

Centers for Disease Control and Prevention

NATIONAL CENTER FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION

Health Promotion and Disease Prevention Research Centers: 2022 Special Interest Project Competitive Supplements (SIPS)

RFA-DP-22-003

03/04/2022

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Overview

Participating Organization(s)

Centers for Disease Control and Prevention

Components of Participating Organizations

Components of Participating Organizations:

National Center for Chronic Disease Prevention and Health Promotion

Notice of Funding Opportunity (NOFO) Title

Health Promotion and Disease Prevention Research Centers: 2022 Special Interest Project Competitive Supplements (SIPS)

Activity Code

U48

Notice of Funding Opportunity Type

New

Agency Notice of Funding Opportunity Number

RFA-DP-22-003

Assistance Listings Number(s)

93.135

Category of Funding Activity

HL - Health

NOFO Purpose

This Notice of Funding Opportunity (NOFO) will provide supplemental funding to Prevention Research Centers (PRCs), currently funded under CDC RFA-DP-19-001 to conduct Special Interest Projects (SIPs) to design, test, evaluate, disseminate and translate effective applied public health prevention research on interventions (i.e. programs, practices, policies, or strategies) and tools developed in real-world settings to address the leading causes of illness, disabilities, and death in the United States. Research projects announced in this NOFO align

with public health priorities associated with Healthy People 2030 topic areas: Cancer and Adolescents; Cancer and Health Care Access and Quality; Children with Disabilities and Care Access and Quality; Environmental Health and Emergency Preparedness; Older Adults and Dementia; People with Disabilities and Mental Health and Mental Disorders; Women, Emergency Preparedness, and Health Care Access and Quality.

Key Dates

Publication Date:

To receive notification of any changes to RFA-DP-22-003, 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:

The LOI date will generate once the Synopsis is published if Days or a Date are entered.
02/03/2022

Application Due Date:

03/04/2022
03/04/2022

On-time submission requires that electronic applications be error-free and made available to CDC for processing from the NIH eRA system on or before the deadline date. Applications must be submitted to and validated successfully by Grants.gov no later than 5:00 PM U.S. Eastern Time.

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

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

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

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

Scientific Merit Review:

04/26/2022

Secondary Review:

06/20/2022

Estimated Start Date:

09/30/2022

Expiration Date:
03/05/2022

Required Application Instructions

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

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

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

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

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

Executive Summary

- **Purpose.** Public health practitioners need scalable, feasible interventions and tools. Applied public health prevention researchers can engage communities to develop and evaluate health promotion and disease prevention interventions, disseminate new science, and translate proven effective interventions into public health practice and policy for population health benefit. This NOFO will provide supplemental funding to Prevention Research Centers (PRCs), currently funded under RFA-DP-19-001 to conduct Special Interest Projects (SIPs) to design, test, evaluate, disseminate, and translate effective applied public health prevention research strategies to include interventions (i.e., programs, practices, policies, or strategies) and tools developed in real-world settings to address the leading causes of illness, disability, and death in the United States. Research strategies align with public health priorities such as the Healthy People 2030 topic areas: Cancer and Adolescents; Cancer and Health Care Access and Quality; Children with Disabilities and Care Access and Quality; Environmental Health and Emergency Preparedness; Older Adults and Dementia; People with Disabilities and Mental Health and Mental Disorders; Women, Emergency Preparedness, and Health Care Access and Quality.
- **Mechanism of Support.** Cooperative Agreement
- **Funds Available and Anticipated Number of Awards.** The estimated total level of funding (direct and indirect for entire project period in dollars) that is available for the NOFO is $8,280,000. The estimated total funding (direct and indirect) for the first year (12-month budget period for all SIP proposals is $1,990,000. It is anticipated that up to 14 awards will be made. Awards issued under this NOFO are contingent upon availability of funds and a sufficient number of meritorious applications. Because the nature and scope of the proposed research will vary from application to application, it is also anticipated that the size and duration of each award may also vary. The total amount

awarded, and the number of awards will depend upon the number, quality, duration and cost of the applications

- **Budget and Project Period.** The estimated total funding (direct and indirect) for the first 12-month budget period, 9/30/2022 - 9/29/2023, is $1,990,000. The estimated total funding (direct and indirect) for the entire project period, 9/30/2022 to 9/29/2024, is $8,280,000. See Section VIII. Other Information - Special Interests Project Descriptions for the funding amount and project period for each individual SIP.
- **Application Research Strategy Length:** Page limits for the Research Strategy are clearly specified in Section IV. Application and Submission Information of this announcement.

- **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III, 1.A. are eligible to apply.
- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. NOTE: CDC does not make awards to individuals directly only to institutions/organizations. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply.
- **Number of PDs/PIs.** Applications may include more than one PI; however, the first PI listed on the application will be the contact PI for all correspondence **(Note: the Core PRC PI should be listed as the PI on all SIP applications. The SIP PIs should be listed as CO-PIs)**. Any additional PIs are permitted but would be referred to as Co-PIs.
- **Number of Applications.** Applicants may apply to more than one SIP; however, a separate application is required for each SIP. Multiple applications for the same SIP from the same institution are not permitted (e.g., only one application per SIP per institution is allowed).
- **Application Type.** New
- **Special Date(s).** Pre-Application Informational Call is scheduled for January 18, 2022; 1:30-3:30pm. Call-in information to be provided.
- **Application Materials**. See Section IV.1 for application materials. Please note that Form F is to be used when downloading the application package, https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/research-forms-f.pdf

Section I. Funding Opportunity Description

Statutory Authority

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

1. Background and Purpose

The CDC Prevention Research Centers (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 health research and activities for disease prevention and health promotion.

CDC administers the PRC Program and provides leadership, technical assistance, and oversight. Funded PRCs are able to compete for SIPs, research projects sponsored by CDC, HHS, and other federal agencies, to conduct research and other activities in priority areas. Funded PRCs are encouraged to apply for SIPs that expand and strengthen their PRC's mission and increase their applied public health research activities.

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

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

Healthy People 2030 and other National Strategic Priorities
This NOFO supports efforts that align with the following public health priorities:

Healthy People 2030

- Social Determinants of Health: health care access and quality
- Health topics and the associated SIPs:
    - Cancer and Adolescents: 22-001
    - Cancer and Health Care Access and Quality: 22-002
    - Children with Disabilities and Care Access and Quality: 22-003
    - People with Disabilities and Mental Health and Mental Disorders: 22-004
    - Environmental Health and Emergency Preparedness: 22-005
    - Older Adults and Dementia: 22-006
    - Women, Emergency Preparedness, and Health Care Access and Quality: 22-007

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

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

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

- Domain 1: epidemiology and surveillance;
- Domain 2: environmental approaches that promote health and support and reinforce healthful behaviors;
- Domain 3: health care system interventions; and
- Domain 4: community programs linked to clinical services
    - https://www.cdc.gov/chronicdisease/center/nccdphp/how.htm

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 22-001: Process, Outcome, and Cost Evaluation of Free Sunscreen Dispensers in Outdoor Community Settings

This project will help to fill research gaps on the impact of free sunscreen dispensers on sun-safety knowledge, attitudes, beliefs, and behaviors. Findings from this project will help to inform best practices for future community-level skin cancer prevention efforts, including work being done by CDC-funded Comprehensive Cancer Control programs.

SIP 22-002: Electronic Health Record Study to Examine Factors and Diagnostic Pathways that Facilitate Early Ovarian Cancer Diagnoses

This project will contribute to the evidence base for recommendations and best practices that clinicians and health care systems might use in identifying ovarian cancers earlier. Shifting the majority of ovarian cancer cases to earlier stages at diagnosis may lead to significant population-based increases in survival.

SIP 22-003: Improving and evaluating measures to identify tics and tic disorders including Tourette syndrome in children in epidemiologic studies and clinical settings

This project will help to (a) Improve early identification and treatment of tics to improve outcomes among people with tic disorders and co-occurring conditions; and (b) Improve how tic disorders, including Tourette syndrome (TS), are defined and measured to improve our understanding of how many people have TS, particularly among minority and underserved populations through testing and evaluating the use and accuracy of measures to identify tics and tic disorders in a demographically diverse sample of children from the general population. Improved measures can improve epidemiologic and surveillance work to better understand the prevalence of tic disorders including Tourette syndrome. If available accurate tic screeners could improve the identification and referral for treatment not only for tic disorders including TS, but also might improve identification of common mental, emotional, and behavioral disorders like attention-deficit/hyperactivity disorder (ADHD)and obsessive-compulsive disorder (OCD). Early identification and treatment may lead to improved outcomes among children with these disorders.

SIP 22-004: Disability and Health Data Collaborative: Using Data to Promote the Health and Wellness of People with Disabilities
This project will allow for improved characterization and evaluation of the health and wellness of people with disabilities. Improving access to disability data will provide an evidence-base for informed health care policy and resource allocation. Over time, increased data linkages and collaborators may use this resource to evaluate interventions designed to improve the health and well-being of people with disabilities, particularly if implemented early in the life course with the aim of promoting positive adult outcomes.

SIP 22-005: Building Resilience Against Climate Effects (BRACE): Enhancing Practical Guidance to Support Climate and Health Adaptation Planning
This project would improve the utility of the BRACE conceptual framework, by providing expanded and enhanced guidance, resources, and tools to empower communities to prepare for climate change, and address hazards such as heat waves, flooding events, and vector-borne disease. This will particularly help disproportionately impacted communities directly experiencing the inequitable health impacts of climate change. An improved BRACE package will also enhance the technical assistance Climate and Health Program (CHP) is able to provide to Climate-Ready States and Cities Initiative (CRSCI) grant recipients and other partners.

SIP 22-006: Dementia Risk Reduction Research Network – Collaborating Centers
This project will fund the Dementia Risk Reduction Research Network, a national network of academic, public health, and community partners that will improve interventions and management for people at increased risk for developing Alzheimer's disease and related dementias (ADRD) with the ultimate goal of reducing the burden of ADRD, especially for populations disproportionately impacted.

SIP 22-007: COVID-19 and Women: An Assessment of Challenges and Lessons Learned to Enhance Public Health Emergency Preparedness for Women and Families
This project seeks to obtain unique insights from women to help federal entities, stakeholder organizations, and local, statewide, and tribal communities develop effective preparedness and response plans and implement mitigation strategies to reach women and families put at increased risk in public health emergencies.

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

2. Approach

Specific information for the following is provided in Section VIII- Other Information - Special Interests Project Descriptions for each SIP:

- Objectives/Outcomes
- Public Health Priorities
- Target Population

- Collaboration/Partnerships
- Recruitment Plan
- Annual Action Plan
- Evaluation/Performance Measurement
- Dissemination Plan
- Translation Plan
- References

SIP recipients may be asked to participate in the PRC Program Evaluation Reporting System (PERS) to collect data that are used to evaluate Special Interest Projects.

Objectives/Outcomes
Specific information for each SIP is provided in Section VIII- Other Information - Special Interests Project Descriptions for each SIP.

Target Population
Specific information for each SIP is provided in Section VIII- Other Information - Special Interests Project Descriptions for each SIP.

Collaboration/Partnerships
Specific information for each SIP is provided in Section VIII- Other Information - Special Interests Project Descriptions for each SIP.

Evaluation/Performance Measurement
Specific information for each SIP is provided in Section VIII- Other Information - Special Interests Project Descriptions for each SIP.

Translation Plan
Specific information for each SIP is provided in Section VIII- Other Information - Special Interests Project Descriptions for each SIP.

3. Funding Strategy

Section II. Award Information

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

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

Estimated Total Funding:
$8,280,000

Anticipated Number of Awards:
14

The anticipated number of awards for each SIP is shown in **Section VIII. Other Information - Special Interests Project Descriptions** of this announcement.

SIP funding will be awarded as a supplement to recipients currently funded under RFA-DP-19-001.

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

Award Ceiling:
$0
Per Budget Period

Award Floor:
$0
Per Budget Period

Total Period of Performance Length:
2 year(s)

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

HHS/CDC grants policies as described in the HHS Grants Policy Statement (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf) will apply to the applications submitted and awards made in response to this NOFO.
If you are successful and receive a Notice of Award, in accepting the award, you agree that the award and any activities thereunder are subject to all provisions of 45 CFR Part 75, currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:
06 (Public and State controlled institutions of higher education)

20 (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. Additional Information on Eligibility

Competition is limited to the 26 institutions currently funded under CDC RFA-DP-19-001.

CDC Grant #	PRC Recipient
U48 DP006377	Emory University
U48 DP006393	Georgia State University
U48 DP006376	Harvard University
U48 DP006384	Johns Hopkins University
U48 DP006411	Morehouse School of Medicine
U48 DP006396	New York University School of Medicine - CUNY
U48 DP006404	University of Alabama at Birmingham
U48 DP006413	University of Arizona
U48 DP006374	University of California, San Francisco
U48 DP006399	University of Colorado, Denver
U48 DP006392	University of Illinois, Chicago
U48 DP006389	University of Iowa
U48 DP006382	University of Maryland, College Park
U48 DP006381	University of Massachusetts Medical School, Worcester
U48 DP006397	University of Michigan, Ann Arbor
U48 DP006414	University of Minnesota
U48 DP006379	University of New Mexico
U48 DP006400	University of North Carolina Chapel Hill
U48 DP006394	University of Rochester
U48 DP006401	University of South Carolina at Columbia
U48 DP006408	University of Texas Houston

U48 DP006398 University of Washington

U48 DP006383 University of Wisconsin, Madison

U48 DP006395 Washington University at St. Louis

U48 DP006391 West Virginia University

U48 DP006380 Yale University

The institution name, EIN, and DUNS of the SIP applicant must match the information of the institution funded under RFA-DP-19-001 as listed in the Notice of Award.

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

Special eligibility requirement(s) may apply to each SIP proposal (see Section VIII. Other Information for Special Interest Project Descriptions).

If an application is incomplete or does not meet the responsiveness criteria in the special eligibility requirements listed in this section, it will be deemed non-responsive and will not enter into the peer review process.

4. Justification for Less than Maximum Competition

Competition is limited to recipients funded under RFA-DP-19-001 because they are uniquely positioned to perform, oversee, and coordinate applied public health promotion and chronic disease prevention research due to their established relationships with community partners.

5. Responsiveness

A SIP application will be responsive if it meets the following requirements:

Each SIP application, and SF 424 (R&R) must be submitted as a New Application (field 8) and must include the following:

Field 4a. Enter the SIP number and the current PRC Award number (e.g., DP00123)
Field 4b. Enter Title of SIP (e.g., enter as much of the SIP Title as allowable)
Field 4c. leave field blank

- **SIP 22-001:** Process, Outcome, and Cost Evaluation of Free Sunscreen Dispensers in Outdoor Community Settings
- **SIP 22-002**: Electronic Health Record Study to Examine Factors and Diagnostic Pathways that Facilitate Early Ovarian Cancer Diagnoses
- **SIP 22-003**: Improving and evaluating measures to identify tics and tic disorders including Tourette syndrome in children in epidemiologic studies and clinical settings
- **SIP 22-004**: Disability and Health Data Collaborative: Using Data to Promote the Health and Wellness of People with Disabilities
- **SIP 22-005**: Building Resilience Against Climate Effects (BRACE): Enhancing Practical Guidance to Support Climate and Health Adaptation Planning
- **SIP 22-006**: Dementia Risk Reduction Research Network – Collaborating Centers
- **SIP 22-007**: COVID-19 and Women: An Assessment of Challenges and Lessons Learned to Enhance Public Health Emergency Preparedness for Women and Families

The institution name, EIN, DUNS, and System for Award Management (SAM) registration of the SIP applicant must match the information of the PRC institution funded under RFA-DP-19-001, as listed in the Notice of Award.

The PRC PI/PD of record, as listed on the Core Notice of Award, must be listed as the SIP PI/PD on the SIP application. Additional SIP PI/PD are permitted but must be listed as the SIP Co-PI/PD on the application and would be referred to as the SIP Co-PI/PD. Other SIP Investigators may be listed as Co-Investigators on the application.

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

If an application requests a funding amount greater than the ceiling for the first 12 months for the specific SIP, HHS/CDC will consider the application non-responsive and it will not enter into the review process (see Section VIII. Other Information - Special Interest Project Descriptions-Availability of Funds). HHS/CDC will notify the applicant that the application did not meet the submission requirements.

Special eligibility requirement(s) apply to the following SIP proposals (see Section VIII. Other Information - Special Interest Project Descriptions).

SIP 22-006

- The applicant's PI and/or key personnel/members of the senior team must have expertise within the field of dementia or cognitive decline, as demonstrated by at least 3 peer-reviewed publications in biosketch, since 2016, focusing in this topic area.
- The applicant's PI and/or key personnel/members of the senior team must have expertise within the field of the ADRD risk factor selected for the project, as demonstrated by at least 3 peer-reviewed publications in biosketch, since 2016, focusing on their selected ADRD risk factor.
- The applicant must provide a current Memorandum of Understanding (MOU) or collaborator letter of support describing access to study population(s) in which the project will be conducted. The applicant must document evidence of access to a population consistent with the target population description contained within this NOFO.
- This evidence should be documented in Appendix A.

SIP 22-007

- Access to the proposed study population(s) as evidenced by a Memorandum of Agreement (MOA) or other documentation. This evidence should be placed in Appendix A.

If an application is incomplete or does not meet these requirements, it will be considered non-responsive and will not enter into the peer review process.

6. Required Registrations

Applicant organizations must complete the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. Applicants must have a valid Dun and Bradstreet Universal Numbering System (DUNS) number in order to begin each of the following registrations.

PLEASE NOTE: For applications due on or after January 25, 2022, applicants must have a unique entity identifier (UEI) at the time of application submission. Grant application forms and instructions will be updated to reflect and require UEI instead of DUNS. If already registered in SAM.gov, a UEI was automatically generated for your entity and is visible in both SAM.gov and Grants.gov. Entities registering in SAM.gov prior to April 2022 must still obtain a DUNS number before registering in SAM and a UEI will be assigned during SAM.gov registration.

- (Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: https://eportal.nspa.nato.int/AC135Public/Docs/US Instructions for NSPA NCAGE.pdf
- System for Award Management (SAM) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, SAM.gov.
- Grants.gov
- eRA Commons

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

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

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

All applicant organizations **must obtain** a 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.

PLEASE NOTE: For applications due on or after January 25, 2022, applicants must have a unique entity identifier (UEI) at the time of application submission. Grant application forms and instructions will be updated to reflect and require UEI instead of DUNS. If already registered in SAM.gov, a UEI was automatically generated for your entity and is visible in both SAM.gov and Grants.gov. Entities registering in SAM.gov prior to April 2022 must still obtain a DUNS number before registering in SAM and a UEI will be assigned during SAM.gov registration.

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 SAM.gov and the SAM.gov Knowledge Base.

If an award is granted, the recipient organization **must** notify potential sub-recipients that no organization may receive a subaward under the grant unless the organization has provided its 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 NOFO does not require cost sharing as defined in the HHS Grants Policy Statement (http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

10. Number of Applications

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

Only PRC institutions currently funded under RFA-DP-19-001 are eligible to apply for Special Interest Projects (SIPs) supplemental funding detailed in this NOFO.

Each currently funded PRC institution may only submit one application per SIP. The institution

name, EIN, DUNS, and System for Award Management (SAM) registration of the SIP applicant must match the information of the PRC institution funded under RFA-DP-19-001, as listed in the Notice of Award.

For CDC grants management purposes, the PRC PI/PD of record, as listed on the Core Notice of Award, must be listed as the SIP PD/PI on the SIP application. Additional SIP PI/PD are permitted but must be listed as the SIP Co-PI/PD on the application and would be referred to as the SIP Co-PI/PD. Other SIP Investigators may be listed as Co-Investigators on the application.

Section IV. Application and Submission Information

1. Address to Request Application Package

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

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

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

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

2. Content and Form of Application Submission

Applicants must use FORMS-G application packages for due dates on or after January 25, 2022 and must use FORMS-F application packages for due dates on or before January 24, 2022.

Application guides for FORMS-G application packages will be posted to the How to Apply - Application Guide page no later than October 25, 2021.

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

When using ASSIST, all mandatory forms will appear as separate tabs at the top of the

Application Information screen; applicants may add optional forms available for the NOFO by selecting the Add Optional Form button in the left navigation panel.

Duplication of Effort

Applicants are responsible for reporting if this application will result in programmatic, budgetary, or commitment overlap with another application or award (i.e. grant, cooperative agreement, or contract) submitted to another funding source in the same fiscal year.

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

Any overlap will be resolved by the CDC with the applicant and the PD/PI prior to award. Report Submission: The applicant must upload the report in Grants.gov under Other Attachment Forms. The document should be labeled: "Report on Programmatic, Budgetary, and Commitment Overlap.

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

Separate Application Submissions Required

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

Applicants must submit only one application per SIP. If an applicant submits more than one application for the same SIP, CDC will only accept the application with the later timestamp.

A revision to an already submitted SIP application is allowable, but it will replace the previously submitted application.

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

Instructions for completing the SF 424 Research and Related (R&R) Face Page form are provided in the SF 424 (R&R) Application Guide.

Each SIP application, and SF 424 (R&R) must be submitted as a New Application (field 8) and must include the correct SIP number in Field 4.a (Federal Identifier), and the SIP Title Field 4.b (Agency Routing Identifier). In Box 4c. of the SF 424 (R&R), applicant must enter the currently funded PRC grant number (refer to Section III. Eligibility Information, 3. Additional Information on Eligibility, for the grant number).

3. Letter of Intent

Due Date for Letter Of Intent 01/21/2022

01/21/2022

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

By the date listed above and in Part 1. Overview Information, prospective applicants are asked to submit an LOI electronically that includes the following information:

- Name of Applicant (PRC Institution)
- SIP number and title
- Descriptive title of proposed SIP research project
- Name, address, and telephone number PRC PD/PI and SIP Co-PD/PI
- Names of other key personnel
- Participating institutions
- Number and title of this notice of funding opportunity: RFA-DP-22-003, Health Promotion and Disease Prevention Research Centers 2022 Supplemental Special Interest Projects (SIPS)

The LOI should be sent electronically to:

Natalie Darling, MPH Scientific Program Official

Extramural Research Program Operations and Services (ERPOS)

Centers for Disease Control and Prevention

4770 Buford Highway, NE Mailstop F-80

Atlanta, GA 30341 Email: researchnofo@cdc.gov

4. Required and Optional Components

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

5. PHS 398 Research Plan Component

The SF424 (R&R) Application Guide includes instructions for applicants to complete a PHS 398 Research Plan that consists of components. Not all components of the Research Plan apply to all Notices of Funding Opportunities (NOFOs). Specifically, some of the following components are for Resubmissions or Revisions only. See the SF 424 (R&R) Application Guide at How to Apply - Application Guide for additional information. Please attach applicable sections of the following Research Plan components as directed in Part 2, Section 1 (Notice of Funding Opportunity Description).

Follow the page limits stated in the SF 424 unless otherwise specified in the NOFO. As applicable to and specified in the NOFO, the application should include the bolded headers in

this section and should address activities to be conducted over the course of the entire project, including but not limited to:

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

Other Research Plan Sections

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

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

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

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

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

- Statement of the use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use; and
- Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified (this section should address archiving and preservation of identifiable and deidentified data).

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

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

Applicants must use FORMS-G application packages for due dates on or after January 25, 2022 and must use FORMS-F application packages for due dates on or before January 24, 2022.

Application guides for FORMS-G application packages will be posted to the How to Apply - Application Guide page no later than October 25, 2021.

Data Management Plan

CDC requires awardees for projects that involve the collection or generation of public health data with federal funds to submit a Data Management Plan (DMP) prior to the initiation of generating or collecting public health data unless CDC will aggregate and disseminate the data. *Public health data* means digitally recorded factual material commonly accepted in the scientific community as a basis for public health findings, conclusions, and implementation. In initial funding applications, the DMP should be addressed within the Resource Sharing Plan section of the PHS 398 Research Plan Component of the application, either as a stand-alone DMP within this section or with a statement explaining why a DMP is not included. The DMP must be updated and submitted to CDC at least annually, or whenever plans for data collection or generation activities change. 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. The contents of the DMP are described in AR-25. Visit link https://www.cdc.gov/chronicdisease/programs-impact/nofo/index.htm for DMP Template and Guidance.

Public health data are expected to be made freely available to the public (in a de-identified format) and archived long-term unless there are compelling reasons not to do so. When it is not feasible to make data freely available to the public, it may be possible to make data available to users on a restricted basis. The DMP should describe the expected level of public access, if any, and must justify the planned access level and describe how privacy and confidentiality will be protected. 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 from ongoing surveillance systems which should be made accessible within 12 months of the end of a collection cycle. 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 data underlying scientific publications such as peer review journal articles, 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 accompanying a scientific paper should consist of a machine-readable version of the data tables shown in the paper.

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-g/general-forms-g.pdf, must be followed along with any additional instructions provided in the NOFO.

RESEARCH PLAN

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

Research Plan components for each SIP are listed in Section VIII. Other Information - Special Interests Project Descriptions of this announcement. The performance period of one to two years for each SIP is also specified in Section VIII.

6. Appendix

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

7. Page Limitations

All page limitations described in this individual NOFO must be followed. For this specific NOFO, the Research Strategy component of the Research Plan narrative is limited to 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. Pages that exceed page limits described in this NOFO will be removed and not forwarded for peer review, potentially affecting an application's score.

8. Format for Attachments

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

and agency staff. Applicants should ensure that all attachments are uploaded to the system.

CDC requires all text attachments to the Adobe application forms be submitted as PDFs and that all text attachments conform to the agency-specific formatting requirements noted in the SF424 (R&R) Application Guide https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf.

9. Submission Dates & Times

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

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

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

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

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

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

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

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

After submission of your application package, applicants will receive a "submission receipt" email generated by Grants.gov. Grants.gov will then generate a second e-mail message to applicants which will either validate or reject their submitted application package. A third and final e-mail message is generated once the applicant's application package has passed validation and the grantor agency has confirmed receipt of the application.

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

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

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

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

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

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

Due Date for Applications 03/04/2022

03/04/2022
Electronically submitted applications must be submitted no later than 5:00 p.m., ET, on the listed application due date.

10. Funding Restrictions

Expanded Authority:

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

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

Public Health Data:

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

Data Management Plan:

Fulfilling the data-sharing requirement must be documented in a Data Management Plan (DMP) that is developed during the project planning phase prior to the initiation of

generating or collecting public health data and must be included in the Resource Sharing Plan(s) section of the PHS398 Research Plan Component of the application.

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

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

Human Subjects:

Funds relating to the conduct of research involving human subjects will be restricted until the appropriate assurances and Institutional Review Board (IRB) approvals are in place. Copies of all current local IRB approval letters and local IRB approved protocols (and CDC IRB approval letters, if applicable) will be required to lift restrictions.

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

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

11. Other Submission Requirements and Information

Risk Assessment Questionnaire Requirement

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

CDC requires all applicants to complete the Risk Questionnaire, OMB Control Number 0920-1132 annually. This questionnaire, which is located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, along with supporting documentation must be submitted with your application by the closing date of the Notice of Funding Opportunity Announcement. If your organization has completed CDC's Risk Questionnaire within the past 12 months of the closing date of this NOFO, then you must submit a copy of that questionnaire, or submit a letter signed by the authorized organization representative to include the original submission date, organization's EIN and DUNS.

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

Duplication of Efforts

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

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

Application Submission

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

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

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

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

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

The applicant organization must ensure that the 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.

PLEASE NOTE: For applications due on or after January 25, 2022, applicants must have a unique entity identifier (UEI) at the time of application submission. Grant application forms and instructions will be updated to reflect and require UEI instead of DUNS. If already registered in SAM.gov, a UEI was automatically generated for your entity and is visible in both SAM.gov and Grants.gov. Entities registering in SAM.gov prior to April 2022 must still obtain a DUNS number before registering in SAM and a UEI will be assigned during SAM.gov registration.

If the applicant has an FWA number, enter the 8-digit number. Do not enter the letters "FWA" before the number. If a Project/Performance Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the Project/Performance Site operates under and appropriate Federal Wide Assurance for the protection of human subjects and complies with 45 CFR Part 46 and other CDC human subject related policies described in Part II of the SF 424 (R&R) Application Guide and in the HHS Grants Policy Statement.

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

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

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

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 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?

- 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?

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?

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?

- 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 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?

- 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?

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 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?

- 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?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

- Does the project use critical partnerships or collaborations?

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

Review Criteria for each SIP:

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

2. Additional Review Criteria

As applicable for the project proposed, *reviewers will evaluate* the following additional items while determining scientific and technical merit, and in providing an overall impact/priority score, but *will not give separate scores* for these items.

Protections for Human Subjects
If the research involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the HHS/CDC Requirements under AR-1 Human Subjects Requirements (https://www.cdc.gov/grants/additional-requirements/ar-1.html).

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

Inclusion of Women, Minorities, and Children
When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the policy on the Inclusion of Women and Racial and Ethnic Minorities in Research (https://www.cdc.gov/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 four points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 4) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section (https://grants.nih.gov/grants/olaw/VAChecklist.pdf).

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

Dual Use Research of Concern
Reviewers will identify whether the project involves one of the agents or toxins described in the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern, and, if so, whether the applicant has identified an IRE to assess the project for DURC potential and develop mitigation strategies if needed.

For more information about this Policy and other policies regarding dual use research of concern, visit the U.S. Government Science, Safety, Security (S3) website at: http://www.phe.gov/s3/dualuse. Tools and guidance for assessing DURC potential may be found at: http://www.phe.gov/s3/dualuse/Pages/companion-guide.aspx.

3. Additional Review Considerations

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

Sub-awards and Community Involvement

Reviewers will consider an applicant's proposed plan to competitively award subcontracts 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 SIPs objective and public health priorities.

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

New additional requirement: CDC requires recipients for projects and programs that involve data

collection or generation of data with federal funds to develop and submit a Data Management Plan (DMP) for each collection of public health data.

Investigators responding to this Notice of Funding Opportunity should include a detailed DMP in the Resource Sharing Plan(s) section of the PHS 398 Research Plan Component of the application. The AR-25 outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.

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

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

- A description of the data to be collected or generated in the proposed project;
- Standards to be used for the collected or generated data;
- Mechanisms for, or limitations to, providing access to and sharing of the data (include a description of provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights - this section should address access to identifiable and de-identified data);
- Statement of the use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use; and
- Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified (this section should address archiving and preservation of identifiable and de-identified data).

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

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

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

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

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

Indirect costs could include the cost of collecting, managing, sharing and preserving data.

Indirect costs on grants awarded to foreign organizations and foreign public entities and performed fully outside of the territorial limits of the U.S. may be paid to support the costs of compliance with federal requirements at a fixed rate of eight percent of modified total direct costs exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000. Negotiated indirect costs may be paid to the American University, Beirut, and the World Health Organization.

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

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

4. Review and Selection Process

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

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

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

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

Specific funding preferences may apply to each SIP proposal (see Section VIII. Other Information - Special Interests 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 with 41 U.S.C. 2313, CDC is required to review the non-public segment of the OMB-designated integrity and performance system accessible through SAM (currently the Federal Recipient Performance and Integrity Information System (FAPIIS)) prior to making a Federal award where the Federal share is expected to exceed the simplified acquisition threshold,

defined in 41 U.S.C. 134, over the period of performance. At a minimum, the information in the system for a prior Federal award recipient must demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics. CDC may make a Federal award to a recipient who does not fully meet these standards if it is determined that the information is not relevant to the current Federal award under consideration or there are specific conditions that can appropriately mitigate the effects of the non-Federal entity's risk in accordance with 45 CFR §75.207.

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

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

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

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

5. Anticipated Announcement and Award Dates

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

Section VI. Award Administration Information

1. Award Notices

Any applications awarded in response to this NOFO will be subject to the 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).

PLEASE NOTE: For applications due on or after January 25, 2022, applicants must have a unique entity identifier (UEI) at the time of application submission. Grant application forms and instructions will be updated to reflect and require UEI instead of DUNS. If already registered in SAM.gov, a UEI was automatically generated for your entity and is visible in both SAM.gov and Grants.gov. Entities registering in SAM.gov prior to April 2022 must still obtain a DUNS number before registering in SAM and a UEI will be assigned during SAM.gov registration.

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

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

2. CDC Administrative Requirements

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

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

Specific requirements that apply to this NOFO are the following:

AR-1: Human Subjects Requirements

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

AR-6: Patient Care
AR-9: Paperwork Reduction Act Requirements

AR-10: Smoke-Free Workplace Requirements

AR-11: Healthy People 2030

AR-12: Lobbying Restrictions

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

AR-14: Accounting System Requirements

AR-16: Security Clearance Requirement

AR-22: Research Integrity

AR-24: Health Insurance Portability and Accountability Act Requirements

AR-25: Data Management and Access

AR-26: National Historic Preservation Act of 1966

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

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

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

AR-31: Research Definition

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

Organization Specific ARs:

AR-8: Public Health System Reporting Requirements

AR-15: Proof of Non-profit Status

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

3. Additional Policy Requirements

The following are additional policy requirements relevant to this NOFO:

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

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

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

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

• For guidance on administering your project in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

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

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

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

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

Copyright Interests Provision This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. Pursuant to applicable grant regulations and CDC's Public Access Policy, Recipient agrees to submit into the National Institutes of Health (NIH) Manuscript Submission (NIHMS) system an electronic version of the final, peer-reviewed manuscript of any such work developed under this award upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. Also at the time of submission, Recipient and/or the Recipient's submitting author must specify the date the final manuscript will be publicly accessible through PubMed Central (PMC). Recipient and/or Recipient's submitting author must also post the manuscript through PMC within twelve (12) months of the publisher's official date of final publication; however, the author is strongly encouraged to make the subject manuscript available as soon as possible. The recipient must obtain prior approval from the CDC for any exception to this provision.

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

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

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

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

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

Non-compliance with this Policy may result in suspension, limitation, restriction or termination of USG-funding, or loss of future USG funding opportunities for the non-compliant USG-funded research project and of USG-funds for other life sciences research at the institution, consistent with existing regulations and policies governing USG-funded research, and may subject the institution to other potential penalties under applicable laws and regulations.

Data Management Plan(s)

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

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

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

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

4. Cooperative Agreement Terms and Conditions

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

- The PRC PI/PD of record, as listed on the Core Notice of Award, must be listed as the PD/PI on the SIP application. Additional SIP PI/PDs are permitted but would be referred to as a SIP Co-PD/PI. Other SIP Investigators may be listed as Co-Investigators on the application
- Obtaining appropriate Institutional Review Board approvals for research involving human subjects for all participating
- Adhering to the rights and responsibilities of the PD/PI as described in each SIP description under Section VIII, Award Administration.
- Coordinating of all CDC required reporting submissions and prior approval requests with the PRC PI.
- Participating in the PRC Network as applicable.

HHS/CDC Responsibilities

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

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

SIP Sponsor (Project Scientist) will:

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

PRC Program Project Officer (PO) will:

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

ERPOS Scientific Program Official (SPO) will:

Named in the Notice of Grant Award (NGA) as the Scientific Program Official. Provide for normal overall scientific oversight and assure overall scientific and programmatic stewardship of the award. Collaborate with the PRC Program to monitor performance against approved project objectives. Assure assessment of the public health impact of the research conducted under this NOFO.

5. Reporting

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

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

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

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for recipients of Federal grants to report

information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later.

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

A. Submission of Reports

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

1. **Yearly Non-Competing Grant Progress Report**, is due 90 to 120 days before the end of the current budget period. The RPPR form (https://grants.nih.gov/grants/rppr/index.htm; https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf) is to be completed on the eRA Commons website. The progress report will serve as the non-competing continuation application. Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.
2. **Annual Federal Financial Report (FFR) SF 425** (https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.htm) is required and must be submitted through eRA Commons **within 90 days after the end of the calendar quarter in which the budget period ends.**
3. **A final progress report**, invention statement, equipment/inventory report, and the final FFR are required **90 days after the end of the period of performance.**

B. Content of Reports

1. Yearly Non-Competing Grant Progress Report: The grantee's continuation application/progress should include:
    - Description of Progress during Annual Budget Period: Current Budget Period Progress reported on the RPPR form in eRA Commons (https://grants.nih.gov/grants/rppr/index.htm). Detailed narrative report for the current budget period that directly addresses progress towards the Measures of Effectiveness included in the current budget period proposal.

- Research Aims: list each research aim/project

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

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

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

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

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

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

estimated FFR.

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

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

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

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

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

- Additional Reporting Requirements:

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

- <u>Yearly Non-Competing Grant Progress Report</u>
    - Dissemination of research results refers to sharing information with practice, academic, and community audiences.
    - Translation of Research findings refers to implementation of research or scientific findings into public health programs or practice.
    - New Budget Period Proposal: Detailed Operational Plan refers to the Annual Action Plan. **Refer to Section VIII**. Special Interest Project Descriptions, Annual Action Plan, for additional information.
    - Publications/Presentations/Tools/Other Products:
        - Include peer reviewed publications and presentations, evaluated research and practice tools, and other products from the SIP, along with other

publications and presentations resulting from this award during the budget period.

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

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

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

2. Annual Federal Financial Reporting The Annual Federal Financial Report (FFR) SF 425 is required and must be submitted through the Payment Management System (PMS) within 90 days after the end of the 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 is 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 on the Payment Management System (PMS) can be found at https://pms.psc.gov.

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

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

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

- Research Aim/Project Overview: The PI should describe the purpose and approach to the project, including the outcomes, methodology and related analyses. Include a discussion of the challenges, successes and lessons learned. Describe the collaborations/partnerships and the role of each external partner.
- Translation of Research Findings: The PI should describe how the findings will be translated and how they will be used to inform policy or promote, enhance or advance the impact on public health practice. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers and other potential end users. The PI should also provide a discussion of any research findings that informed policy or practice during the course of the Period of Performance. If applicable, describe how the findings could be generalized and scaled to populations and communities outside of the funded project.
- Public Health Relevance and Impact: This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project related beyond the immediate study to improved practices, prevention or intervention techniques, or informed policy, technology or systems improvements in public health.
- Publications; Presentations; Media Coverage: Include information regarding all publications, presentations or media coverage resulting from this CDC-funded activity. Please include any additional dissemination efforts that did or will result from the project.
- Final Data Management Plan: Applicants must include an updated final Data Management Plan that describes the data collected, the location of where the data is

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

6. Termination

CDC may impose other enforcement actions in accordance with 45 CFR 75.371- Remedies for Noncompliance, as appropriate.

The Federal award may be terminated in whole or in part as follows:

(1) By the HHS awarding agency or pass-through entity, if the non-Federal entity fails to comply with the terms and conditions of the award;

(2) By the HHS awarding agency or pass-through entity for cause;

(3) By the HHS awarding agency or pass-through entity with the consent of the non-Federal entity, in which case the two parties must agree upon the termination conditions, including the effective date and, in the case of partial termination, the portion to be terminated; or

(4) By the non-Federal entity upon sending to the HHS awarding agency or pass-through entity written notification setting forth the reasons for such termination, the effective date, and, in the case of partial termination, the portion to be terminated. However, if the HHS awarding agency or pass-through entity determines in the case of partial termination that the reduced or modified portion of the Federal award or subaward will not accomplish the purposes for which the Federal award was made, the HHS awarding agency or pass-through entity may terminate the Federal award in its entirety.

7. Reporting of Foreign Taxes (International/Foreign projects only)

A. Valued Added Tax (VAT) and Customs Duties – Customs and import duties, consular fees, customs surtax, valued added taxes, and other related charges are hereby authorized as an allowable cost for costs incurred for non-host governmental entities operating where no applicable tax exemption exists. This waiver does not apply to countries where a bilateral agreement (or similar legal document) is already in place providing applicable tax exemptions and it is not applicable to Ministries of Health. Successful applicants will receive information on VAT requirements via their Notice of Award.

B. The U.S. Department of State requires that agencies collect and report information on the amount of taxes assessed, reimbursed and not reimbursed by a foreign government against commodities financed with funds appropriated by the U.S. Department of State, Foreign Operations and Related Programs Appropriations Act (SFOAA) (“United States foreign assistance funds”). Outlined below are the specifics of this requirement:

1) Annual Report: The recipient must submit a report on or before November 16 for each foreign country on the amount of foreign taxes charged, as of September 30 of the same year, by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant during the prior United States fiscal year (October 1 – September 30), and the amount reimbursed and unreimbursed by the foreign government. [Reports are required even if the recipient did not pay any taxes during the reporting period.]

2) Quarterly Report: The recipient must quarterly submit a report on the amount of foreign taxes charged by a foreign government on commodity purchase transactions valued at 500 USD or

more financed with United States foreign assistance funds under this grant. This report shall be submitted no later than two weeks following the end of each quarter: April 15, July 15, October 15 and January 15.

3) Terms: For purposes of this clause:

"Commodity" means any material, article, supplies, goods, or equipment;

"Foreign government" includes any foreign government entity;

"Foreign taxes" means value-added taxes and custom duties assessed by a foreign government on a commodity. It does not include foreign sales taxes.

4) Where: Submit the reports to the Director and Deputy Director of the CDC office in the country(ies) in which you are carrying out the activities associated with this cooperative agreement. In countries where there is no CDC office, send reports to VATreporting@cdc.gov.

5) Contents of Reports: The reports must contain:

a. recipient name;

b. contact name with phone, fax, and e-mail;

c. agreement number(s) if reporting by agreement(s);

d. reporting period;

e. amount of foreign taxes assessed by each foreign government;

f. amount of any foreign taxes reimbursed by each foreign government;

g. amount of foreign taxes unreimbursed by each foreign government.

6) Subagreements. The recipient must include this reporting requirement in all applicable subgrants and other subagreements.

Section VII. Agency Contacts

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

Application Submission Contacts

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

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

Scientific Research Contact(s)

Natalie J. Darling MPH,

Scientific Program Official Extramural Research Program Operations and Services

Centers for Disease Control and Prevention

4770 Buford Highway, NE Mailstop F-80

Atlanta, GA 30341

Telephone: (770) 488-5740

Email: researchnofo@cdc.gov

Note: Include SIP NOFO number, RFA-DP22-003, in the email subject line when submitting questions.

Peer Review Contact(s)

Jaya Raman, Ph.D.,

Scientific Review Official Extramural Research Program Operations and Services

Centers for Disease Control and Prevention

4770 Buford Highway, NE

Mailstop F-80 Atlanta, GA 30341

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Financial/Grants Management Contact(s)

Sharon Cassell

Grants Management Specialist

Office of Grants Services/Office of Financial Resources

Centers for Disease Control and Prevention

4770 Buford Highway, NE Mailstop F-80

Atlanta, GA 30341

Telephone: 770-488-2703

Email: zpr0@cdc.gov

Section VIII. Other Information

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

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

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

Special Interest Project Descriptions

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

SIP 22-001: Process, Outcome, and Cost Evaluation of Free Sunscreen Dispensers in Outdoor Community Settings

Project Description
Sunscreen can prevent sunburn and reduce skin cancer risk when used as directed [1]. However, sunscreen use remains low. For example, only about 15% of US high school students report using sunscreen most of the time or always when outside for an hour or more on a warm, sunny day [2]. To encourage sunscreen use, many communities across the country have installed free sunscreen dispensers in public outdoor spaces [3]. The provision of free sunscreen is noted by the Community Preventive Services Task Force as a potential component of community-level skin cancer prevention interventions, particularly in outdoor recreational and tourism settings [4]. However, little is known regarding how free sunscreen dispensers are used by community members, let alone the impact of the presence of free sunscreen dispensers on sun-safety knowledge, attitudes, beliefs, and behaviors [3-6]. There is also a lack of information about the cost of implementing free sunscreen dispensers and the cost-effectiveness of the intervention in relation to other sun-safety interventions [3-5].

The purpose of this SIP is to fill these knowledge gaps through a process, outcome, and cost evaluation of free sunscreen dispensers in outdoor community settings using a community-based participatory research approach. Given the deployment of free sunscreen dispensers in many community settings and the renewed public interest in spending time outside since the COVID-19 pandemic, the findings could be extremely relevant and useful to those considering sun-safety intervention options for their community. Ultimately the findings will inform best practices for future skin cancer prevention efforts, including work being done by CDC-funded Comprehensive Cancer Control programs.

Project Objectives and Outcomes
Specific objectives include 1) summarize the existing evidence base and resources needed to support the implementation of free sunscreen dispensers in outdoor community settings; 2) develop and implement a plan to install and maintain free sunscreen dispensers in a variety of types of outdoor public spaces within at least two communities with different geographic characteristics; 3) Develop and implement an educational intervention to raise awareness of a) the importance of using sun protection to prevent sunburn and reduce skin cancer risk; and b) the availability of free sunscreen from the new sunscreen dispensers; 4) conduct a process evaluation of the installation and maintenance of the free sunscreen dispensers and the educational

intervention; 5) conduct an outcomes evaluation to assess the effects of the sunscreen dispensers and the sun-safety educational intervention on sun protection knowledge, attitudes, beliefs, and behaviors within the community; 6) estimate the cost of the free sunscreen dispensers (based on use of the free sunscreen) and the sun-safety educational intervention; 7) evaluate the cost effectiveness of free sunscreen dispensers and the sun-safety educational intervention compared to other community-based, sun-safety interventions; and 8) disseminate the study findings, including the development and implementation of a translation plan.

Expected outcomes include 1) a summary of existing resources and publications on the provision of free sunscreen dispensers in outdoor community settings; 2) the installation and maintenance of free sunscreen dispensers in at least two communities; 3) implementation of a sun-safety educational intervention; 4) the results from the process, outcomes, cost, and cost-effectiveness evaluations; and 5) products to support dissemination of the evaluation results such as presentations, peer-reviewed publications, slides, and content for social media.

Public Health Priorities

Healthy People 2030 Objectives

- C-10: Reduce the proportion of students in grades 9 through 12 who report sunburn.

CDC Health Impact-5 Initiative
N/A

NCCDPHP Chronic Disease Prevention and Health Promotion Domains
This SIP aligns with the domain of environmental approaches that promote health and support and reinforce healthful behaviors.

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
The applicant is responsible for developing the study protocol, including methods to 1) review and summarize the existing evidence base and resources to support successful implementation of free sunscreen dispensers in outdoor community settings that are accessible to community residents at low or no cost; 2) develop and implement a plan to use a community-based participatory approach to study the feasibility and effectiveness of installing and maintaining free sunscreen dispensers in outdoor public spaces within at least two communities and implement a sun-safety educational intervention in these communities; 3) conduct a process evaluation of the installation and maintenance of the free sunscreen dispensers and the implementation of the sun-safety intervention; 4) conduct an outcomes evaluation to assess the effects of the sunscreen dispensers and the sun-safety educational intervention on sun protection knowledge, attitudes, beliefs, and behaviors within the community; 5) estimate the cost of the free sunscreen dispensers (based on use of the free sunscreen) and the sun-safety educational intervention; 6) evaluate the cost effectiveness of free sunscreen dispensers and the sun-safety educational intervention compared to other community-based, sun-safety interventions; and 7) disseminate

the study findings.

For any proposed data collection efforts, applicants should describe 1) the constructs to be measured; 2) the various stakeholders from which data will be collected (e.g., relevant community-based organizations that would deploy and maintain dispensers, community leaders, community residents); 3) the methods to be used (e.g., surveys, key informant interviews); and 4) the anticipated timing.

Target population
The target populations are users of public outdoor community spaces with special emphasis on students in grades 9 through 12. Applicants may extend the reach of the intervention beyond this population and provide details about the additional target population(s) (e.g., geographical area, demographic characteristics of the general population). Applicants should also describe how the project will include populations that have been underrepresented in past sun-safety interventions.

Collaboration/Partnerships
Applicants are expected to collaborate with organizations and entities that support the accomplishment of the goals of this project and are encouraged to have innovative engagement with relevant community groups, including but not limited to:

- Community-based organizations (e.g., non-profit groups, faith-based groups, local charity groups, parks and recreation organizations)
- New or existing partners who could facilitate dissemination activities (e.g., advocacy groups, dermatologists, state and local health departments, departments of education)

The applicant should establish a community advisory board to support the design and implementation of the intervention. The advisory board should include representation from community-based organizations and members of the target population (i.e., local residents who use public outdoor community spaces).

Recruitment Plan
Applicants are expected to describe their plan to engage and work with community-based organizations and community residents to identify the study sites in each community and recruit participants for each data collection component, including any proposed data collection from community leaders and a sample of patrons of the study sites. It is expected that strategies to overcome potential barriers to recruitment are described.

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

Evaluation Plan /Performance measurement
The applicant's evaluation plan should describe the methods and timeline for any proposed data collection to assess the process and costs of installation and maintenance of free sunscreen dispensers and implementation of the sun-safety educational intervention, use of the free sunscreen, and the effects of the sunscreen dispensers and sun-safety educational intervention on sun-safety knowledge, attitudes, beliefs, and behaviors. The cost-effectiveness portion of the

evaluation should include but is not limited to the costs of installation and maintenance of the sunscreen dispensers in the context of how much sunscreen gets used.

Dissemination Plan
The applicant is expected to disseminate the findings through presentations, peer reviewed publications, the CDC website, the Prevention Research Center's website, and social media. A plan disseminating the results and findings of the project to key audiences, including relevant community-based organizations and public health researchers and practitioners should be included.

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

Translation Plan
The applicant should provide details on the anticipated strategies to implement translation of research findings for public health practice. The strategies should include plans to provide practical guidance on installation and maintenance of free sunscreen dispensers in various outdoor community settings using principles of implementation science [7] and considering relevant challenges, barriers, and recommendations applicable to each intended audience. The strategies should place an emphasis on the need to scale up best practices to increase the reach of the intervention.

Public Health Impact
Sunscreen can prevent sunburn and reduce skin cancer risk when used as directed [1]. Free sunscreen dispensers have become a component of some community-level skin cancer prevention efforts [3, 4]. The potential utility of free sunscreen dispensers as a strategy to promote sun safety lacks an evidence base. Little is known regarding their impact on sunscreen use or sun-safety knowledge, attitudes, beliefs, and behaviors [3-6]. There is also a lack of information about the implementation costs and cost-effectiveness of free sunscreen dispensers [3-5] compared to other community-based sun-safety interventions. Findings from this project will help to fill these research gaps and inform best practices for future community-level skin cancer prevention efforts, including work being done by CDC-funded Comprehensive Cancer Control programs.

Special Eligibility and Responsiveness
If an application requests a funding amount greater than the year one award ceiling of $400,000, 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.

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

following additional review criteria specific to this SIP will be considered in the determination of scientific merit and the priority score. Does the applicant demonstrate:

- Previous experience with the development and implementation of sun-safety interventions, implementation of health-related interventions in outdoor community settings, and community-based participatory research?
- The presence of evaluation expertise on the project team?
- Relationships with relevant community-based organizations, in the form of letters of support, that will participate in implementation of the intervention (i.e., installation and maintenance of free sunscreen dispensers in outdoor community spaces)?
- An approach that will engage relevant community members in community-based participatory research and enable the reach of the intervention to include high school students?

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

- Diversity in the types of outdoor community settings (e.g., parks, pools, playgrounds) the applicant included as study sites within the study communities
- Geographic diversity across the communities included in the study

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, with a maximum of 30 pages. The appendices should include materials that show evidence of the applicant's ability to successfully conduct the proposed project and other evidence deemed necessary to support the contents of the proposal.

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

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

OMB/PRA
OMB/PRA is not expected to apply

Award Administration
CDC Project Scientist/Scientific Collaborator will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards. CDC staff will contribute scientific expertise and consultation at all stages of the project and will provide technical assistance, as requested, on project activities. CDC staff will participate in the presentation of results and may be co-authors on publications and conference presentations. However, CDC

staff will not control, direct, or specify the data collection and will not have contact with human subjects or data collected from human subjects.

References

1. U.S. Food and Drug Administration. Sunscreen: How to Help Protect Your Skin from the Sun. https://www.fda.gov/drugs/understanding-over-counter-medicines/sunscreen-how-help-protect-your-skin-sun.
2. Centers for Disease Control and Prevention. YRBS Explorer. Accessed August 30, 2021. Available at https://yrbs-explorer.services.cdc.gov/#/graphs?questionCode=QNSUNSCREENUSE&topicCode=C08&location=XX&year=2019.
3. Eason CD, Rundle C, Dunnick CA, Hugh J, Dellavalle RP. National trends in free public sunscreen dispensers. J Am Acad Dermatol. 2021;84(4):1109-1111. https://doi.org/10.1016/j.jaad.2020.05.136.
4. The Community Guide. What Works Fact Sheet: Skin Cancer Prevention. https://www.thecommunityguide.org/resources/what-works-skin-cancer-prevention.
5. Wood M, Raisanen T, Polcari I. Observational study of free public sunscreen dispenser use at a major US outdoor event. J Am Acad Dermatol. 2017;77(1):164-166. https://doi.org/10.1016/j.jaad.2017.02.034.
6. Dubas LE, Adams BB. Sunscreen use and availability among female collegiate athletes. J Am Acad Dermatol. 2012;67(5): 876.e1-e6. https://doi.org/10.1016/j.jaad.2011.11.962.
7. Estabrooks PA, Brownson RC, Pronk NP. Dissemination and Implementation Science for Public Health Professionals: An Overview and Call to Action. Prev Chronic Dis. 2018;15:E162. http://dx.doi.org/10.5888/pcd15.180525.

SIP 22-002: Electronic Health Record Study to Examine Factors and Diagnostic Pathways that Facilitate Early Ovarian Cancer Diagnoses

Project Description

Most ovarian cancers are diagnosed at advanced stages [1,2]. However, when diagnosed early, a woman's 5-year survival could be as high as 92% [1,3]. Despite prior focus on improving survival from late-stage disease, overall survival from ovarian cancer has not increased substantially over the last 20 years [1,4]. Other than ensuring treatment is received from a gynecologic oncologist, there are few evidence-based recommendations to improve clinical/public health practice from late-stage disease.

Comparatively little is known about women with early-stage ovarian cancer, including factors which may have led to an early-stage diagnosis. Prior studies have largely focused on symptoms, showing that specific symptoms are associated with early stages [5-9]. However, there are still significant gaps in understanding factors that lead to early diagnoses [3]. Most studies are based on the most common histologic subtype; however, ovarian cancer is a heterogenous disease consisting of many different tumor types affecting the ovaries [3]. More subtype-specific investigation into clinical- and patient- level characteristics can provide a better understanding of the pathways to diagnosis, including patient, provider specialty and clinical systems factors (like

diagnostic tests or consults) among women who were diagnosed with early-stage ovarian cancers and provide baseline information for shifting diagnoses.

The purpose of this SIP is to support a multi-site study involving three Prevention Research Centers that will work together to conduct research to address gaps in knowledge of early-stage ovarian cancer in women by examining electronic health record data as defined by HealthIT.gov [10] for factors associated with early diagnoses that may provide critical information on health-systems changes to help shift ovarian cancers to earlier diagnosis. Specifically, this project aims to 1) comprehensively examine patient- and health-systems factors associated with early-stage ovarian cancer diagnoses; 2) model pathways to diagnosis, comparing different types of healthcare systems and 3) model potential public health impact of interventions. It is especially important to examine pre-diagnostic timeframes and pathways to diagnosis, as well as pre-existing patient factors and conditions (gynecologic and other conditions) to help define factors that led to early diagnosis. The synthesis of this knowledge may lead to the identification of specific recommendations (like timely diagnostic tests, for example) that can be implemented to shift cases from late to earlier stage diagnoses.

Project Objectives and Outcomes

Applicants are expected to achieve the following goals and objectives.

- Objective 1: Identify a conceptual framework, variables, and social or latent constructs to examine early stage ovarian cancer diagnoses based on confirmed availability of variables in electronic health records and reflecting an understanding of the current literature of factors related to early stage ovarian cancer diagnoses, such as symptoms, comorbidities and other co-occurring conditions, histology, and genetics/family or personal cancer history.
- When constructing the study sample, investigators would be expected to consider patient, physician care, and healthcare system characteristics and diversity in terms of age, race, ethnicity, and treatment from various geographic and clinical settings.
- Objective 2: Examine pre-diagnostic pathways within each health system for early- vs. late-stage diagnoses and compare these factors and pathways between different types of health systems, possibly examining a closed health system as one example.
- Investigators are expected to identify potential levers within the health systems that may shift diagnoses to earlier stage by examining the health records dataset (for medical history like co-morbidities, prior diagnoses, clinical symptoms, clinical encounters across clinical settings including labs, medications, and imaging/pathology reports, specialty visits, time intervals between encounters, and patient sociodemographic characteristics and patient-reported outcome). Some possible questions are: what are the patterns of procedural pre-diagnostic work-ups for specific symptoms of ovarian cancer that lead to earlier diagnoses? What conditions may facilitate or mask diagnoses?
- Objective 3: Model potential impact of interventions to shift diagnoses to early stage on the morbidity or mortality. Some of the methods that may be considered include dynamic simulation modeling or microsimulation where factors of the patient, physician care, and healthcare system can be examined simultaneously.
- Objective 4: Identify public health messages for health systems and women as applicable from the results from objectives 1-3 above.

Prevention Research Centers funded under this SIP will partner with health systems and work collaboratively to accomplish objectives 1-4 listed above

Public Health Priorities

Healthy People 2030 Objectives

- C11: Increase the proportion of cancer survivors who are living 5 years or longer after diagnosis
- AHS 04: Reduce the proportion of persons who are unable to obtain or delayed in obtaining necessary medical care

CDC Health Impact-5 Initiative
N/A

NCCDPHP Chronic Disease Prevention and Health Promotion Domains
This SIP aligns with the Center's priorities:

- Domain 1. Epidemiology and surveillance
- Domain 3: Health system strategies to improve the delivery and use of clinical and other preventive services

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

Study design and methods

- Applicants are to propose a study design and methods to include:
- Concatenate or harmonize electronic health record data from multiple years or multiple sources (if applicable) and describe how the project will determine eligibility based on longitudinal records available given that pre-diagnostic work-up information is of interest.
- Develop or identify conceptual framework, variables, and social or latent constructs to examine based on confirmed availability in electronic health records.□□
- Examine and model the pre-diagnostic pathway within and between health systems. Identify potential levers within the health systems that may shift diagnoses to earlier stage.
- Examine potential interventions and the outcomes/impact of those intervention(s) within the health system; the application should include detailed plans on modeling techniques and approach
- Examine a diverse study sample in terms of inequities associated with age, race, ethnicity, and treatment from various geographic and clinical settings. □
- Compare health care delivery settings or delivery models□□

Additionally, the application should describe:

- Project team's experience in working with large datasets, electronic health records, dynamic systems modeling, or ovarian cancer research/expertise

- Geographic areas or racial inequities or disparities that this project may address
- Sample characteristics, including a list of proposed variables available in the electronic health records that could be examined in the study population.
- The sample size calculations
- Partnerships with health systems and proposed coordination with other Prevention Research Centers funded under this SIP

Target population
The target population for this SIP is women diagnosed with ovarian cancer. Electronic health records of women diagnosed with ovarian cancer should include longitudinal data from the health system for a minimum of one year. The applicant is expected to provide additional details about the target population given their proposed approach (e.g., geographic area, demographic characteristics).

Collaboration/Partnerships
The applicant is expected to collaborate with large integrated health delivery systems serving various U.S. geographic populations to support the accomplishment of the goals of this project. Applicants should provide documentation of current or planned partnerships with organizations necessary to conduct the proposed project. Applicants may consider establishing an advisory board with representation from public health disciplines and members of the target population of women diagnosed with ovarian cancer to support phases of the research and objectives. The advisory board may assist with public health message development, and dissemination and translation of findings.

Recruitment Plan
The applicant is expected to describe how partnerships with large integrated health delivery systems who have or can facilitate access to a larger sample of ovarian cancer patients' electronic health records will be identified and executed.

Annual Action Plan
The applicant is expected to provide a 12-month action plan using SMART goals and objectives to include a progressive timeline for completion of activities.

Evaluation Plan /Performance measurement
Provide an evaluation plan and performance measures to assess project performance and progress. A resource regarding evaluation can be found at https://www.cdc.gov/eval/index.htm

Dissemination Plan
The applicant is expected to provide a dissemination plan that describes how the results from the research will be shared with academic, practice, and community-based audiences (including public health and/or health system messages). It is anticipated that the investigators will prepare at least one scientific article that describes the methodological approach or study outcomes and present at one national conference.

Data Management Plan
In Appendix A, include a data management plan that addresses the 5 elements of AR-

25. https://www.cdc.gov/grants/additional-requirements/ar-25.html. For DMP template and guidance, visit link: https://www.cdc.gov/chronicdisease/programs-impact/nofo/index.htm

Translation Plan
The applicant is expected to provide a translation plan that describes how the results from the research could be adopted by other institutions or implemented and sustained after project completion. The applicant should provide details on the anticipated strategies to translate the research findings for key audiences.

Public Health Impact
Successful completion of this project will contribute to the evidence base for recommendations and best practices that clinicians and health care systems might use in identifying ovarian cancers earlier. Shifting the majority of ovarian cancer cases to earlier stages at diagnosis may lead to significant population-based increases in survival.

Special Eligibility and Responsiveness
If an application requests a funding amount greater than the year one award ceiling of $250,000, 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

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 **i**n the determination of scientific merit and the priority score.
Does the applicant demonstrate:

- Evidence of access to the study population?
- Evidence that any data proposed for the project (and any necessary software) is or will be readily available for analysis upon award in the form of Letters of Support from healthcare systems?
- Evidence that the health system(s) have an adequate number of ovarian cancer patients diagnosed and that the longitudinal dataset has sufficient power to detect differences in outcomes proposed?
- Evidence of a diverse sample of participants (a sample that reflects the overall pattern of ovarian cancer incidence in the United States and/or those who are disproportionately affected by ovarian cancer) from various geographic and clinical systems including but not limited to well-established managed care or integrated delivery systems?
- Evidence of proposed coordination to work with other funded Prevention Research Centers to promote the goals and objectives of the SIP
- Evidence of appropriate methodologic expertise in analysis of electronic health records, large datasets, data modeling?
- Evidence of previous ovarian cancer research in the form of past publications or prior grants/funding within the last four years?

- Evidence of prior experience participating in a cancer-related multi-site initiative within the last 5 years?

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

- Geographic variability and representation across the United States (South, Northeast, Midwest, West) and urban vs rural representation.
- Collaborations with differing healthcare delivery models e.g., a traditional fee-for-service model or a well-established public or private managed care or integrated care delivery model.
- Collaboration with a closed healthcare system where patients generally obtain care within the healthcare system and are typically followed for longer periods and there is a longitudinal record of the patient's encounters with the healthcare system over a period of at least one year prior to diagnosis.

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

Availability of Funds
It is anticipated that approximately $1,500,000 is available to fund 3 Prevention Research Centers for a 2-year project period. The average award for each recipient is expected to be approximately $225,000 for year one. The year one ceiling is $250,000. Funding may vary and is subject to change. **Funding available includes direct and indirect costs.**

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

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

Award Administration
CDC Project Scientist/Scientific Collaborator will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards. CDC staff will serve as collaborators and/or co-investigators on this project and will provide technical assistance on project activities such as providing consultation on the design of the protocol, data collection and analysis, and data interpretation and dissemination of results. CDC staff may foster communication and collaborative research with the funded PRCs, co-author manuscripts, and participate in the dissemination of results. However, CDC staff will not have contact with human subjects or data collected from human subjects.

References

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SIP 22-003: Improving and evaluating measures to identify tics and tic disorders including Tourette syndrome in children in epidemiologic studies and clinical settings

Project Description

Persistent tic disorders, including Tourette syndrome (TS), are characterized by the presence of tics for over a year, and can be associated with significant impairment in multiple domains (e.g., family, school, social relationships) (1). Children with tic disorders often have co-occurring disorders, including attention-deficit/hyperactivity disorder (ADHD) and obsessive-compulsive disorder (OCD) (2). As many as 25% of children have tics at some time during development, between 15 and 20% of children have current tics, and approximately 1% of children have a persistent tic disorder, although estimates vary (3-7). Prevalence estimates of children with

previous diagnoses of tic disorders are lower than estimates by clinical assessment, suggesting that approximately half of children meeting criteria for a tic disorder may not have a diagnosis (1). Improving the timely identification of tic disorders can expedite referral to appropriate treatment if needed, which can promote healthier outcomes. In addition, using better tic measures in epidemiologic studies could improve the accuracy of prevalence estimates.

CDC-supported work on Tourette syndrome over the past 7 years has focused on the development and validation of a 10-item tic screener (Motor or Vocal Inventory of Tics, MOVeIT) and two diagnostic instruments (Description of Tic Symptoms, DoTS; Diagnostic Interview Schedule for Children tic disorder module, DISC-5), with the intent of using all three of the measures in epidemiological studies, and the screener in clinical settings. To date, preliminary, unpublished, analyses of validation studies conducted through expert tic clinics have been promising, with the three measures demonstrating high sensitivity (90-98%) and good specificity (82-98%) compared to expert clinical assessment. However, the two instruments (MOVeIT, DoTS) that have been evaluated in general population settings had lower sensitivity (72% MOVeIT, 64% DoTS) and specificity (67% MOVeIT, 58% DoTS) compared to expert clinical assessment in those settings. Thus, new, or revised measures are needed that have higher sensitivity and specificity in general community settings. As a next step to inform the development of improved measures, CDC is currently funding work to compile all data collected in previous development and validation studies to identify items from these three existing instruments that perform well in general community settings. Results of these analyses are intended to inform potential revisions or improvements to the measures and will be shared with the grantee. The current measures are also available from CDC by request.

The purpose of this SIP is to build on previous work to develop revised measures (tic screener and tic disorder diagnostic measures) and evaluate these revised measures in a general community sample of children. The primary objective is a focus on a screening measure and a diagnostic measure to identify children with tics and tic disorders in community/population-based epidemiologic studies and estimate population prevalence. Future work can evaluate how the measures perform in clinical settings. For epidemiologic studies focused on providing accurate prevalence estimates, screening and diagnostic measures are needed that have both high sensitivity and specificity (both ≥ 90%) to best determine the prevalence of tics and tic disorders (i.e., minimal false positives and false negatives). Recent research suggests that parents and children contribute differently in the report of tics and therefore, measures that capture information reported from both are needed. Teacher report can also be considered. Given the substantially higher prevalence of tics compared to persistent tic disorders, it is expected that the project will collect validation data for the screener, and pilot data for the diagnostic measure.

Project Objectives and Outcomes

The objectives of this SIP are to develop and evaluate two revised measures for identifying 1) tics (screening measure) and 2) tic disorders (diagnostic measure) in children and adolescents for use in epidemiologic studies. The screening measure should attempt to achieve sufficiently high sensitivity to identify most cases of tics and tic disorders in a general population of children and adolescents (≥90%), while being sufficiently specific (≥90%) to avoid requiring referring too many children to diagnostic follow-up. The screening measure should also be short (preferably ≤ 10 questions) and include indicators for both motor and vocal tics. If the proposed

measure includes >5 question, analyses should also be conducted to determine if a shorter (2-5 questions) screener can be used to identify tics in a population or general clinical setting (outside an expert tic clinic). The diagnostic measure should be designed to provide valid estimates of the prevalence of having a tic disorder in epidemiologic studies of general populations of children and adolescents. The desired diagnostic measure will allow for identification of the four primary tic disorders: provisional tic disorder, persistent motor tic disorder, persistent vocal tic disorder, and Tourette syndrome, based on the Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5) (*2*) criteria in a population setting. Both the screening and diagnostic measures should be practical to use in epidemiologic studies (brief and simple to administer and score without expert judgement). Both the screening and diagnostic measure could adapt or incorporate measures that have been validated in samples including both children with and without tic disorders (e.g., MOVeIT, DoTS, DISC).

Screening, identification, and referral for services are important roles of public health. Once validated measures are available, the program can pursue new research and epidemiologic studies of tic disorders to better define the prevalence of tic disorders, co-occurring conditions, and other sequelae. In addition, the measures can be evaluated for use in clinical settings to improve identification of tics and tic disorders and used in research studies as a validated and standard way to assess for tic disorders. Use of validated measures of tics and tic disorders in epidemiologic studies could improve the accuracy of prevalence estimates based on these studies. Improving early identification and treatment of tics might improve outcomes among people with tic disorders, and ultimately improve the health and well-being of those affected by tics and tic disorders such as Tourette syndrome.

Public Health Priorities
Healthy People 2030 Objectives

- AHSR01: Increase the ability of primary care and behavioral health professionals to provide more high-quality care to patients who need it (AHSR01)
- MHMD-03: Increase the proportion of children with mental health problems who get treatment

CDC Health Impact-5 Initiative
N/A

NCCDPHP Chronic Disease Prevention and Health Promotion Domains
N/A

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
The applicant should include:

- Methods for data collection as related to the study purpose, including recruitment and enrollment of study participants, inclusion and exclusion criteria, study procedures,

human subjects protection, and data management including protection of personal identifiers.

- A plan for study design and sampling strategies to recruit participants that include a diverse population of children (e.g., race/ethnicity, sex, urban/rural).
- How new measures will be developed, or existing measures will be revised and then evaluated in a general population setting for sensitivity, specificity, positive predictive value, and negative predictive value, and whether an iterative process will be used to improve the measure during testing. If the applicant plans to incorporate additional revisions of the measures during testing, a plan for the development of revised versions should be described.
- A defined "gold standard" for the identification of both tics and tic disorders that will be used for validation of the instruments, and justification for the selection of the proposed gold standard. Gold standards might include, but are not limited to, expert clinical assessment.
- An analytic plan including development of scoring algorithms, the calculation of psychometric statistics for the performance of the tic screener and tic disorder diagnostic instruments such as sensitivity and specificity, data management approach, and demographic characteristics of the population of children and adolescents in which the screening and diagnostic measures will be developed and tested.
- Power analyses to determine optimal sample sizes to identify enough children with tics to evaluate whether the screener has ≥90% sensitivity and specificity for identifying tics in a general population sample compared with the gold standard. Power analyses can be based upon a population prevalence of tics among children 4-17 years as 15%. Analyses for persistent tic disorders (i.e., Tourette syndrome, persistent motor tic disorder, persistent vocal tic disorder - prevalence of 1%) will likely be underpowered and can be considered as pilot data for this project.

Target population

The target population for this work is children (and their parents) representing diversity in race/ethnicity and sociodemographic characteristics. The average age of onset for tic disorders, including TS, is 4 to 6 years, and tic severity often peaks between 8-12 years of age (8,9). Tics and tic disorders are more common among boys (1, 2, 4). Differences in prevalence by race/ethnicity are not well understood. Ideally, the final measures will be appropriate for use in school-aged children and adolescents, aged 4-17 years.

The applicant is expected to describe the size and characteristics of the population that will be the source for recruitment for screening and assessment, and the expected recruitment numbers by age, sex, race/ethnicity, and poverty level (or other sociodemographic characteristics).

Collaboration/Partnerships

If the applicant does not have clinical expertise in tic disorders, it is expected that the applicant will partner to obtain appropriate expertise in the assessment and diagnosis of tics and tic disorders. Experts in tic disorders may be identified through the Tourette Association of America Centers of Excellence (10).

Recruitment Plan

A plan for timing of recruitment to meet the overall sample size based on power analysis should be described. In addition, the applicant should describe the expected age, sex, and race/ethnicity distribution of the recruited population. The applicant is expected to describe recruitment and incentive strategies to maximize participation (e.g., by parents, children, teachers, and/or health care providers) in the study, including prior success using those recruitment strategies for the specified populations.

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

Evaluation Plan /Performance measurement
Applicant should describe an evaluation plan to include ongoing (monthly) evaluation of recruitment and instrument performance should be included as part of the project activities. The evaluation plan should include how performance will be measured to demonstrate that the SMART project goals and objectives are met, as outlined in the SIP proposal, and ability to meet project milestones and adhere to established timelines.

Dissemination Plan
A final report including a detailed description of methodology, participant characteristics, questions tested, and question/instrument performance should be prepared. Specifically, the report should include the estimated sensitivity and specificity of the screening and diagnostic measures for the identification of tics and persistent tic disorders, respectively, compared to a gold standard in a general population of children and adolescents, with adequate statistical precision. The applicant is also expected to publish the results of the project in peer-reviewed journals, in collaboration with CDC.

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

Translation Plan
Translation of the findings is not required for this project. However, the applicant can collaborate and/or share findings with key partners such as primary care providers, and the Tourette Association of America. The applicant can also recommend future translation activities as part of the final report.

Public Health Impact
The proposed research will help to address Improve early identification and treatment of tics to improve outcomes among people with tic disorders and co-occurring conditions; and (b) Improve how tic disorders, including TS, are defined and measured to improve our understanding of how many people have TS, particularly among minority and underserved populations through testing and evaluating the use and accuracy of measures to identify tics and tic disorders in a demographically diverse sample of children from the general population. Improved measures can improve epidemiologic and surveillance work to better understand the prevalence of tic disorders

including Tourette syndrome. If available accurate tic screeners could improve the identification and referral for treatment not only for tic disorders including TS, but also might improve identification of common mental, emotional, and behavioral disorders like ADHD and OCD. Early identification and treatment may lead to improved outcomes among children with these disorders.

Special Eligibility and Responsiveness
If an application requests a funding amount greater than the year one award ceiling of $300,000, 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.

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

The investigators should demonstrate:

- The project team has expertise in the assessment and identification of tic disorders
- Access to the proposed population of children
- Previous experience in recruiting a sufficient sample size (i.e., similar to sample proposed here) of children in the appropriate age range from a general population setting (e.g., primary care, school)
- Statistical expertise to design and conduct psychometric analyses
- Epidemiologic expertise in design of studies to evaluate accuracy of screening and diagnostic tools.

Funding Preferences
None

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

Availability of Funds
It is anticipated that approximately $550,000 is available to fund 1 Prevention Research Center for a 2-year project period. The average award is expected to be approximately $275,000 for year one. The year one ceiling per recipient is $300,000. Funding may vary and is subject to change. **Funding available includes direct and indirect costs.**

Research Status
It is expected that this project will be non-exempt research involving human subjects. It is

anticipated that this project will require local IRB approval. Applicants should provide a federal-wide assurance number for each performance site included in the project.

OMB/PRA
OMB/PRA is not expected to apply

Award Administration
CDC Project Scientist/Scientific Collaborator will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards. CDC staff will serve as consultants on this project and will provide technical assistance as requested. CDC will monitor the recipient's progress through monthly conference calls and review of the annual Research Performance Progress Report (RPPR). CDC staff may be co-authors on manuscripts. However, CDC staff will not be substantially involved in data collection design or analysis and will not perform any data collection or have contact with human subjects or data collected from human subjects or receive datasets from awardees.

References

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SIP 22-004: Disability and Health Data Collaborative: Using Data to Promote the Health and Wellness of People with Disabilities

Project Description
The purpose of this SIP is to implement a multi-site research study and establish a framework for a Disability and Health Data Collaborative (DHDC). The project will use existing administrative data to describe health and wellness status and disparities among adults with intellectual and developmental disabilities (IDD). The intention is to create a research platform to improve access to national disability data. Building upon lessons learned from the previously CDC-funded Disability and Health Multi-State Medicaid Data Analysis Project, this new effort will focus on the use of state Medicaid data and data linkages to better characterize and evaluate the health and wellness of people with IDD. It will also establish a framework for expanding data sources, disabilities, and health conditions in the DHDC.

According to the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (42 U.S.C. §15001 et seq), developmental disability is defined as a severe, chronic disability of an individual that (i) is attributable to a mental or physical impairment or a combination of mental and physical impairments; (ii) is manifested before the person attains the age 22; (iii) is likely to continue indefinitely; (iv) results in substantial functional limitations in 3 or more of the following areas of major life activity: self-care; receptive or expressive language; learning; mobility; self-direction; capacity for independent living; and economic self-sufficiency. A subset of developmental disability is intellectual disability, which is "characterized by significant limitations in both intellectual functioning and in adaptive behavior, which originates before the age of 18" (Schalock et al, 2010).

In 2002, a report from the U.S. Surgeon General highlighted disparities in health status and health care for people with IDD (HSS, 2002). Two decades later, the ability to surveil the health status and health care utilization of people with IDD remains limited and fragmented (Friedman et al., 2018; Havercamp et al., 2019; Krahn, 2019). To address the lack of national information to guide informed decision-making and reduce the health disparities experienced by people with IDD, policy makers, public health professionals, and researchers have turned to other data sources, such as administrative data, state IDD service agency registries, and survey data (Bonardi et al, 2019). Specific states have utilized data linkages to create an improved knowledge base on the health and resource needs of people with IDD (Bonardi et al., 2019). At the federal level, through a 5-year cooperative agreement (i.e., DD16-1603, Improving the Health of People with Mobility Limitations and Intellectual Disabilities through State-based Public Health Programs), CDC/NCBDDD supported the MultiState Medicaid Data Analysis Project (Bonardi et al., 2019), which expanded activities examining Medicaid data for persons with intellectual and developmental disabilities (IDD). The resulting 10-state collaborative has accessed and utilized Medicaid claims data within their states to identify patterns of health and health care utilization for both children and adults with IDD (Lauer et al., 2021; Lindgren et al., 2021; Lu et al., 2020; McDermott et al., 2018; McDermott, Royer, Mann, Armour, 2018). While people with IDD comprise a relatively small segment of the overall population, individuals with IDD have significant health and support needs and receive a disproportionate share of federal and state health care resources (Fujiura et al., 2018; Zuvekas et al., 2020). With total disability-associated health care expenditures estimated to represent 36% of national health care spending (Khavjou et al. 2020), evidence-based interventions to improve the health status and well-being of people with IDD are not only important for long-term quality of life among people

with IDD but may also be impactful for reducing health care costs overall.

Project Objectives and Outcomes

The objectives of this SIP are to:

- Create a research collaborative consisting of contributors from multiple jurisdictions (i.e., states, Washington D.C., and U.S. territories) to harness the power of administrative data, to describe and evaluate the health status and service use of people with disabilities in the U.S.
- Evaluate whether the use of restricted state- or jurisdiction-level Medicaid data or the unified Transformed Medicaid Statistical Information System (T-MSIS) could be utilized and accessed.
- Describe or evaluate at least 2 areas of health and wellness and/or service use for people with IDD documented in Medicaid data.
- Develop a Phase 1 Road Map for the expansion of the collaborative to include additional sites, disabilities, comparison groups, data sources and linkages, and to include a publicly available disability data platform of disability and health administrative data.

The expected outcomes are:

- Establishment of a framework for a disability and health administrative data research collaboration.
- Access to individual-level, jurisdiction-wide Medicaid data for each jurisdiction or from the combined T-MSIS data to include individuals with IDD, comparative population groups (e.g., Medicaid members without IDD but with other types of disabilities or no claims history of disability, general population, etc.), and health and service use indicators.
- Creation of a combined dataset from participating sites with at least 2 published analyses of a key health indicator or use of services by individuals with IDD.
- Development of a plan for data linkages and use of the DHDC platform, including a DHDC road map, to expand contributing jurisdictions, types of disabilities, comparative groups (people with IDD who have other types of health insurance coverage or who lack health insurance, dual enrollees, etc.), data sources (e.g., Medicare, all-payer claims data, state developmental disabilities services; Special Olympics, Inc.; National Core Indicators survey data; Home and Community-based Needs Assessment survey data; mortality data, etc.).

Public Health Priorities

Healthy People 2030 Objectives

- Mental Health and Mental Disorders:
  - DHO1 - Reduce the proportion of adults with disabilities who delay preventive care because of cost
  - DH02 - Reduce the proportion of adults with disabilities who experience serious psychological distress
- Public Health Infrastructure:
  - DHR02 - Increase the proportion of state and DC health departments with programs aimed at improving health in people with disabilities

- Health Care Access and Quality — General
  - AHSS08 - Increase the proportion of adults who get recommended evidence-based preventive health care

CDC Health Impact-5 Initiative
This project aligns with CDC's HI-5 initiative by evaluating social determinants of health to support positive cognitive development and to prevent and support individuals with Traumatic Brain Injury. https://www.cdc.gov/policy/hst/hi5/index.html.

NCCDPHP Chronic Disease Prevention and Health Promotion Domains
N/A

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

The applicant is expected to provide a plan that includes data coverage from at least 4 jurisdictions (States or Territories) each meeting the following criteria:

- Minimum Total State Population of 2,000,000 residents as reported on ACS at the outset
- Direct access to jurisdiction-wide Medicaid Data for all Members with and without IDD (i.e., not only those with disabilities or waivers) from 01/01/2010 – 12/31/2021.
- Allows outside analysts (i.e., from the PRC) access to necessary data (including, but not limited to statewide Medicaid data for all Members) or has an established analyst/contractor that is either an employee of the Medicaid agency or the analyst's firm that has worked with the Medicaid agency in the past and can create a contract/Memorandum of Understanding, with the Medicaid agency, to have access to the data.
- The applicant should provide plans and timelines for:
- Convening DHDC jurisdictional contributors and for any ongoing collaboration between these groups.
- Accommodating data de-identification practices in such a way that data cannot be linked back to individuals but can be linked to future datasets, for example using a hashing algorithm.
- Establishment of data sharing agreement(s) for the DHDC to include a linked dataset with full access for designated CDC personnel.
- Addressing IRB and other regulatory reviews and agreements including Data Use Agreements.
- Creation of the linked dataset, data cleaning, management, storage, and analysis.
- Selection of 2 key analyses and plan for conducting analyses, write-up, appropriate agency clearances (including CDC clearance), and submission to a peer-reviewed journal.
- Contributing technical and scientific expertise to the development a Disability and Health Data Plan ("Road Map").

Study design and methods

- The applicant is to provide a plan to create and utilize a multi-site administrative dataset based on individual-level, jurisdiction-wide Medicaid data for each jurisdiction or from the combined T-MSIS data to include individuals with IDD, comparative population groups (e.g., Medicaid members without IDD but have other types of disabilities or no claims history of disability, general population, etc.), and health and service use indicators.
- The applicant is to propose and carry out analyses of key health indicators or use of services by individuals with IDD. Suggested areas of analysis include:
  - Access to care
  - Types of care needed and utilized
  - Disparities and health equity
  - Specific health conditions
  - Health outcomes to include broader quality of life and wellness

Target population

Individuals with a disability in the US, not necessarily limited to but must include adults with intellectual and developmental disabilities (IDD).

Collaboration/Partnerships

The applicant is expected to propose a plan to collaborate with stakeholders including:

- State and local disability programs
- State and local health departments
- Federal agencies
- Partner organizations
- Health Care Providers
- Disability service providers
- People with disabilities

Recruitment Plan

The applicant is expected to provide a plan to recruit sites that can provide appropriate jurisdiction-wide Medicaid data and serve as collaborators in the DHDC. This project uses existing administrative datasets, so recruitment centers on accessing those data at the individual patient level and not on direct contact or collection of new data with human subjects.

Annual Action Plan

Provide a 12-month action plan for each of the 2 project years using SMART goals and objectives to include a progressive timeline for completion of activities.

Evaluation Plan /Performance measurement

The applicant is expected to provide a plan to achieve SMART project goals and objectives that result in the project outcomes described above while adhering to an established timeline developed early in the project. The evaluation plan should include an assessment of the proportion and socio demographics of the population included in the DHDC dataset compared to

the US adult population based on 2020 Census estimates; quality of data content on IDD/non-IDD status and relevant health indicators; and a plan for DHDC road map.

Dissemination Plan
The applicant is to provide a plan to disseminate findings from the project in at least one professional meeting per year, in peer-reviewed journals, as well as a final report to include a detailed description of the process, lessons learned, and list of resources.

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

Translation Plan
The applicant is expected to contribute to a translation plan to include a DHDC Road Map. The Road Map should specify how the DHDC platform could be expanded to serve as a representative data platform for analyzing and evaluating health and service use and needs for adult US citizens with disabilities. The expansions are likely to include jurisdictions, types of disabilities, comparative groups (people with IDD who have other types of health insurance coverage or who lack health insurance, dual enrollees, etc.), data sources (e.g., Medicare, all-payer claims data, state developmental disabilities services; Special Olympics, Inc.; National Core Indicators survey data; Home and Community-based Needs Assessment survey data; mortality data, etc.) in order to serve as a representative data platform for analyzing and evaluating health and service use and needs for adult US citizens with disabilities.

Public Health Impact
This project will allow for improved characterization and evaluation of the health and wellness of people with disabilities. Improving access to disability data will provide an evidence-base for informed health care policy and resource allocation. Over time, increased data linkages and collaborators may use this resource to evaluate interventions designed to improve the health and well-being of people with disabilities, particularly if implemented early in the life course with the aim of promoting positive adult outcomes.

Special Eligibility and Responsiveness
If an application requests a funding amount greater than the year one award ceiling of $240,000, 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.

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

- The ability to conduct the activities of the project as describe above,
- Access and use of Medicaid data for the proposed data platform,

- At least two years of direct experience with Medicaid or claims-based data and experience utilizing ICD and other codes to identify the IDD population,
- Project team expertise in the assessment and identification of specific health conditions in large administrative datasets as evidenced in the Research & Related Senior/Key Person Section of the SF424 (R&R) and they have access to the datasets for the proposed collaborative.
- Expertise in linkage of data from administrative datasets.
- Success in providing administrative data from multiple contributing jurisdictions in other research projects.
- Commitment to establishing a shared data resource through a research collaboration.

Funding Preferences
None

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

Availability of Funds
It is anticipated that approximately $480,000 is available to fund 1 Prevention Research Center for a two-year project period. The average award for the recipient is expected to be approximately $240,000 for year one. The year one ceiling is expected to be $240,000. Funding may vary and is subject to change. **Funding available includes direct and indirect costs.**

Research Status
Human subjects research review will be necessary. Because this project is based on using existing data, does not contain any new data collection efforts, and because personally identifiable information will be stripped or masked from the submitted dataset, it is anticipated the project would be ruled "exempt"; however, this has yet to be determined.

OMB/PRA
OMB/PRA is not expected to apply

Award Administration
CDC Project Scientist/Scientific Collaborator will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards. CDC staff will serve as collaborators and/or co-investigators on this project and will have joint responsibility for project activities such as content of data sharing and collaboration standards, data set and variable determination, analysis, data interpretation, dissemination of results, and content of the road map. CDC staff may be co-authors on manuscripts. CDC staff will have access to deidentified, or aggregated data collected for the project.

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SIP 22-005: Building Resilience Against Climate Effects (BRACE): Enhancing Practical Guidance to Support Climate and Health Adaptation Planning

Project Description

Climate change intensifies existing climate-sensitive health threats and creates new challenges by exposing more people in more places to hazardous weather and climate conditions (1). Regions of the United States experience climate change and its impacts on health differently, due to location-specific climate risks and exposures. The health risks from the changing climate are influenced by one's exposure to the climate threat, individual sensitivity to the threat, and adaptive capacity or the ability to respond or cope with the threat. Consequently, there are pronounced inequities in climate vulnerability that public health programs aim to address. The Climate and Health Program (CHP) in the Division of Environmental Health Science and Practice (DEHSP) leads CDC's efforts to enable communities to prepare for and respond to the health impacts of climate change. CHP works to promote public health climate resilience through the Building Resilience Against Climate Effects (BRACE) framework (2).

The purpose of this project is to enhance the utility of the BRACE conceptual framework by establishing a field-tested, complete suite of technical guidance and capacity building materials and tools for public health practitioners. This enhanced BRACE package will be accessible and useful to practitioners who are working in diverse U.S. regions facing a range of short- and long-term climate threats and who have a diverse range of resources and climate expertise. This will expand the impact of BRACE in enhancing climate resilience and equity and minimizing the negative health impacts of climate change that are already occurring and intensifying over time.

BRACE is a five-step process intended to help health officials develop and implement adaptation strategies and programs to help communities prepare for the health effects of climate change. The five sequential steps of the BRACE framework include:
Step 1: Anticipate Climate Impacts and Assessing Vulnerabilities - Identify the scope of climate impacts, associated potential health outcomes, and populations and locations vulnerable to these health impacts.
Step 2: Project the Disease Burden - Estimate or quantify the additional burden of health outcomes associated with climate change.
Step 3: Assess Public Health Interventions - Identify the most suitable health interventions for the identified health impacts of greatest concern.
Step 4: Develop and Implement a Climate and Health Adaptation Plan - Develop a written adaptation plan that is regularly updated. Disseminate and oversee implementation of the plan.

Step 5: Evaluate Impact and Improve Quality of Activities - Evaluate the process. Determine the value of information obtained and activities undertaken to improve current and future interventions.

The CHP's flagship cooperative agreement is the Climate-Ready States and Cities Initiative (CRSCI). CRSCI grant recipients use BRACE to identify and estimate the health effects of climate change in their communities, choose public health interventions for the health impacts of greatest concern, and develop and implement climate health adaptation plans. In 2021, a funding opportunity announcement was published for a new five-year funding cycle (CDC-RFA-EH21-2101 Building Resilience Against Climate Effects: Implementing and Evaluating Adaptation Strategies that Protect and Promote Human Health). BRACE is also used by tribes and territories through the Climate-Ready Tribes Initiative and Climate-Ready Territories Initiative. Many jurisdictions without direct CDC funding, ranging from counties to regional compacts, also implement aspects of BRACE. This project will enhance the ability of these stakeholders to use the BRACE framework in their jurisdictions. BRACE has a proven track record through 10 years of utilization by CRSCI grantees. However, there is a need to augment and enhance BRACE to maintain its relevance and provide more support to a range of stakeholders with varying capacities. This project will help address the following needs:

- **Comprehensive, practical, evidence-based guidance for each step of the BRACE framework:** The BRACE package will be enhanced with evidence-based, practical guidance on how to conduct key activities for each of the five steps, tailored for various jurisdiction types. Currently, not all steps include detailed technical guidance from CHP. Additionally, the state of the science has progressed, and more information is now available that may influence how BRACE is implemented (such as downscaled regional climate models, assessments of intervention effectiveness, and best practices for evaluation).
- **Justice, equity, diversity, and inclusion (JEDI) principles presented as the core of the BRACE framework.** CHP partnered with the American Public Health Association's (APHA) Center for Climate, Health, and Equity in 2020-2021 to develop The JEDI Playbook. Initially, this was intended to be a separate companion to BRACE, with specific and practical recommendations for incorporating these principles into each step. However, it is optimal for this content to be fully integrated into BRACE guidance. The already developed JEDI Playbook content would enhance the degree to which BRACE directly and explicitly incorporates JEDI principles.
- **Incorporation of mitigation activities to achieve co-benefits:** American communities are already experiencing the effects of climate change, though we can still take action to curb its extent. It is well understood that responding to climate change involves a two-pronged approach: 1) reducing emissions of and stabilizing the levels of heat-trapping greenhouse gases in the atmosphere ("mitigation") and 2) preparing for and adapting to the changes that are already happening and expected in the future ("adaptation"). Many climate actions can achieve both outcomes. BRACE was originally developed as an adaptation approach, but since that time, more has been learned about how climate mitigation pays significant near-term dividends in improved health and reduced disparities that can be realized at local scale. Accordingly, it is optimal to expand BRACE to include mitigation.

The Climate and Health Program will use the enhanced BRACE package developed by this SIP to help build our public health system's capacity to undertake climate adaptation and local-scale mitigation planning on the scale that is required. CRSCI grantees will be encouraged to use the enhanced package. In addition, CHP will promote the enhanced BRACE package to non-funded jurisdictions.

Project Objectives and Outcomes

The objectives of this SIP are:

- Develop, pilot test, evaluate, and refine a revised BRACE package, consisting of a suite of technical guidance and capacity building materials and tools for public health practitioners, to ensure it is feasible, practical, and accessible;
- Develop a practical overarching description of the BRACE framework, recommendations on how to prepare for climate and health adaptation work, and practical, stand-alone, user-friendly guidance on how to implement each of the five steps for the enhanced BRACE package;
- Develop practical guidance on the implementation of climate mitigation activities that lead to health co-benefits for the enhanced BRACE package;
- Incorporate JEDI concepts in the context of climate and health into the enhanced BRACE package; and
- Include information about how to tailor BRACE in jurisdictions with minimal resources or those who lack staff trained in climate and health planning in the enhanced BRACE package.

Expected outcomes of this SIP are:

- Comprehensive, field-tested, evidence-based suite of BRACE technical guidance and capacity building materials and tools for public health practitioners to plan and implement climate and health adaptation and mitigation interventions;
- Enhanced BRACE package will have a consistent look and feel and will be organized into an interactive and cohesive inventory; and
- Products to support dissemination of enhanced BRACE package.

Public Health Priorities

This project aligns with CDC priorities to support state, local, and tribal health departments, advance evidence-based health policies, and prevent illness, injury, disability, and premature death. It also supports the following other National Public Health Priorities:

- The Guide to Community Preventive Services
  - Priority area of Preparedness and Response
- National Stakeholder Strategy for Achieving Health Equity; specifically
  - Strategy 2: Develop and support partnerships among public, nonprofit, and private entities to provide a comprehensive infrastructure to increase awareness, drive action, and ensure accountability in efforts to end health disparities and achieve health equity across the lifespan
  - Strategy 13: Support and implement policies that create the social, environmental, and economic conditions required to realize healthy outcomes
- The strategic plan of the United States Global Change Research Program (3)

- The White House priorities of climate and racial equity (4)
  - Specifically, this project will support CDC's response to:
- E.O.14008, "Tackling the Climate Crisis at Home and Abroad" (5)
- E.O. 13990 "Executive Order on Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis" (6)
- 86 FR 8845 "Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking" (7)

Healthy People 2030 Objectives
This project supports Healthy People 2030 objectives:

- Improve emergency preparedness and response by building community resilience
  - EH-D02: Reduce heat-related morbidity and mortality
  - EH-01: Reduce the number of days people are exposed to unhealthy air
  - IVP-01: Reduce fatal injuries, improve respiratory health
- PREP-D03: Increase the proportion of adults who know how to evacuate in case of a hurricane, flood, or wildfire
- PREPD04: Increase the proportion of adults who have an emergency plan for disasters

CDC Health Impact-5 Initiative
This project supports HI-5 initiatives including:

- Clean Diesel Bus Fleets
- Public Transportation System

NCCDPHP Chronic Disease Prevention and Health Promotion Domains
N/A

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
The applicant should describe in detail the study design and methods, including the following:

- How the current BRACE package will be assessed, in terms of strengths and gaps. The plan should include consultation with CHP staff regarding known strengths and limitations of the current BRACE framework, which CHP has gathered through technical assistance experience with CRSCI grant recipients. The plans should also include consultation with current CRSCI recipients.
- Methods for gathering expert input on how to revise the BRACE package;
- How the draft suite of materials, resources, and tools will be developed into an enhanced BRACE package;
- How the draft enhanced package will be field tested using standard evaluation methods, which may be qualitative, quantitative, or ideally both using mixed method design. Considerations should be given to engaging implementation partners who represent a range of US geographic regions facing diverse climate threats, have a range of

technological capacities and previous experience with BRACE, and who are engaged in a mix of both adaptation- and mitigation-focused efforts; and
- Plans to incorporate evaluation insights and finalize the enhanced BRACE package.

Target population
The primary target population for the revised BRACE package are city and state health department staff who work closely with disproportionately impacted communities to plan for the health impacts of climate change and protect health.

The evaluation component of this project should also ensure that populations disproportionately affected by climate change are included. This may be accomplished through ensuring:
- Participating organizations and health departments selected to participate are serving socially and economically marginalized populations; and
- Frontline, community-based organizations (i.e., comprised of members from the community) with a climate equity focus are consulted.

Collaboration/Partnerships
The success of this project hinges on strong collaborations. In proposing collaboration efforts, the applicant should describe how it will:
- Work with CHP staff to document experiences providing technical assistance to CRSCI grantees and other insights gathered from using BRACE and working with partners in the field;
- Engage with experts in the field. This could involve convening an advisory panel of climate and health adaptation practitioners, experts from a range of US geographic regions and jurisdiction types (e.g., cities and states), and members from disproportionately affected communities, via frontline community-based organizations working for environmental or climate justice;
- Identify 2-3 current CDC CRSCI grant recipients who will review, pilot, and provide evaluation feedback on components of the BRACE framework;
- Identify 1-2 public health organizations or agencies engaged in climate and health planning who are not current CRSCI grant recipients who will review, pilot, and provide evaluation feedback on components of the BRACE framework; and
- Identify 2-3 frontline, community-based organizations with a climate equity mission who will review, pilot (if feasible), and provide evaluation feedback on components of the BRACE framework.

Recruitment Plan
The applicant should clearly describe a recruitment plan appropriate to the proposed approach. Specifically, the applicant should describe recruitment plans for:
- Experts working the field of climate and health adaptation from a range of US geographic regions and types of jurisdictions;
- CRSCI grant recipients;
- Public health organizations or agencies engaged in climate and health planning who are not current CRSCI grant recipients; and
- Frontline, community-based organizations with a climate equity mission.

The applicant may consult a list of funded recipients on the CHP webpage (https://www.cdc.gov/climateandhealth/crsci_grantees.htm). The applicant may contact the principal investigators shown on recipient webpages to assess interest in collaboration. The applicant may identify other relevant stakeholders through those CRSCI points of contact. Once funded, CHP can also provide suggestions and guidance about appropriate partners.

This project is not anticipated to involve any recruitment, direct contact, or follow-up with human subjects.

Annual Action Plan
Provide a 12-month action plan using goals and objectives to include a progressive timeline for completion of activities. Goals and objectives should be SMART: specific, measurable, achievable, relevant, and timebound.

Evaluation Plan /Performance measurement
Applicants are expected to develop an evaluation plan. The purpose of the evaluation is to improve the comprehensiveness, feasibility, acceptability, and utility of the BRACE package, based on experience, expertise, and input from climate and health practitioners. After the enhanced BRACE package has been drafted, additional evaluation should also be used to refine and finalize the BRACE package.

The applicant should describe:

- The evaluation plan, starting with engaging stakeholders. The evaluation plan, ideally following the CDC Evaluation Framework, should include explicit evaluation questions and associated metrics or indicators, data sources, and methods. The evaluation should use approaches and methods appropriate for the stated purpose. A developmental evaluation approach is encouraged, since this will generate evaluation insights on a rapid and ongoing basis to support decision making;
- How evaluation findings will be used to expand and improve the BRACE package. The applicant should document the findings systematically and transparently (e.g., organized by evaluation questions and indicators and accessible to collaborators) and should also track how findings are incorporated into the final products; and
- How evaluation findings will be shared with the CHP and key collaborators.

Dissemination Plan
The applicant is expected to describe how the enhanced BRACE materials will be packaged into a cohesive, visually appealing, user-friendly and accessible format that adheres to CDC web templates and branding standards. CDC's CHP will host the materials on its website. All public-facing materials must be Section 508 compliant. The applicant is expected to develop a dissemination plan for the project including publications, presentations, and other communications materials to support the dissemination of findings that support the revised BRACE package to national, state, and local organizations involved in climate and health planning.

Data Management Plan

If the applicant is collecting public health data, a standalone data management plan that addresses the 5 elements of AR-25 must be submitted in Appendix A.

Translation Plan
The applicant should propose potential approaches for the use of project findings and BRACE materials and tools by CHP and CRSCI grant recipients such as model practices, protocols, and policies.

Public Health Impact
This project would improve the utility of the BRACE conceptual framework, by providing expanded and enhanced guidance, resources, and tools to empower communities to prepare for climate change, and address hazards such as heat waves, flooding events, and vector-borne disease. This will particularly help disproportionately impacted communities directly experiencing the inequitable health impacts of climate change. An improved BRACE package will also enhance the technical assistance CHP is able to provide to CRSCI grant recipients and other partners.

Special Eligibility and Responsiveness
If an application requests a funding amount greater than the year one award ceiling of $350,000, 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.

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

- Does the applicant demonstrate evidence that the project team will include staff with the skills and expertise needed to develop and implement the proposed methodology?
- Does the applicant have experience and expertise with evaluation methods that generate timely feedback for incorporation into programs?
- Does the applicant identify appropriate partners to accomplish the goals/objectives of the project?
- Does the applicant show evidence of support from key collaborators in the form of Letters of Support?

Funding Preferences
None

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

Availability of Funds
It is anticipated that approximately $700,000 is available to fund 1 Prevention Research Center for a 2-year project period. The average award is expected to be approximately $350,000 for year one. The year one ceiling per recipient is $350,000. Funding may vary and is subject to change. **Funding available includes direct and indirect costs.**

Research Status
It is expected that this project will not involve human subjects research. It is anticipated that this project will not require local or CDC IRB approval. Applicants should provide a federal- wide assurance number for each performance site included in the project.

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

Award Administration
CDC Project Scientist/Scientific Collaborator will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards. CDC staff will serve as consultants on this project, and will provide technical assistance, as requested, on project activities such as evaluation design, data collection and analysis, and data interpretation and dissemination of results. CDC staff may be co-authors on manuscripts. However, CDC staff will not have contact with human subjects or identifiable data collected from human subjects.

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SIP 22-006: Dementia Risk Reduction Research Network – Collaborating Centers

Project Description

Alzheimer's disease and related dementias (ADRD), often beginning with less severe cognitive decline and problems with thinking and memory, are the 6th leading cause of death in the United States [1]. Although ADRD currently has no cure, modifiable risk factors and interventions play an important role in the progression of ADRD and certain factors may reduce the risk for or delay the development of symptoms of cognitive decline [2-4]. The Advisory Council on Alzheimer's Research, Care, and Services (Advisory Council) of the National Alzheimer's Project Act (NAPA) has recognized the importance of developing a national goal to address modifiable risk factors to prevent or delay onset of ADRD and identified the following 14 risk and protective factors for ADRD for consideration in that goal based on their available scientific evidence and ripeness for public health intervention [5]: Alcohol, Cognitive Activity, Depression, Diabetes, Diet, Hearing Loss, Hyperlipidemia, Hypertension, Obesity, Physical Activity, Sleep, Smoking/Tobacco Use, Social Isolation, and Traumatic Brain Injury.

The purpose of the project is to implement promising, evidence-informed interventions and solutions to reduce risk for dementia and improve quality of life for persons with symptoms of cognitive decline. The overall objective of the Dementia Risk Reduction Research Network is to facilitate the translation and expansion of evidence-based research on dementia risk reduction into public health practice. The Network is also expected to collaborate and leverage the expertise of each collaborating center and other related CDC supported projects (e.g., Building our Largest Dementia Infrastructure (BOLD) Public Health Center of Excellence on Risk Reduction) and establish partnerships with relevant communities, healthcare systems, public health practitioners, and other stakeholders and sectors.

This SIP will focus on interventions to reduce the risk for ADRD by targeting the 14 modifiable risk factors identified by the NAPA Advisory Council (in bold above). Each Collaborating Center within the Network will concentrate their efforts on primarily one of these identified risk factors for their project. The applicant's senior team should bring expertise in the selected risk reduction topic area AND expertise in dementia or cognitive decline in order to implement effective approaches for persons with mild symptoms of cognitive decline. There are numerous ongoing longitudinal, clinical, and other research studies (e.g., SPRINT, MIND 2.0, FINGER, , U.S. POINTER) to assess whether risk reduction interventions focusing on these factors may prevent or delay cognitive decline and/or dementia. This SIP is intended to complement NOT duplicate those efforts. Applicants are encouraged to apply evidence from existing research and interventions to inform their proposed projects. Projects should utilize the most promising dementia risk reduction evidence to create, enhance, and/or integrate programs to address one of the aforementioned risk and protective factors in populations with symptoms or a diagnosis

of mild cognitive impairment (MCI) [6]. The projects will measure impact on quality of life for the target population and costs associated with implementing the intervention(s). It is not expected that significant progress towards achieving health outcomes (i.e., delaying or preventing dementia) will be made during the project period. It is expected that projects will provide additional evidence to the field to inform approaches and longer-term projects to address dementia through risk reduction.

Project Objectives and Outcomes
Specific objectives of this project include:

- Examining the literature and incorporating best practice or other recommendations to maximize the impact of the project on the target population throughout the project period.
- Identifying and implementing effective interventions to reduce risk for ADRD.
- Partnering with impactful and relevant organizations and other stakeholders.
- Collaborating with other members of the Network through monthly conference calls, e-mail, online meetings, or other channels to share knowledge, best practices, and other resources (e.g., survey instruments, protocols, program toolkits) to enhance intervention implementation, effectiveness, evaluation, program reach, and impact.
- Evaluating the effectiveness of the interventions, including but not limited to quality of life, overall health, and social connectedness.
- Assessing the costs of planning and implementing interventions.
- Disseminating findings from the project. This may include publishing research articles, presenting at conferences and meetings, convening webinars, and other efforts.

Public Health Priorities

Healthy People 2030 Objectives

- DIA-02: Reduce the proportion of preventable hospitalizations in older adults with diagnosed Alzheimer's disease and other dementias.
- DIA-03: Increase the proportion of adults with Subjective Cognitive Decline (SCD) who have discussed their confusion or memory loss with a health care professional.
- OA-01: Increase the proportion of older adults with reduced physical or cognitive function who engage in light, moderate, or vigorous leisure-time physical activities

CDC Health Impact-5 Initiative
N/A

NCCDPHP Chronic Disease Prevention and Health Promotion Domains

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

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

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

Target population

The intended target population is people with mild symptoms of cognitive decline or MCI who are at increased risk for developing ADRD, as identified in the project description. The project must address specific populations with one or more risk factors for ADRD and have mild symptoms of cognitive decline or MCI . If the applicant chooses to focus their project on protective factors for ADRD, they still must select and describe a target population with one or more risk factors for ADRD. The applicant must identify the target population and describe how the population is at increased risk for ADRD in their application consistent with the aims of the project.

The applicant should provide information on the demographic characteristics of the target population with respect to gender and race/ethnicity. It is important that the target population is sufficiently diverse with respect to these characteristics due to the disparities in the prevalence of Alzheimer's disease and related dementias and in many of the risk and protective factors that exist across groups.

Collaboration/Partnerships

The applicant should engage in collaboration with experts in brain or cognitive health, the risk or protective factor topic area (e.g., smoking), aging/gerontology, and other relevant stakeholders. The applicant should engage and work with relevant stakeholders from the public heath perspective to maximize the impact for their project, including health care systems and other Networks as appropriate. The applicant is also expected to collaborate with the other funded Collaborating Centers within the Network, other related CDC funded projects, as well as other organizational units at their institution.

Recruitment Plan

The applicant should describe a plan to recruit the relevant project participants.

Annual Action Plan

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

Evaluation Plan /Performance measurement
The applicant should describe an evaluation plan that meets SMART goals, consistent with the CDC evaluation framework (http://www.cdc.gov/eval/framework/). The evaluation plan must at minimum include as a component but is not limited to:

- The level of public health impact the project achieved and its scalability.
- The extent to which the implementation of the project addresses the target population described in the project application.
- A listing and description of resources created and provided to the intended audience(s).
- The resources and costs involved in implementing the project.
- All collaborative efforts that occurred throughout the project.

Dissemination Plan
Applicants should develop a dissemination plan that will be implemented by the awardee to, at minimum, publish and present the results of findings publicly (for example, through a scholarly article and presentation at a national conference), prepare a detailed report of findings for dissemination, and notify/educate appropriate health professionals, organizations, and/or professional societies about the results of the project. The applicant is also expected to regularly share results and findings with the other awarded Centers of the Network and other organizations with CDC-funded ADRD projects. All results, findings, reports, or processes developed under this cooperative agreement should be shared with CDC.

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

Translation Plan
The applicant should describe the strategies to translate the findings of the research and must at minimum:

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

Public Health Impact
This project will fund the Dementia Risk Reduction Research Network, a national network of academic, public health, and community partners that will improve interventions and

management for people at increased risk for developing ADRD with the ultimate goal of reducing the burden of ADRD, especially for populations disproportionately impacted [7].

Special Eligibility and Responsiveness

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

- The applicant's PI and/or key personnel/members of the senior team must have expertise within the field of dementia or cognitive decline, as demonstrated by at least 3 peer-reviewed publications in biosketch, since 2016, focusing in this topic area.
- The applicant's PI and/or key personnel/members of the senior team must have expertise within the field of the ADRD risk factor selected for the project, as demonstrated by at least 3 peer-reviewed publications in biosketch, since 2016, focusing on their selected ADRD risk factor.
- The applicant must provide a current Memorandum of Understanding (MOU) or collaborator letter of support describing access to study population(s) in which the project will be conducted. The applicant must document evidence of access to a population consistent with the target population description contained within this NOFO. This evidence should be documented in Appendix A.

If an application requests a funding amount greater than the year one award ceiling of $300,000, 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.

Additional Review Criteria

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

- Does the applicant provide a compelling approach for accomplishing the project objectives?
- Does the applicant demonstrate evidence of successful experience working with federal, state, or local public health and healthcare systems or other stakeholders relevant to the proposed project?
- Does the applicant demonstrate successful experience evaluating the impact of public health interventions?
- Does the applicant describe successful experience creating translation and dissemination products targeting public health practitioners, non-governmental organizations, and/or decision makers? The applicant should include recent quantifiable examples where possible.

Funding Preferences

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

- Diversity of proposed research topics (non-duplication of topics).
- Diversity of study population.
- Geographic diversity.

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

Availability of Funds
It is anticipated that approximately $3,000,000 is available to fund up to 5 Prevention Research Centers for a 2-year project period. The average award for each recipient is expected to be approximately $250,000 for year one. The year one ceiling per recipient is $300,000. Funding may vary and is subject to change. **Funding available includes direct and indirect costs.**

Research Status
It is expected that this project will be non-exempt research involving human subjects. It is anticipated that this project will require local IRB approval. It is expected that this project will not require CDC IRB approval. Applicants should provide a federal-wide assurance number for each performance site included in the project.

OMB/PRA
OMB/PRA is not expected to apply

Award Administration
CDC Project Scientist/Scientific Collaborator will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards. CDC staff will serve as consultants on this project, and will provide significant technical assistance, as requested, on project activities such as evaluation design, data collection and analysis, and data interpretation and dissemination of results. CDC staff may be co-authors on manuscripts and other products. However, CDC staff will not have contact with human subjects or identifiable data collected from human subjects.

Any products/materials resulting from this award may be developed collaboratively and co-branded, such as scientific papers and presentations or other forms or written documentation/products. CDC staff will only act as coauthors if CDC staff meet the CDC authorship criteria policy.

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SIP 22-007: COVID-19 and Women: An Assessment of Challenges and Lessons Learned to Enhance Public Health Emergency Preparedness for Women and Families

Project Description

The COVID-19 pandemic has had a disproportionate impact on persons identified as women, in large part due to the pre-existing and compounded effect of economic and social factors, mental health challenges, and barriers to health care [1,2]. For example, women generally earn less than men [3], and this status exacerbates economic challenges for women and their families during the pandemic. Women are overrepresented in service and informal sector jobs that have been heavily impacted during the pandemic [4]. Also, women represent a large proportion of frontline healthcare workers who have reported added occupational stress due to providing healthcare services during the pandemic [5-7]. Unpaid caregiving during the pandemic has placed a disproportionate burden on women who are often the primary caregivers for children and older adults [8-10]. Mental health issues for women related to financial and other stressors are also noted during the pandemic [11]. Polls indicate that women are more likely than men to report negative mental health effects from worrying about COVID-19 [12]. There has also been a heightened risk of intimate partner violence (IPV) for women during the pandemic, with variations in IPV reporting and response depending on the population and outcomes studied [13-16]. In addition, the pandemic has impacted the availability and utilization of women's healthcare services such as sexual and reproductive health services and preventive care such as mammography screening [1, 17-21].

Despite the unique burdens and challenges experienced by many women during the pandemic, it is likely that many women have also demonstrated strength and resilience to successfully overcome challenges and manage critical resources for themselves and their families. There is an emergence of research documenting the medical and physiological effects of COVID-19 on women [22-25]. However, there is limited information on how women succesfully cope with social determinants of health (SDOH)- related challenges during the pandemic [26-31]. SDOH challenges may include, but are not limited to, challenges with finances, employment, housing, obtaining food, ensuring quality education or care for child or adult dependents, experiences with domestic violence, race or gender discrimination, or seeking health care (access to health care is

identified in Healthy People 2030 as a SDOH)[32]. To the extent that these challenges can be anticipated and addressed, emergency preparedness and response can be optimized for the special needs and challenges identified for women and families.

The purpose of this SIP is to develop and implement a process to engage with whome who are disproprotionately impacted by the SARCS-CoV-2 pandemic to: document women's unique factors and experiences that place them more or less at risk during the pandemic (including COVID-19 vaccine perceptions and experiences); summarize information regarding effective management of social, physical, and mental health challenges and resources during the pandemic; and highlight indicators of women's resilience during the pandemic. Examples of disproportionately affected populations include persons who are identified as women from low socioeconomic status (SES) households; women from rural households; tribal households; women caregivers; pregnant and postpartum women; and African American or Black, Hispanic or Latino, American Indian and Alaska Native, Native Hawaiian and Other Pacific Islander, or Asian women. It is hoped that enhanced knowledge about the unique needs and challenges experienced by women during COVID-19, and knowledge of effective strategies that women use may help to improve emergency preparedness and response efforts for women during COVID-19 and other public health emergencies.

Project Objectives and Outcomes

This project aims to document experiences, challenges, indicators of resilience, and lessons learned by women and families during and related to COVID-19 and the pandemic, including information on: SDOH challenges; mental health challenges; caregiving experiences; physical and mental health care; utilization and management of personal, social, and healthcare resources during the pandemic; and use of health technology to access needed health services.

Objectives:
1. Assess women's experiences, challenges, successes, and lessons learned regarding women's experiences with SDOH and managing resources to address social, mental, and physical health during the COVID-19 pandemic, including acceptance and utilization of COVID-19 vaccinations.
2. Generate a detailed report of project findings.
3. Provide a report of recommendations for public health practice, including strategies that can be considered or implemented into emergency preparedness plans that are tailored to women and families to optimize effective preparedness and response during infectious disease outbreaks and other public health emergencies.
4. Develop products that summarize findings tailored for scientific and general audiences, including products that use plain language and data visualization.

We are interested in identifying which SDOH women have found to be a challenge or concern as they deal with the interactions of SDOH, physical health, mental health, and the healthcare system during COVID-19, and how women have managed these challenges during the pandemic. These challenges could have been exacerbated broadly by the pandemic (e.g., job and childcare challenges created by shelter in place orders; reduced access to routine health care and assistive services for caregiving) or they could have resulted directly from COVID-19 illness experienced

by women or their family members (e.g., accumulated medical, financial, or psychosocial costs). Additionally, feedback and insights are requested from women regarding barriers and facilitating factors related to physical and mental health promotion during COVID-19, including COVID-19 vaccination for women and their families.

Expected outcomes:

- Increased awareness of how COVID-19 impacts women and families.
- Enhanced understanding of barriers and facilitators related to women managing and overcoming challenges experienced during COVID-19.
- Increased understanding of emergency preparedness (including mitigation, response, and recovery) tailored for women and families.
- Completed reports of project findings and recommendations for public health practice and emergency preparedness.

Results from this project will be used to enhance emergency preparedness and response during current and future public health emergencies by helping to ensure that the needs of disproportionately affected women and families are effectively anticipated and addressed—particularly related to SDOH and mental health needs. Selected information from this project may also be used to model predictors of susceptibility and resilience for COVID-19 and other public health emergencies and develop effective preparedness and response plans. The project can help federal entities, partner organizations, and local, statewide, and tribal communities obtain unique insights from women to help better prepare for public health emergencies.

Public Health Priorities

This project addresses five Healthy People 2030 Focus Areas. The specific objectives are listed below:

Emergency Preparedness

- PREP D02: Increase the proportion of adults who engage in preparedness activities for a widespread outbreak of a contagious disease after recently receiving preparedness information on outbreaks

SDOH – Health care quality & access

- AHS – 04: Reduce the proportion of persons who are unable to obtain or delayed in obtaining necessary medical care

Community Support

- ECBP – D07: Increase the number of community-based organizations providing population-based primary prevention services

Mental Health & Mental Disorders

- DH – D01: Reduce the prevalence of anxiety or depression among family caregivers of persons with disabling conditions

Health Communication

- AHS – R02: Increase the use of telehealth to improve access to health services
- HC/HIT: Increase the proportion of adults with broadband access to the Internet

CDC Health Impact-5 Initiative Not applicable.

NCCDPHP Chronic Disease Prevention and Health Promotion Domains
Domain 2*:* Environmental approaches. This domain promotes health and supports and reinforces healthy behaviors in communities.
Domain 4: Community-clinical linkages. This domain focuses on strategies that link community and clinical services to ensure that people with or at high risk of chronic diseases have access to the resources they need to prevent or manage these diseases.

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
It is expected that the applicant will:

- Utilize systematic qualitative and/or quantitative approaches to achieve the study objectives and outcomes outlined in the SIP.
- Justify and clearly describe the study methods used, including data sources and measures; activities related to data collection; data collection mode, sampling, and recruitment; and potential analyses.
- Include study participants who are primarily women from one or more of the priority populations noted in this SIP.
- Include participatory approaches that actively engage women to provide meaningful information that can benefit themselves, families, and other women.

Target population
The priority populations for this proposal are adult women (aged 18 and older) from diverse cultural or economic backgrounds who were disproportionately affected during COVID-19. Examples of priority populations include women residing in low SES, rural, or tribal geographic areas; women caregivers; pregnant and postpartum women; and African American or Black, Hispanic or Lation, American Indian and Alaska Native, Native Hawaiian and Other Pacific Islander, or Asian women. The priority populations will be inclusive of all adult women, regardless of employment, disability, sexual orientation, preferred language, education, or health literacy status.

Collaboration/Partnerships
Applicant is expected to work with multisector partnerships and collaborations that result when various segments come together and shift from competitive to cooperative approaches to solving challenges affecting a whole community. The applicant's multisector partnerships/collaborations may include new or existing partners, including, but not limited to:

- *Community*—recognized community experts, including but not limited to local residents; community health workers; community health representatives/advisors; community groups or organizations
- *Government*—state and local public health; local government; community health centers; Area Agency on Aging; aging services
- *Nonprofit*—community-based organizations; statewide non-profit organizations; faith-based institutions/services; state and national associations

- *Private*—business segment providing services to customers (i.e., retail, restaurants, hotels, sales and similar fields, transportation; internet, cable, phone providers); public sector schools and libraries

Recruitment Plan
Applicant is expected to describe plans to recruit participants as part of the study design and methods section. Recruitment plans for data collection should consider parameters to ensure participants and samples reflect characteristics of the communities and geographies they represent.

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

Evaluation Plan /Performance measurement
Applicant is expected to develop an evaluation and performance management plan to assess project performance and evaluate progress on the extent to which project objectives and anticipated outcomes were met. The plan is expected to identify, but not be limited to, responsible parties, source of information used to assess progress toward project objectives and outcomes, and determination of project feasibility. Plan should include SMART project goals and objectives and plans to remediate any anticipated barriers. Applicants may also consider including an evaluation plan to describe lessons learned about the study process and effective engagement with study participants.

A resource regarding evaluation can be found at: https://www.cdc.gov/eval/index.htm.

Dissemination Plan
Applicant is expected to develop a dissemination plan that will, at minimum, prepare a detailed report of findings, present the results of findings to the academic institution and notify/educate project participants and communities about the results using a participatory approach that actively engages with project participants and partner communities. It is also anticipated that the applicant will prepare an outline for a proposed scientific manuscript. Applicants should also share project findings in plain language with data visualization for use by the public. All reports or processes developed under this cooperative agreement should be shared with CDC**.**

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

Translation Plan
The applicant is expected to provide a detailed translation plan with the anticipated strategies to translate the research findings for key audiences and their partners, including project participants and their families, members of the public, emergency management organizations, and state and local decisionmakers for public health practice. The translation plan should: a) describe recommended approaches on how the results from the project could be implemented and

sustained; and b) identify potential successes and challenges; and c) and determine promising practices that are effective, scalable, and sustainable after the funding cycle.

Public Health Impact
This SIP seeks to obtain unique insights from women to help federal entities, partner organizations, and local, statewide, and tribal communities develop effective preparedness and response plans and implement mitigation strategies to reach women and families put at increased risk in public health emergencies.

Special Eligibility and Responsiveness
If an application requests a funding amount greater than the year one award ceiling of $250,000, 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.

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

- Access to the proposed study population(s) as evidenced by a Memorandum of Agreement (MOA) or other documentation. This evidence should be placed in Appendix A.

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

- Does the applicant provide a compelling approach for accomplishing the research objectives?
- Is the proposed strategy to recruit and retain hard to reach populations appropriate?
- Do the investigators show previous research expertise that have provided high quality outputs and contributed to improvements in public health practice?
- Does the applicant demonstrate experience working or conducting applied research with one or more of the following priority populations of adult women (aged 18 and older) from diverse cultural or economic backgrounds: women residing in low SES, rural, or tribal geographic areas; women caregivers; pregnant and postpartum women; and/or women from the following racial or ethnic groups -- African American or Black, Hispanic or Latino, American Indian and Alaska Native, Native Hawaiian and Other Pacific Islander, or Asian women.
- Are the priority populations inclusive of all adult women, regardless of employment, disability, sexual orientation, preferred language, education, or health literacy status?
- Does the applicant have experience with implementation of community engaged and participatory research approaches?
- Does the applicant describe a plan to: a) collaborate or partner with public health preparedness entities (e.g., local health departments, emergency management services, etc.) to advise or assist in the design of the study (identifying priority populations, suggesting research questions/study domains/indicators, etc.); and b) help interpret,

disseminate, and utilize findings that will be useful for responders to develop plans that are culturally and gender appropriate for the unique needs of women during public health emergencies?

- Does the applicant describe experience creating translation and dissemination products tailored to general audiences, as well as public health practitioners, non-governmental organizations, and/or decision makers?
- Does the applicant describe systematic, qualitative and/or quantitative approaches to achieve the study objectives and outcomes outlined in the SIP? For example:
    - For qualitative approaches, does the applicant describe methodologically sound and feasible approaches for: recruiting, selecting, and engaging with the priority population(s); developing questionnaires or other qualitative data collection instruments; conducting in-depth interviews, focus groups, town hall meetings, or other active engagement methods for collecting qualitative data; and analyzing qualitative data?
    - For quantitative approaches, does the applicant describe methodologically sound and feasible approaches for: selecting a pilot or representative sample that reflects a diversity of women from one or more priority populations for this proposal; developing and testing new or utilizing existing tested survey items to gather data to address the objectives of the proposal; and analyzing and reporting quantitative data?
    - For mixed-method approaches, does the applicant describe methodologically sound and feasible qualitative and quantitative approaches as mentioned above?

Funding Preferences
Preference will be given to applicants who prioritize disproportionately affected populations in their study – including women from low socioeconomic status (SES) households; women from rural households and tribal households; women who are caregivers for dependent children or older adults; pregnant and postpartum women; and African American or Black, Hispanic or Latino, American Indian and Alaska Native, Native Hawaiian and Other Pacific Islander, or Asian women.

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

Availability of Funds
It is anticipated that approximately $500,000 is available to fund two Prevention Research Centers for a 1-year project period. The average award for each recipient is expected to be approximately $250,000. The year one ceiling per recipient is $250,000. Funding may vary and is subject to change. **Funding available includes direct and indirect costs.**

Research Status
Research Projects It is expected that this project will be non-exempt research involving human

subjects. It is anticipated that this project will require local IRB approval. Applicants should provide a federalwide assurance number for each performance site included in the project.

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

Award Administration
CDC Project Scientist/Scientific Collaborator will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards. CDC staff will serve as consultants on this project, and will provide technical assistance, as requested, on project activities such as evaluation design, data collection and analysis, and data interpretation and dissemination of results. CDC staff may be co-authors on manuscripts. However, CDC staff will not have contact with human subjects or identifiable data collected from human subjects.

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