will be devoted to the project. For each person, describe their demonstrated knowledge, experience, and ability in conducting the project described above.

Annual Action plan

Provide a detailed timeline for defining milestones, completing proposed activities and a

detailed report within the 12-month project period.

Dissemination plan

Provide a plan for disseminating the methodology and results of this project through peer-reviewed manuscripts and other types of communication (webinar for programs, fact sheet for programs, etc.).

Public Health Impact

In 2006, the Institute of Medicine recommended that every cancer survivor should receive an individualized survivorship care plan. While there has been increased implementation of survivorship care plans, there is limited evidence that survivorship care plans increase survival among cancer survivors. This project will help improve care for cancer survivors by determining the health impact of survivorship care plans.

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 determining the scientific merit and priority score:

Does the applicant demonstrate:

- Access to existing data that includes:
    - cancer survival
    - receipt of cancer survivorship plans
    - clinical and sociodemographic elements noted above (Study design and Methods)
- Ability to design a study capable of comparing survival differences among cancer survivors by survivorship care plan status?
- Ability to secure data and obtain IRB approval within 4 months of start of project?
- Ability to conduct the study and perform all analyses within the one- year project period?
- Experience with survival analyses?

Funding Preferences

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

- Racial/ethnic diversity of study population to ensure that the results adequately represent all populations.
- Number of cancer types examined

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 $450,000 is available to fund 2 Prevention Research Center(s) for a 1-year project period. The average award for each recipient is expected to be approximately $225,000 for year one. The year one ceiling is $450,000. 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. Hewitt M, Greenfield S, Stovall E. From Cancer Patient to Cancer Survivor: Lost in Transition. Washington DC: National Academies Press; 2006.

SIP 18-003 Enhancing Surveillance of Fluorosis

Project Description

Community water fluoridation (CWF) is recognized as one of the 10 major public health achievements of the 20st century (1). Since 1945, CWF has played an important role in reducing tooth decay in children and tooth loss in adults (1, 2). US Scientific reviews, including those by the Community Preventive Services Task Force, have concluded that CWF is effective in reducing the prevalence and severity of tooth decay in communities (2). In addition to drinking water, some children ingest other sources of fluoride, such as from toothpaste and fluoride supplements. While these sources have contributed to the decline in tooth decay, they also have increased the chance of dental fluorosis, a visually detected change in a tooth's appearance (2). Dental fluorosis can only develop when too much fluoride is taken in during the time teeth are developing under the gums, from birth through 8 years of age (1, 2). In 2015, the US Public Health Service (USPHS) lowered the recommended concentration of fluoride in water to provide a better balance of reducing tooth decay while limiting the chance of dental fluorosis (3). Ongoing surveillance activities will monitor any changes in tooth decay, dental

fluorosis, and fluoride intake that may occur following implementation of the USPHS recommendation.

A common surveillance measure for fluorosis used at the community level or population level is Dean's Index with six categories, i.e., normal, questionable, very mild, mild, moderate, and severe. The inclusion of a "questionable" category and the subjective nature of categorizing milder forms based on visual assessment, however, are among the factors that can affect examiner reliability (4, 5). In addition, the public health relevance of each of six categories of fluorosis severity included in Dean's Index needs further examination and the possibility of reducing the number of categories considered. The purpose of this SIP is to enhance the measurement of fluorosis by developing modified measures(s) that are valid, reliable, and feasible for surveillance at the community level. To assure the public's health, these measures would focus on a more reliable clinical assessment of fluorosis.

More specifically, the project aims to improve the reliability, validity, and public health relevance of fluorosis detection and measurement by:

- Modifying Dean's Index or another fluorosis index (e.g., reducing the number of fluorosis classifications) (6-9);
- Identifying promising technology, e.g., digital image analysis of photographs (10), to assess or enhance clinical assessment of presence and severity of fluorosis.

Public Health Priorities

Healthy People 2020 Topic and Objectives:

OH-1 Reduce the proportion of children and adolescents with dental caries experience.

OH-2 Reduce the proportion of children and adolescents with untreated dental decay.

OH-3 Reduce the proportion of adults with untreated dental decay.

OH-13 Increase the proportion of the U.S. population served by community water systems with optimally fluoridated water.

National Prevention Strategy: This initiative takes into account the delay in receipt of preventive interventions such as Community Water Fluoridation, which aligns with the National Prevention Strategy goal of reduction in health disparities of underserved populations. The goal to reduce health disparities includes empowering the public with tools and information to make healthy choices. This project will include guidance on how to measure fluoride risk, and help to improve messaging and identify best dental preventive approaches.

NCCDPHP Chronic Disease Prevention and Health Promotion Domains: This project aligns with Domain #1 Epidemiology and Surveillance, which focuses on providing data and conducting research to inform, prioritize, deliver, and monitor programs and population health.

Project Activities and Submission Requirements:

The applicant should demonstrate the ability to produce a detailed project plan addressing the activities below:

- Assess the current state of the science to evaluate the appropriateness, relevance, and accuracy of Dean's Index and, potentially, other indices in current use, to assess dental

fluorosis at the community level.

- Complete an analysis of existing data – public-use or approved by local IRB, to determine the strengths and weaknesses of a simplified measure compared to the original measure. Simplification would include fewer categories of severity of the Dean's Fluorosis Index. Gather sufficient sample size to ensure validity of estimates for the correlation between fluorosis presence and severity on upper incisors compared to late-forming posterior teeth, excluding 3rd molars.
- Conduct an assessment, e. g. an environmental scan, of upcoming and new technology that could be used to assess changes in the appearance or structure of the tooth surface associated with dental fluorosis.
- Convene a small working group of researchers, recognized for their subject matter expertise related to the key objectives of the project, in order to facilitate and inform the process of the accomplishing the project aims to modify e.g. Dean's Fluorosis index.
- Evaluate the potential of emerging technologies, e.g., digital image analysis, to improve validity and reliability of detecting and quantifying fluorosis severity, in place of or in combination with examiner visual assessment, as measured by Dean's Index or a modified index.

Applications submitted in response to this SIP should consider the following areas as they develop and address the project aims.

Study design and methods

Describe the design of the research study and methodology capable of:

- Comparing reliability and validity of a simplified index with Dean's Index consisting of 6 categories
- Utilizing existing data – either public use or another data set approved by local IRB for this project
- Identifying modified measures that are valid, reliable, and feasible for surveillance at the community level.

Target population

U.S. children and adolescents, aged 6 years and older.

Collaboration/Partnerships

The applicant is expected to consult with other experts in the field who have knowledge of ongoing research in fluorosis measurement and emerging technologies related to this project's aims and project activities.

The applicant is expected to provide a description of key staff who will be devoted to the project. For each person, describe their demonstrated knowledge, experience, and ability in planning and conducting research proposed in the application.

Annual Action Plan

Provide a detailed timeline for defining milestones, completing proposed activities and a detailed report within the 12-month project period.

Dissemination Plan

Describe a plan to disseminate the findings of the research using scientific publications in the peer-reviewed literature; presentations at relevant scientific meetings

Public Health Impact

This project can improve the measurement of dental fluorosis. In addition, findings could guide development of new examination protocols and innovative or new technology that may be more valid and reliable.

Additional Review Criteria

In addition to the standard review criteria used to evaluate the scientific and technical merit of research applications (Significance, Approach, Innovation, Investigators, and Environment) 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:

- Knowledge of dental public health and published research relevant to evaluating fluorosis indices?
- Familiarity with data sources that can be used to complete the evaluation of indices used for clinical examiner assessment of fluorosis?
- Identification and access to an existing data set to be used to accomplish the study objectives?

Funding Preferences

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

- Generalizability of the findings to the US 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 $300,000 is available to fund 1 Prevention Research Center(s) for a 1-year project period. Funding may vary and is subject to change. The year one ceiling is $300,000.

Research Status

This project may involve human subjects research including exempt research.

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

Award Administration

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

References

1. Achievements in Public Health, 1990-1999: Fluoridation of Drinking Water to Prevent Dental Caries. MMWR 1999, 48(41): 933-940.
2. Fluoride Recommendations Workgroup. Recommendations for using fluoride to prevent and control dental caries in the United States. MMWR 2001; 50(No.RR-14):1-42.
3. U.S. Department of Health and Human Services Federal Panel on Community Water Fluoridation. U.S. Public Health Service Recommendation for Fluoride Concentration in Drinking Water for the Prevention of Dental Caries. Public Health Rep 2015; 130(4):318-331.
4. Kumar JV, Swango PA, Opima PN, Green EL, Dean's Fluorosis Index: an Assessment of Examiner Reliability. J Pub Health Dent, 2000, 60(1): 57-59
5. Rozier RG, Epidemiologic Indices for Measuring the Clinical Manifestations of Dental Fluorosis: Overview and Critique, 1994, Adv Dent Res 8(1):39-556.
6. Kumar JV, Swango PA, Fluoride Exposure and dental fluorosis in Newburgh and Kingston, New York: policy implications, 1999, Community Dent Oral Epidemiol, 27:171-80.
7. Bhagavatula P, Levy SM, Broffitt B, Weber-Gaspharoni K, Warren JW, Timing of fluoride intake and dental fluorosis on late-erupting permanent teeth, Community Dent Oral Epidemiol, 2016 Feb;44(1):32-45.
8. Buzalaf MA, Levy SM, Fluoride intake of children: considerations for dental caries and dental fluorosis, Mongr Oral Sci, 2011;22:1-19.
9. Funmilayo AM, Mojirade AD, Dental Fluorosis and its Indices, What's New? Journal of Dent and Med Sci, 2014, 13(7):55-60.
10. Estai M, Kanagasingam Y, Huang B, Checker H, Steele L, Kruger E, Tennant M. The efficacy of remote screening for dental caries by mid-level dental providers using a mobile teledentistry model. Community Dent Oral Epidemiol 2016; 44:435–441.

Appendix - Questions from Potential Applicants and Responses from CDC, February 14, 2018:

General NOFO question:

Q1. I am interested in conducting additional research on preventing disability due to depression and mental distress. I saw the announcement for administrative supplements to the centers. Would you be able to tell me which currently funded centers, if any, may be interested in disability prevention, functional improvement and/or mental health?

A1. The NOFO discusses eligibility requirements and specifies that eligibility is limited to the 26 current Prevention Research Centers. The NOFO also outlines that collaboration is encouraged within and external to PRC institutions. Thus, an application must be submitted by a currently funded PRC, but can be a collaboration with one or more PRCs and include partners

from non-PRC institutions. The PRCP website (www.cdc.gov/prc) lists currently funded Centers, their Core Research Project focus, and contact information.

Specific SIP Topic Questions:

SIP 18-001 Targeting Treatment Gaps: Describing When, How Quickly, And Why Persons with Epilepsy Are Referred For Specialty Care

Q2. On this RFP — when referral is discussed to a specialist, does this mean a neurologist or an epilepsy only neurologist (an epileptologist). In epilepsy this would be at a level 2 vs a level 3 epilepsy center level. In many rural areas of the country (for example), a neurologist would be more likely available (hopefully).

A2. The NOFO describes a referral to mean neurologist or neurology clinic; however, the NOFO further indicates the intent to capture and describe the referral with all available detail. This may include neurologist, neurology clinic, epileptologist, epilepsy center or other similar categories.

Q3. I am planning to submit an application with collaborators at [one of the 26 PRCs}. We plan to submit similar applications with the plan to work collaboratively together (using different study datasets) to address the stated aims of the RFA. In effect, we would be requesting our applications to be "linked" or considered together.

I realize that any/all decision are made my CDC (with input from reviewers), but wanted to see if you had any suggestions re how we might make this specific request to reviewers and indicate in some way that our applications are intended to be considered together. The specific SIP we are applying for indicates that 2 grants will be awarded.

I am pasting our aims below. Would it be possible for us to briefly discuss? Any suggestions/input would be much appreciated!

A3. The NOFO discusses eligibility requirements and specifies that eligibility is limited to the 26 current Prevention Research Centers. The NOFO also outlines that collaboration is encouraged within and external to PRC institutions. Thus, an application must be submitted by a currently funded PRC, but can be a collaboration with one or more PRCs and include partners from non-PRC institutions. The PRCP website (www.cdc.gov/prc) lists currently funded Centers, their Core Research Project focus, and contact information.

SIP 18-002 Effect of Survivorship Care Plans on Cancer Survival

None

SIP 18-003 Enhancing Surveillance of Fluorosis

None