

Centers for Disease Control and Prevention

NATIONAL CENTER FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION

Health Promotion and Disease Prevention Research Centers: 2021 Special Interest Project Competitive Supplements (SIPS)

RFA-DP-21-004

03/03/2021

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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: 2021 Special Interest Project Competitive Supplements (SIPS)

Activity Code

U48

Amendment 1.0 made February 11, 2021 and include the following updates:

Overview.

- **Executive Summary,** under **"Funds Available and Anticipated Number of Awards",** the estimated total funding for entire project period for combined SIPs was increased to $10,080,000; estimated total funding for first 12-month budget was increased to $4,210,000; and estimated number of awards to 14.
- **Number of PDs/PIs** amended to include the following text: **(CORE PRC PI should be listed as the PI on all SIP applications. The SIP PIs can be listed as CO-PIs)**.

Section II. Award Information

- Estimated Total Funding increased to $10,080,000
- Anticipated Number of Awards increased to 14
- Award Ceiling for combined SIPS increased to $4,335,000

Section III. Eligibility Information

- In **Responsiveness**, SF424 instructions for fields 4a, 4b and 4c were amended.

Section VIII. Other Information

- **SIP21-002 (Availability of Funds)**:
  - **12 month ceiling for SIP21-002 was corrected to $300,000**.
  - The text **"Funding is anticipated for up to two awards"** was added.
- **SIP21-003 (Project Description, Project Objectives, Funding Preferences)**:
  - The project description and project objectives were edited to reflect only one project and not multiple projects. References to more than one project were removed.
  - **Diversity in AAEBI Interventions was added in Funding Preferences**.
- **SIP21-008 (Availability of Funds, Additional Review Criteria)**:
  - **Number of anticipated awards was increased to three (3).**
  - **Total estimated funding for entire project period was increased to $1,500,000**.
  - Text was added to first bulleted item under additional review criteria: **Specifically for research topic 1 (Examining psychosocial characteristics associated with mortality and/or patient-reported outcomes (e.g., physical functioning, general health, mental health, pain, and social functioning), including adverse childhood experiences, work loss, and other measures of socio-economic deprivation, self-reported experiences of racism).**
- **Questions from Potential Applicants and CDC Responses and Questions and Responses from the pre-application call** added to end of Section VIII.

Notice of Funding Opportunity Type

New

Agency Notice of Funding Opportunity Number

RFA-DP-21-004

Assistance Listings (CFDA) Number(s)

93.135

Category of Funding Activity

HL - Health

NOFO Purpose

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: Adolescent Health, Arthritis, Cancer Prevention and Care, Drug and Alcohol Use, Maternal, Infant and Child Health, Mental Health and Mental Disorders, Physical Activity, and Health care access and quality.

Key Dates

Publication Date:
To receive notification of any changes to RFA-DP-21-004, 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.
1/24/2021

Application Due Date:
03/03/2021
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:
04/09/2021

Secondary Review:
05/14/2021

Estimated Start Date:
09/30/2021

Expiration Date:
02/25/2021

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

Required Application Instructions

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

(both in the Application Guide and the NOFO) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

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

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: Adolescent Health, Arthritis, Cancer Prevention and Care, Drug and Alcohol Use, Maternal, Infant and Child Health, Mental Health and Mental Disorders, Physical Activity, 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 **$10,080.000**. The estimated total funding (direct and indirect) for the first year (12-month budget period for all SIP proposals is **$4,210,000**. 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, 9/30/2021 - 9/29/2022, is **$4,210,000**. The estimated total funding (direct and indirect) for the entire project period, 9/30/2021 to 9/29/2024, is $10,080,000. 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 can 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 (eg, only one application per SIP per institution is allowed).
- **Application Type.** New
- **Special Date(s).** Pre-Application Informational Call is scheduled for January 14, 2021; 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 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: adolescent health, arthritis, cancer, drug and alcohol use; maternal, infant, and child health, mental health and mental disorders, physical activity, and health care access and quality

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

The following are the current SIPs and associated topic areas:

- Adolescent Health: 21-001
- Alcohol Use: 21-002
- Arthritis: 21-003

- Cancer Prevention and Care: 21-004, 21-005, 21-006
- Epilepsy: 21-007
- Lupus: 21-008
- Maternal, Infant and Child Health: 21-009
- Health Care Access and Quality: 21-010

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 21-001: Integrating social emotional well being w/ physical activity & nutrition practices in school-based out-of-school time (OST) programs: a demonstration project.

This project will contribute to findings on the feasibility, appeal, and effectiveness of an integrated approach (i.e. offering physical activity and serving foods in ways that support social-emotional climate and learning, SEL/SEC). Findings will increase the understanding of the social and emotional competencies and skills that guide youth's relationships with themselves and the influence of these competencies and skills on academic engagement and achievement as well as health behaviors and outcomes. If this approach is found to be effective, efforts to bring it to scale could benefit the millions of youth who participate in OST programming.

SIP 21-002: Examining Contexts of Alcohol Availability and Accessibility

This project will contribute findings on how the context of alcohol availability or aspects of the delivery of alcoholic beverages impacts excessive drinking and related harms. This will inform state and local public health options for regulating the availability of alcohol to create healthier communities.

SIP 21-003: Evaluating alternative delivery models for arthritis-appropriate evidence-based physical activity and self-management interventions

With the 2020 COVID-19 pandemic, arthritis-appropriate evidence-based programs (AAEBIs) are being redesigned to overcome barriers imposed by social distancing and shelter in place. These interventions are largely being delivered online which may be barrier to some adults with arthritis, especially those with poor physical and mental health outcomes. This project will 1) identify strategies for recruitment and retention of hard to reach populations to AAEBIs; and 2) assess whether there is sufficient evidence for wide-scale dissemination of packaged AAEBIs delivered in alternative modes. These results will advance AAEBI dissemination even in the absence of the COVID-19 epidemic.

SIP 21-004: Development, Evaluation and Dissemination of an Evidence-Based Intervention to Increase Sun Safety among Outdoor Workers

This project will investigate strategies to implement sun safety interventions among underserved and understudied work sectors. This can contribute to the increase in the availability and implementation of evidence-based interventions to improve sun safety and reduce ultraviolet (UV) exposure among underserved and understudied sectors of outdoor workers.

SIP 21-005: Feasibility of a Model Cancer Screening Surveillance Report Using All-Payer Claims Data

This project will demonstrate the feasibility of a model cancer screening surveillance report that uses data from an all-payer claim database (APCD). The model cancer screening surveillance report could provide an applied prevention research tool to improve public health practice in communities with disparities in cancer screening. If successful, the model surveillance report could be used by state cancer programs and their stakeholders to plan and evaluate health system, clinic, and community interventions to improve cancer screening.

SIP 21-006: Increasing Genetic Counseling Referrals Among Patients At-Risk for BRCA-Associated Cancers

The purpose of this project is to increase appropriate referrals to genetic counseling for those patients who have a family cancer history or a mutation probability score (based on a risk algorithm) and assess if system-level interventions to increase access address racial/ethnic disparities in referral and utilization of cancer genetic services. It is expected that with the implementation of evidence-based changes at the health care system level, such as automated referrals, electronic health record (EHR) enhancements, and changes in clinical processes,?this project will improve the timely identification and referral of patients at high risk for *BRCA*-related cancers to genetic counseling.

SIP 21-007: Epilepsy incidence and etiology: important information for public health prevention and health promotion in the US community

This project will inform incidence and social determinants of epilepsy including risk factors and protective factors that affect epilepsy incidence. Information about epilepsy incidence (any types from all ages) and related risk and protective factors from large, population representative pediatric and/or adult epilepsy data in the U.S. will provide invaluable information for academic researchers, advocacy groups, and other government agencies to help better guide interventions or services for preventing epilepsy, treating and rehabilitating people with epilepsy, and minimizing their health disparities and adverse outcomes.

SIP 21-008: Examining approaches to improve care and management of people with lupus

This project will inform prevention research topics that can improve care and management of adults with lupus. The proposed research will improve understanding of how psychosocial characteristics, physical activity, counseling for physical activity, and self-management may impact lupus outcomes. Public health professionals can use these findings to develop approaches to potentially intervene and improve outcomes among adults with lupus.

SIP 21-009: Mental Health of Mothers Study (MHOMS) and Substance Use Evaluation Network

This project builds upon and extends the work funded by Division of Reproductive Health (DRH), Program in Support of Mom (PRISM, DP 15-005), that compares depression outcomes and treatment rates between the PRISM intervention (enhanced standard of care) and Massachusetts Child Psychiatry Access Program for Moms (MCPAP for Moms, i.e., usual care). The project provides information on how state perinatal psychiatric access programs impact treatment engagement and other individual-level maternal outcomes.

SIP 21-010: Engagement of Community Health Workers to Reduce Racial Discrimination and Improve Hypertension Management

This project provides research evidence and validated indicators for community engagement with community health workers (CHWs) in order to reduce racial discrimination and improve the well being and management of hypertension (HTN) among racial and ethnic minority groups disproportionately affected by HTN.

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.

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:
$ 10,080,000

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:
$ 4,335,000
Per Budget Period

Award Floor:
$ 0
Per Budget Period

Total Period of Performance Length:
3 year(s)

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

HHS/CDC grants policies as described in the HHS Grants Policy Statement

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

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:
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** eligible to apply.

Foreign (non-US) organizations must follow policies described in the HHS Grants Policy Statement (http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf), and procedures for foreign organizations described throughout the SF424 (R&R) Application Guide. International registrants can confirm DUNS by sending an e-mail to ccrhelp@dnb.com, including Company Name, D-U-N-S Number, and Physical Address, and Country. Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: https://eportal.nspa.nato.int/AC135Public/Docs/US%20Instructions%2 0for%2 0NSPA%20NCAGE.pdf.

Foreign Organizations **are not** eligible to 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, 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 21-001: Integrating social emotional well being with physical activity & nutrition practices in school-based out-of-school time (OST) programs: a demonstration project.**
- **SIP 21-002: Examining Contexts of Alcohol Availability and Accessibility**
- **SIP 21-003: Evaluating alternative delivery models for arthritis-appropriate evidence-based physical activity and self-management interventions**
- **SIP 21-004: Development, Evaluation and Dissemination of an Evidence-Based Intervention to Increase Sun Safety among Outdoor Workers**
- **SIP 21-005: Feasibility of a Model Cancer Screening Surveillance Report Using All-Payer Claims Data**
- **SIP 21-006: Increasing Genetic Counseling Referrals Among Patients At-Risk for BRCA-Associated Cancers**
- **SIP 21-007: Epilepsy incidence and etiology: important information for public health prevention and health promotion in the US community**
- **SIP 21-008: Examining approaches to improve care and management of people with lupus**
- **SIP 21-009: Mental Health of Mothers Study (MHOMS) and Substance Use Evaluation Network**
- **SIP 21-010: Engagement of Community Health Workers to Reduce Racial Discrimination and Improve Hypertension Management**

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 Notice of Award, must be listed as the SIP PD/PI on the SIP application. Additional PD/PIs are permitted, but would be referred to as a Co-PD/PI.

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 (see Section VIII. Other Information - Special Interest Project Descriptions), 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.

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

SIP 21-001

- The applicant must provide documented evidence of access to the study population (e.g., school-based OST program(s)) and an existing relationship with the identified OST program(s) in the form of memorandum of agreement, contract or letter of support with/from an OST program/(s) for the project period. The evidence should be labeled and placed in Appendix A. Letters of support or MOUs must demonstrate willingness to participate in evaluation activities.
    - The applicant must provide demonstrated prior experience (i.e., reports, publication) conducting and/or evaluating interventions with K-12 school or OST settings, as evidenced in the Research & Related Senior/Key Person Section of the SF424 (R&R). The evidence should be labeled and placed in Appendix A.

SIP 21-003

- Access to current AAEBI licensing agreements.
    - Responsiveness Criteria: Letter (s) of support or a memorandum of agreement demonstrating access to current AAEBI licensing agreements. Evidence should be clearly labeled and placed in Appendix A of the application.

- Access to the proposed study populations for the entire study duration.
    - Responsiveness Criteria: Letter (s) of support or memorandum of agreement from collaborating organizations documenting access to the proposed population for the entire course of the research project. Evidence should be clearly labeled and placed in Appendix A of the application.

SIP 21-004

- Access to one or more worksites and their outdoor workers to conduct the intervention is required. Evidence of this access should be a letter of support or memorandum of agreement; this evidence should be placed in Appendix A of the application.

SIP 21-005

- Access to All Payers Claims Data (APCD) or equivalent
- Responsiveness Criteria: In Appendix A, the applicant must provide documentation (e.g. a current letter of support or memorandum of agreement) that the applicant will have access to the critical datasets for the study.

SIP 21-006

- Applicant must provide documented evidence, in the form of letters of support, or memorandum of understanding from each cancer center, health system, or clinic where the intervention will be implemented.
    - The evidence should demonstrate that the health system has agreed to participate in the study and will implement the intervention in accordance with the study protocol. Evidence should be clearly labeled and placed in Appendix A.

SIP 21-007

- Evidence of access to study populations and/or specified data source
    - The applicant must provide documentation, e.g. a letter of support or memorandum of agreement, demonstrating evidence of access to the study

population and existing administrative claims and other data relevant for the project, necessary to carry out the proposed study. The evidence must be clearly labeled and placed in Appendix A of the application.

- Evidence of expertise in epilepsy
    - The applicant must provide evidence that the project team includes experts in epilepsy research, as evidenced in the Research & Related Senior/Key Person Section of the SF424 (R&R). The evidence must be clearly labeled and placed in Appendix A of the application.

SIP 21-009

- The institution must demonstrate previous or current relationships/collaborations with state perinatal psychiatric access programs. Responsiveness Criteria: Evidence of this criteria can be demonstrated through Letters of Support or Memoranda of Understanding.

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.

- (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, https://www.sam.gov/portal/SAM/.
- Grants.gov
- eRA Commons

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

All Program Directors/Principal Investigators (PD/PIs) must also work with their institutional officials to register with the eRA Commons or ensure their existing 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.

Additionally, all applicant organizations must register in the **System for Award Management (SAM)**. Organizations must maintain the registration with current information at all times during which it has an application under consideration for funding by CDC and, if an award is made, until a final financial report is submitted or the final payment is received, whichever is later. SAM is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the SAM internet site at https://www.sam.gov/index.html.

If an award is granted, the recipient organization **must** notify potential sub-recipients that no organization may receive a subaward under the grant unless the organization has provided its DUNS number to the recipient organization.

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

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

9. Cost Sharing

This 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.

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

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

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

When using ASSIST, all mandatory forms will appear as separate tabs at the top of the Application Information screen; applicants may add optional forms available for the NOFO by selecting the Add Optional Form button in the left navigation panel.

Duplication of Effort

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

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

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

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

Separate Application Submissions Required

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

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

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

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 of PI of Record/ PRC PD/PI and SIP Co-SIP PD/PI
- Names of other key personnel
- Participating institutions
- Number and title of this notice of funding opportunity: RFA-DP-20-004, Health Promotion and Disease Prevention Research Centers 2021 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: ndarling@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 https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/generalforms-e.pdf and https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf for additional information. Please attach applicable sections of the following Research Plan components as directed in Part 2, Section 1 (Notice of Funding Opportunity Description).

Follow the page limits stated in the SF 424 unless otherwise specified in the NOFO. As applicable to and specified in the NOFO, the application should include the bolded headers in this section and should address activities to be conducted over the course of the entire project, including but not limited to:

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

Other Research Plan Sections

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

All instructions in the SF424 (R&R) Application Guide https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf and
here: https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf must be followed along with any additional instructions provided in the NOFO.

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

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

- 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).

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

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-e/general-forms-e.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 three 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 03/03/2021

03/03/2021
Electronically submitted applications must be submitted no later than 5:00 p.m., ET, on the listed application due date.

10. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review.

11. 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.

Protecting Life in Global Health Assistance:

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

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.

12. Other Submission Requirements and Information

Risk Assessment Questionnaire Requirement

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

(https://www.fapiis.gov/), including past performance on federal contracts as per Duncan Hunter National Defense Authorization Act of 2009; Do Not Pay list; and System for Award Management (SAM) exclusions.

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

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

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management (SAM). Additional information may be found in the SF424 (R&R) Application Guide.

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

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

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

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

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the CDC mission (http:// www.cdc.gov/ about/ organization/ mission.htm), all applications submitted to the CDC in support of public health research are evaluated for scientific and technical merit through the CDC peer review system.

Overall Impact
Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria
Reviewers will consider each of the review criteria below in the determination of scientific

merit and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance **Maximum Points:** 0

Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s) **Maximum Points:** 0

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?

Innovation **Maximum Points:** 0

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach **Maximum Points:** 0

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility, and will particularly risky aspects be managed?

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

Environment **Maximum Points:** 0

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?

2. Additional Review Criteria

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

Protections for Human Subjects

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

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

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

Inclusion of Women, Minorities, and Children
When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the policy on the Inclusion of Women and Racial and Ethnic Minorities in Research (https://www.cdc.gov/maso/Policy/Policy_women.pdf and the policy on the Inclusion of Persons Under 21 in Research (https://www.cdc.gov/maso/Policy/policy496.pdf).

Vertebrate Animals
The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following 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

Reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

Resource Sharing Plan(s)

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

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

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

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

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

- 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.

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).

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

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

2. CDC Administrative Requirements

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

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

Specific requirements that apply to this NOFO are the following:
AR-1: Human Subjects Requirements

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

AR-9: Paperwork Reduction Act Requirements

AR-10: Smoke-Free Workplace Requirements AR-11: Healthy People 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: Distinguishing Public Health Research and Public Health Nonresearch AR-32: FY 2015 Enacted General Provisions

AR-6: Patient Care

Organization Specific ARs:

AR-8: Public Health System Reporting Requirements A

R-15: Proof of Non-profit Status

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

3. Additional Policy Requirements

The following are additional policy requirements relevant to this NOFO:

HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items and Printing Publications This policy supports the Executive Order on Promoting Efficient Spending (EO 13589), the Executive Order on Delivering and Efficient, Effective, and Accountable Government (EO 13576) and the Office of Management and Budget Memorandum on Eliminating Excess Conference Spending and Promoting Efficiency in Government (M-35-11). This policy 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/additionalrequirements/ar-25.html outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.

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

4. Cooperative Agreement Terms and Conditions

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

- The PRC PI/PD of record, as listed on the Notice of Award, must be listed as the PD/PI on the SIP application. Additional SIP PD/PIs are permitted, but would be referred to as a Co-PD/PI.
- 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 **120 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.

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

- 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 120 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.

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

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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.

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.

SIP 21-001 Integrating social emotional wellbeing with physical activity & nutrition practices in school-based Out-of-School Time programs: a demonstration project.

Project Description

CDCs Whole School, Whole Child, Whole Community (WSCC) is a multi-component framework for addressing health in K-12 schools. The WSCC model is student centered and emphasizes the role of the community in supporting the school, and the connections between health and academic achievement, and the importance of evidence-based policies and practices. [1] School-based out-of-school time (OST) programs are a natural extension of the WSCC model. This project supports the development, implementation, and evaluation of existing program or intervention efforts to further integrate social-emotional climate and learning (SEC/SEL) into existing OST programs that already provide physical activity and healthy eating opportunities. This approach has implications for health equity among students and in communities. OST programs are often present in schools and community organizations serving racial and ethnic minority students and students from economically disadvantaged communities [2], where they also have higher participation rates. [3] The Community Guide recommends out-of-school time academic programs to improve achievement outcomes and promote health equity for students. [2] To ensure inclusivity, OST programs should equip staff with the skills and resources needed to support children with chronic health conditions through daily management and potential emergencies.

CDC Healthy Schools currently funds 16 state departments of education and two NGOs to work with school-based OST programs to adopt evidence-informed standards to address healthy eating and physical activity, such as the National Afterschool Association's HEPA Standards 2.0 [4]. State awardees are also working to ensure that youth with chronic conditions (e.g., asthma, diabetes, food allergies) can fully participate in program offerings. Awardees have noted an increased prioritization of social and emotional health within OST, the need to better communicate how efforts to offer physical activity and nutritious foods can complement rather than compete with SEL/SEC initiatives, and a paucity of resources to navigate the management of chronic conditions in OST.

Designing opportunities for physical activity and healthy eating with SEL/SEC in mind has the potential to enhance multiple dimensions of child health. The social and emotional competencies and skills that guide youth's relationships with themselves and others (e.g. relationship skills,

self-awareness, self-regulation, coping skills) can influence academic engagement and achievement as well as health behaviors and outcomes. For example, self-regulation and decision making can be important in adopting and maintaining heathy behaviors (e.g., engaging in adequate physical activity, making healthy food choices). [5, 6] Evaluations of integrated programs need to consider whole-child outcomes related to both physical and emotional well-being, being healthy, safe, supported, challenged, and engaged. The purpose of this SIP is to evaluate the feasibility, appeal, and effectiveness of an integrated approach (i.e. offering physical activity and serving foods in ways that support SEL/SEC).

Project Objectives and Outcomes

Specific objectives for this two-year SIP are to:

- Conduct formative work within the first three months of year one to identify
    - SEC/SEL supporting PA/NUTR policies & practices that the OST program(s) already have in place, and
    - district and/or OST program policies and protocols for identifying youth with chronic conditions and managing and responding to symptoms in OST programs.
- Facilitate OST program self-assessment(s) to identify and prioritize
    - existing policies and practices that could be modified in their implementation to better support SEC/SEL (e.g., increase use of cooperative/collaborative games and activities, discourage elimination games), allowing children to help select, prepare, and clean up foods and beverages), and
    - additional evidence-informed policies & practices that programs are interested in adopting to jointly address PA/NUTR and SEC/SEL.
- Support programs in prioritizing and adopting PA/NUTR best practices that clearly align with SEL skills and competencies (e.g., eliminating use of food as a reward and withholding PA or food as punishment; staff model health behaviors and positive self-talk).
- Develop and deliver trainings to increase staff skills in providing PA, and food and beverages (if served), in ways that support social-emotional skill development in youth as part of a training strategy that is responsive to staff turnover.
- Ensure programs can support inclusivity by having policies, protocols, and staff training to support youth with chronic conditions (e.g., food allergies, diabetes, asthma).
- Evaluate the impact of the intervention on program policies, site climate, staff instructional practices, staff satisfaction, youth PA levels and PA enjoyment, and youth social-emotional skills.

Expected Outcomes

Outcomes will be collected at the site/program, staff, and youth levels.

Site/program level outcomes focus on:

- the adoption and implementation of evidence-informed organizational policies and practices that advance healthy eating, physical activity;
- safe and active participation among youth with chronic conditions;

- indicators of a supportive social-emotional climate (e.g., training program staff on cultural competence/culturally-responsive practices, establishing clear rules/expectations, reinforcing students? positive behaviors, providing structured opportunities for students to learn and practice social emotional skills and health behaviors, connecting students to caring peers and adults).

Staff level outcomes focus on how these policies and practices are being implemented; specifically, the extent to which staff use SAFE instructional practices [7,8]; role model health behaviors; and sit and interact with youth during meals and snacks.

Individual level outcomes address:

- youth perceptions of the social environment at the OST program, relationships with peers and adults, feeling challenged;
- social-emotional skills such as self-regulation, resistance skills, decision-making;
- minutes of overall and moderate-to-vigorous physical activity, and enjoyment of physical activity;
- self-efficacy to choose a fruit or vegetable as part of a meal or snack at OST.

Public Health Priorities

Healthy People 2030 Objectives

- PA-06: Increase the proportion of adolescents who do enough aerobic physical activity
- PA-07: Increase the proportion of adolescents who do enough muscle-strengthening activity
- PA-09: Increase the proportion of children who do enough aerobic physical activity
- AH-03: Increase the proportion of adolescents who have an adult they can talk to about serious problems

CDC Health Impact-5 Initiative

School-Based Programs to Increase Physical Activity

NCCDPHP Chronic Disease Prevention and Health Promotion Domains

This SIP addresses environmental approaches that promote health and support and reinforce healthful behaviors in school-based OST programs.

Project Activities and Submission Requirements

SIP applicants are expected to present a Research Plan that addresses the following requirements:

Study design and methods

The design must allow for the measurement of 1) change in outcomes over time and 2) implementation attributes that can be used to describe program design and delivery characteristics and, potentially, to help explain outcomes and experiences. OST programs can often be more responsive and flexible in their approach than schools; accordingly, applicants are encouraged to consider designs that allow for mid-course data review and programmatic adjustments.

Target population

This SIP focuses on existing multipurpose OST programs offered to K-12 students on the school site outside of school hours (e.g., before and/or after school) for at least the duration of the school year. Multipurpose OST programs may have larger population reach and more sustained contact hours with youth than specialty programs and be more likely to serve meals or snacks. Programs may be run by the school, school district, or community-based organizations (e.g., 21st Century Community Learning Centers, Boys & Girls Clubs, YMCAs) and include a variety of activities, such as academic support, music, etc.

This SIP is not intended to support OST programs that restrict participation based on skill (e.g., programs that require try outs or auditions). Applicants are encouraged to collaborate with programs in economically disadvantaged communities, such as those operating in schools that have a high free-or reduced- priced lunch (FRPL) eligibility rate (≥75%) or an identified student percentage ≥40% (i.e., meets USDA?s community eligibility provision).

The SIP includes activities to review and strengthen policies and protocols to ensure that youth with chronic conditions can safely participate in physical activity and eating occasions. Applicants are encouraged to consider the local prevalence of chronic conditions, such as diabetes, food allergies, asthma, seizure disorders, and obesity when identifying program sites.

Collaboration/Partnerships

The applicant must have existing relationships with providers of school-based OST programming, such as school-districts and/or organizations that run programs on school sites. The applicant should describe how individuals responsible for implementing the intervention will be involved in program planning and evaluation. Applicants are encouraged to incorporate opportunities for youth engagement in the study design and in communications of results.

Recruitment Plan

Applicants are expected to describe their plan to recruit school-based OST program(s) and school-aged program participants (e.g. e.g., elementary, middle, and/or high-school students).

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 should provide an evaluation plan and performance measures/outcomes for each year of the project, and for the overall project, including a timeline for the completion of proposed activities. The goal of the evaluation is to assess the effect of SEC/SEL integration in PA/NUTR programs in OST at the individual and program level, and to identify program and process characteristics that may influence implementation. The first-year evaluation is expected to include the results of formative work conducted to understand program context, climate, priorities etc. and approach to supporting youth with chronic conditions. Applicants are expected to use or adapt existing tools or assessments for data collection; apply a framework or theory to guide their identification of facilitators or barriers to identifying, adopting, and implementing policies/practices; and identify opportunities for mid-course data reviews, discussion, and program adjustment as needed. The plan should include a way of assessing program staff

perceptions of/satisfaction with the intervention. The applicant must describe how the evaluation will address the sub-population of youth with chronic conditions, which will likely be a small proportion of overall participants but the focus of some SIP activities.

The plan should include both outcome and implementation indicators, potentially including: Participant demographics and how closely they reflect school or district demographics.

Program characteristics (e.g., staff: youth ratio, staff turnover, total enrollment/size, types of PA, staff training and experience level, participation in federal meal or snack programs etc.)

Program delivery characteristics:

- Resources involved in implementing an integrated approach
- Site level policy/practice adoption and implementation.
- Staff instructional practices and reported facilitators and barriers to implementation
- Youth outcomes, using validated measures, related to physical activity, self-efficacy to eat nutritious foods, program engagement and SEL opportunities.

Dissemination Plan

Applicants are expected to develop a dissemination plan for sharing and discussing results of the evaluation study. The plan should at a minimum address 1) sharing and discussing results with participating OST programs, 2) developing a peer-reviewed publication, and 3) sharing via the NOPREN/PAPREN+ School Wellness network.

All results, findings, reports or processes developed under this cooperative agreement should be shared with CDC. The applicants are encouraged to consider developing communications to share results with a variety of stakeholders including school district leadership, state boards of education, OST administrators, families, and public health researchers and practitioners using audience-specific products.

Data Management Plan

If an 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.Visit link https://www.cdc.gov/chronicdisease/programs-impact/nofo/index.htm for DMP Template and Guidance.

Translation Plan

The applicant is expected to propose potential approaches for the translation of the intervention. This should include translation products designed to provide OST program staff with the information and skills needed to support youth with chronic conditions, such as model policies, practices and protocols based on current federal, state and local regulations; or, sample communications to notify parents of any differing policies or available care during out of school time activities versus during the school day. If the intervention is found to be effective, the applicant is expected to summarize findings and opportunities for key decision-making audiences (e.g., OST and school administrators) and present implementation considerations relevant for each audience (e.g., feasibility, organizational capacity, resources needed, relevance). The applicants are encouraged to consider a range of translation products (e.g.,

webinar, training materials, infographic or brief, toolkit, talking points) and distribution channels to ensure audience fit and reach.

Public Health Impact

This project supports the development, implementation, and evaluation of an intervention to further integrate social-emotional climate and learning into existing out-of-school time efforts to support physical activity and healthy eating. This project will increase our understanding of the social and emotional competencies and skills that guide youth?s relationships with themselves and the influence of these competencies and skills on academic engagement and achievement as well as health behaviors and outcomes. If this approach is found to be effective, efforts to bring it to scale could benefit the millions of youth who participate in OST programming.

Special Eligibility and Responsiveness Requirements

In order to successfully design, implement, and evaluate a program that meets the SIP objectives within the two-year period, the applicant must have already identified willing OST program collaborators (i.e., school-districts and/or organizations that run programs on school sites) and have previously worked in either K-12 school or OST settings.

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

- The applicant must provide documented evidence of access to the study population (e.g., school-based OST program(s)) and an existing relationship with the identified OST program(s), in the form of memorandum of agreement, contract or letter of support with/from an OST program/(s) for the project period. The evidence should be labeled and placed in Appendix A. Letters of support or MOUs must demonstrate willingness to participate in evaluation activities.
- The applicant must provide demonstrated prior experience (i.e., reports, publication) conducting and/or evaluating interventions with K-12 school or OST settings, as evidenced in the Research & Related Senior/Key Person Section of the SF424 (R&R). The evidence should be labeled and 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 evidence of project team expertise in youth development or child psychology and/or experience measuring social-emotional wellbeing in school-aged populations (i.e., at least 1 peer publication)?
- Does the applicant provide evidence of project team expertise in physical activity measurement (i.e., at least 3 peer publications)?
- Does the applicant provide evidence of team member or collaborator experience working with school nursing staff (i.e., at least 1 funded project)?
- Does the applicant adequately describe how the proposed research team will support and collaborate with the OST program staff to design and carry out the intervention?

- Does the applicant describe prior experience developing and delivering skills-focused trainings (as opposed to knowledge transfer events)?
- To what extent does the applicant identify validated data collection tools and methods?
- Does the applicant describe prior experience creating translation and dissemination products targeting school or OST audiences, non-governmental organizations, and/or families?
- Does the applicant identify activities designed to support safe participation among youth with chronic conditions?
- Does the respondent identify how this scope of work could continue/operate should schools and OST programs remain closed to in person instruction and activities?

Funding Preferences

None

Research Plan Length and Supporting Material

The Research Strategy Section of the Research Plan is limited to a maximum of 12 pages. Supporting material included as appendices may not exceed 10 PDF attachments. The appendices should include materials that show evidence of the applicant's ability to successfully conduct the proposed project and other evidence deemed necessary to support the contents of the proposal. Appendices should include the MOU/letter of support (see Special Eligibility and Responsiveness) and proposed data collection instruments and performance indicators.

Availability of Funds

It is anticipated that approximately $800,000 is available to fund one 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. The award recipient will lead the development of the study design and related activities, including data collection measures and protocols.

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 study design, evaluation measures, data collection and analysis, and data interpretation and dissemination of results. CDC staff may be co-authors on manuscripts if they meet CDC authorship criteria. However, CDC staff will not have contact with human subjects or data collected from human subjects.

References

1. CDC Healthy Schools. Whole School, Whole Community, Whole Child Model. Available at: https://www.cdc.gov/healthyschools/wscc/index.htm
2. The Community Preventive Services Task Force. Promoting Health Equity Through Education Programs and Policies: Out-of-School-Time Academic Programs. Atlanta, GA: Centers for Disease Control and Prevention, US Dept of Health and Human Services; 2013.
3. Afterschool Alliance. America After 3PM Special Report: Afterschool in Communities of Concentrated Poverty. Washington, DC: Afterschool Alliance; 2016. Available at: http://www.afterschoolalliance.org/AA3PM/Concentrated_Poverty.pdf
4. National Afterschool Association. HEPA Standards 2.0. 2018. Available at: https://naaweb.org/resources/naa-hepa-standards
5. Bub, K. L., Robinson, L. E., & Curtis, D. S. Longitudinal associations between self-regulation and health across childhood and adolescence. Health Psychology. 2016. 35(11): 1235.
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7. Durlak JA, Weissberg RP, Pachan M. A meta?analysis of after?school programs that seek to promote personal and social skills in children and adolescents. *Am J Community Psychol.* 2010;45(3?4):294?309.
8. Durlak, J. A., Weissberg, R. P., Dymnicki, A. B., Taylor, R. D., & Schellinger, K. B. The impact of enhancing students? social and emotional learning: A meta-analysis of school-based universal interventions. Child Development. 2011. 82(1): 405?433.
9. McCombs JS, Whitaker A, Yoo PY. *The Value of Out-of-School Time Programs.* Santa Monica, CA: RAND Corporation; 2017.
10. Whitley, M.A., Massey, W.V., Camir, M. et al. Sport-based youth development interventions in the United States: a systematic review. BMC Public Health. 2019.19 (89) https://doi.org/10.1186/s12889-019-6387-z10.

SIP 21-002: Examining Contexts of Alcohol Availability and Accessibility

Project Description

Excessive alcohol use contributes to more than 95,000 deaths in the U.S. each year and was responsible for an economic cost of $249 billion in 2010 [1,2]. Excessive alcohol use, which includes binge drinking, heavy drinking, and any drinking by people younger than age 21 years or pregnant women, is associated with acute conditions such as injuries and violence, as well as chronic conditions such as cancers and high blood pressure [2]. Continued applied research is needed to inform public health practice for reducing excessive alcohol use and related harms, including factors that affect alcohol availability and accessibility. The Community Preventive Services Task Force recommends several strategies for regulating the availability of alcohol, including regulating the density of alcohol outlets [3]. Regulating the density of alcohol outlets, or the number and concentration of alcohol retailers (such as bars, restaurants, liquor stores) in an area, is usually done through zoning and licensing restrictions [3]. However, more applied research is needed to assess whether there are variations in the relationship between alcohol

outlet density and its impact on communities based on characteristics of alcohol outlets, such as whether the alcohol is sold for consumption on and/or off the premises, by the types of alcohol sold, or the size of the alcohol outlets [4,5]. For example, spatial analyses could be conducted using detailed information on licensed alcohol outlets in cities to explore whether the density of off-premises alcohol outlets (e.g., liquor stores) is more strongly associated with adverse outcomes (e.g., crime rates, injuries) than on-premises alcohol outlets (e.g., bars, restaurants), accounting for sales of alcohol for carry-out or curbside pickup and the type of alcohol sold in each alcohol outlet (e.g., beer and wine versus liquor only). Research could also compare two areas that have a different composition of alcohol outlet types, or different policies pertaining to alcohol sales at bars and restaurants (e.g., alcohol carry-out or curbside pickup), and assess characteristics of alcohol outlets associated with fewer population-level harms.

In addition, the Community Preventive Services Task Force also recommends against further privatization of retail alcohol sales, and suggests that governments (such as state, county, or city) can effectively regulate the availability of alcohol by maintaining control over the retail sales of alcoholic beverages [6]. In the traditional three-tier system of alcohol regulation, alcohol is produced, distributed to wholesalers, and then sent to retailers for consumers to purchase, which is designed to protect the safety and quality of alcoholic beverages, facilitate efficient collection of alcohol taxes, and to prevent illegal sales (e.g., to minors or intoxicated patrons). However, alcohol is also widely sold by private vendors on the Internet and directly shipped to consumers [7]. Moreover, amid the outbreak of the novel coronavirus (COVID-19) in the U.S. in 2020, across the country, third parties (e.g., restaurants, food delivery services) were increasingly permitted to deliver alcohol directly to consumers [8]. This direct to consumer shipping of alcohol including from online alcohol sales or home delivery of alcohol with other food raises issues such as the following: licensing requirements for operators involved with the alcohol shipment or delivery; the potential for tax evasion; control over product quality (e.g. potential for tainted alcohol); and challenges with age verification procedures to protect against underage drinking [7,9]. Additional scientific evidence on changes in ways that drinkers obtain alcoholic beverages and the impact of the increasing practice of direct to consumer shipping and delivery of alcohol in the U.S. on excessive alcohol use (e.g., binge drinking among adults, underage drinking) or alcohol-related harms could inform future decisions in states about options for regulating alcohol availability. For example, potential research might include conducting a survey of adults and young people to examine associations between the current usual source of alcohol, previous usual sources of alcohol, type of alcohol typically consumed, and drinking patterns. Research using data from reports on completed direct to consumer alcohol shipments and deliveries to estimate the financial losses due to unlicensed alcohol transactions, conducted in collaboration with state or local public health departments and liquor law enforcement agencies, also could inform future alcohol policy discussions.

The purpose of this SIP is to assess under-studied contexts of alcohol availability and associations with excessive alcohol use, alcohol-related harms, or both, which might further inform the development and implementation of strategies for reducing excessive drinking and its impact in states and communities. It is anticipated that this applied public health, community-based research will assess how the context in which alcohol is purchased for consumption, such as certain characteristics of alcohol outlets (e.g., on- versus off-premises alcohol outlets, type of alcohol sold, alcohol outlet size) or direct to consumer shipping and delivery of alcoholic

beverages (e.g., online alcohol sales, home delivery of alcohol) impacts excessive drinking, alcohol-related harms, or both, at the state or local levels.

Project Objectives and Outcomes

The objectives of this SIP are to assess how the context in which alcohol is purchased for consumption, such as certain characteristics of alcohol outlets (e.g., on- versus off-premises alcohol outlets, type of alcohol sold, alcohol outlet size) or delivery of alcoholic beverages (e.g., online alcohol sales, home delivery of alcohol) impacts excessive drinking and related harms.

It is expected that this project will result in the preparation of publications, presentations, and other communications materials to support the dissemination of study findings to organizations involved in the prevention of excessive drinking and related harms, including state and local public health agencies, community coalitions, and other organizations or other stakeholders. The proposed research will improve our understanding of how the context of alcohol availability and access, such as characteristics of alcohol outlets (e.g., on- versus off-premises alcohol outlets, type of alcohol sold, outlet size) or aspects of the delivery of alcoholic beverages (e.g., online alcohol sales, home delivery of alcohol), impacts excessive drinking and related harms, thereby informing state and local public health options concerning the availability of alcohol to reduce excessive drinking and related harms.

Public Health Priorities

Healthy People 2030 Objectives

- SU 10: Reduce the proportion of people aged 21 years and over who engaged in binge drinking in the past month.
- SU 09: Reduce the proportion of people under 21 years who engaged in binge drinking in the past month.
- SU 04: Reduce the proportion of adolescents who drank alcohol in the past month.

CDC Health Impact-5 Initiative: NA

NCCDPHP Chronic Disease Prevention and Health Promotion Domains

Domain 2: Environmental Approaches

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

Applicant should propose applied research to meet the project objectives.

- Describe the study setting and study population.
- Explain the study methods for assessing how the context of alcohol availability, such as certain characteristics of alcohol outlets or aspects of the delivery of alcoholic beverages, impacts excessive drinking and related harms at the state or local levels.
- Describe the data sources and the measures that will be used.
- Explain the role of partners that will be involved in this research project and include letters of support from the key collaborators.

- Describe plans to disseminate the findings of this research project through publications, presentations, and active engagement with state and community partners, as well as other stakeholders.

Target population

Applicant should clearly describe the target population depending on the topic of investigation (e.g., geographical area). Applicants should also identify any subgroups of the population who will benefit from the research.

Collaboration/Partnerships

It is expected that this applied research will be done in collaboration with other public health partners (e.g., public health agencies, epidemiologists).

Recruitment Plan

None

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

Applicants are expected to develop an evaluation and performance management plan. Plan should include SMART project goals and objectives, a plan for performance monitoring, and plans to remediate any anticipated barriers.

Dissemination Plan

Applicants are expected to develop a dissemination plan which, at a minimum, will describe publications, presentations, and other communications materials planned to support the dissemination of study findings to organizations involved in the prevention of excessive drinking and related harms, including state and local public health agencies, community coalitions, and other organizations or other stakeholders.

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

Visit link https://www.cdc.gov/chronicdisease/programs-impact/nofo/index.htm for DMP Template and Guidance.

Translation Plan

Dissemination products (e.g., publications and presentations) should demonstrate that the recipient has assessed how research can be translated to inform public health practice and should include implications for implementation.

Public Health Impact

The proposed research will improve our understanding of how the context of alcohol availability, such as certain characteristics of alcohol outlets or aspects of the delivery of alcoholic beverages impacts excessive drinking and related harms, thereby informing state and local public health options for regulating the availability of alcohol to create healthier communities.

Special Eligibility and Responsiveness

None

Additional Review Criteria

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

- Are proposed methods sufficient to assess how the context in which alcohol is purchased for consumption, such as certain characteristics of alcohol outlets or aspects of the delivery of alcoholic beverages, impacts leading health risk behaviors or population-level harms?
- Does the applicant identify appropriate partners to accomplish the goals/objectives of the study?
- Does the applicant demonstrate relevant experience collaborating with public health organizations to study issues related to alcohol availability, alcohol access, or the associated between alcohol policies and alcohol-related harms?

Funding Preferences

None

Research Plan Length and Supporting Material

The Research Strategy Section of the Research Plan is limited to a maximum of 12 pages. Supporting material included as appendices may not exceed 10 PDF attachments, 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 $600,000 is available to fund up to 2 Prevention Research Centers for a 2-year project period. The average award per recipient is expected to be approximately $150,000 for year one. The year one ceiling is $300,000. Funding is anticipated for up to two awards. Funding may vary and is subject to change. **Funding available includes direct and indirect costs.**

Research Status

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

OMB/PRA

OMB/PRA is not expected to apply

Award Administration

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

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SIP 21-003: Evaluating alternative delivery models for arthritis-appropriate evidence-based physical activity and self-management interventions

Project Description

Regular physical activity and participation in evidence-based self-management education programs, such as the Chronic Disease Self-Management Program (CDSMP), are proven strategies for managing arthritis and other chronic conditions (1-4). Adults with arthritis can engage in routine physical activity independently or through participation in packaged CDC-recognized arthritis-appropriate evidence-based programs (AAEBI) (5). Post-intervention benefits of these programs include improvement in a range of outcomes including pain,

functional limitations, and mental health (1-4). In Spring 2020, community organizations paused delivery of in-person group AAEBIs because of COVID-19 pandemic shelter-in-place and social distancing policies. These organizations initiated delivering AAEBIs in alternative modes with a focus on online delivery. Although these programs are modeled after the packaged AAEBIs, the short- (6 month) and longer-term (12 month) post-intervention effectiveness of these alternatively delivered programs has not been assessed.

Physical and mental health limitations and transportation barriers can restrict participation in community activities (6, 7). Therefore, alternative delivery modes may make AAEBIs more accessible to adults with arthritis who have a high prevalence of limitations and also represent a high percentage of those who are homebound or semi-homebound (8). Currently, alternative delivery modes are primarily online and require broadband, which is a barrier for those with no or limited Internet access. A series of Pew Research Center surveys conducted since 2017 indicates that despite high Internet use in the general population, Internet use is lower among older adults (9), individuals who are disabled (10), those of lower income (11), and rural residents (12). Arthritis prevalence is high in many of these subgroups (13-15). A sweeping transition to online delivery modes may perpetuate documented disparities in intervention participation for adults with arthritis (16). Therefore, in addition to evaluating outcomes associated with interventions delivered online, there is a need to develop and evaluate AAEBIs delivered in alternative modes such as delivery by mail or through phone applications to ensure that adults with arthritis who likely have the greatest need for behavioral intervention can participate.

To date, there is limited information about the short- and longer-term post-intervention physiological benefits of AAEBIs. For example, while routine physical activity can lead to weight loss (17) and improvements in physiological measures such as blood pressure (18), A1C (19), and blood cholesterol (20), it is unknown whether participating in packaged AAEBIs leads to short- and longer-term post-intervention improvements in these measures. Additionally, there is considerable interest in potential costs savings from the AAEBIs. To date, there is no robust evidence that participation in two traditionally delivered AAEBIs (i.e., EnhanceFitness, CDSMP) results in reduced medical utilization 12 months post-intervention (21). However, much of arthritis-attributable medical expenditures and earnings losses have been attributed to the pain and functional limitations that adults with arthritis experience (22, 23). Therefore, expanding intervention reach to include those with poorer health status who have the highest levels of medical utilization and work loss may lead to cost savings.

The purpose of **each** evaluation project is to: 1) assess short- and longer-term post-intervention effectiveness of **one** CDC-recognized AAEBI delivered an using alternative mode; 2) to assess effectiveness of recruitment and retention strategies for hard to reach target populations for that intervention; and 3) to create technical assistance materials to be used in dissemination of that intervention.

Project Objectives and Outcomes

The project will evaluate **one** alternatively delivered CDC-recognized AAEBI that has not been evaluated in their alternatively delivered mode. This can include a CDC-recognized AAEBI that has been redesigned to an alternative delivery mode by the recipient. The intervention is expected to be delivered in a mode that is accessible for hard to reach populations including individuals with disabilities, individuals of lower socio-economic status, and rural residents, all

of which may have very limited or no access to interventions delivered online. The award recipient is expected to collaborate on evaluations with key public health partners and their affiliates (e.g., Y-USA, National Recreation and Parks Association, state and local health departments) who are currently delivering the CDC-recognized AAEBI.

Results from the evaluations of the short- and longer-term effectiveness of the alternatively delivered CDC recognized AAEBIs are expected to be disseminated through the peer-reviewed literature and also used to inform decisions regarding wide-scale dissemination of these programs. The technical assistance products developed for these alternatively delivered AAEBI will be shared with all organizations disseminating these programs. Results from evaluations on effectiveness of recruitment and retention strategies for hard to reach audiences will be disseminated through the peer-reviewed literature and also used to inform technical assistance to increase the reach and availability of CDC-recognized AAEBIs.

Project objectives are:

- Conduct a literature review to identify and incorporate best practices or other recommendations on recruitment and retention of participants in behavioral intervention programs with a focus on hard to reach populations.
- Prepare and submit a report summarizing the results of the literature review on best practices for recruitment and retention of participants in behavioral interventions with a focus on hard to reach populations.
- Evaluate short term and longer-term outcomes for the selected alternatively delivered CDC-recognized AAEBI. Outcomes include arthritis-specific and all-cause pain, physical limitations, mental health status, psychosocial function, weight loss, work loss, health care utilization, medical expenditures and earnings losses, as well as physiologic measures for frequently comorbid conditions (e.g., Hgb A1C, blood pressure, blood cholesterol).
- Evaluate recruitment and retention of the specific target populations in the CDC-recognized AAEBI intervention delivery and evaluation.
- Collaborate with at least one organization that is currently delivering a CDC-recognized AAEBI using an alternative mode or is delivering an AAEBI in a traditional format and has the capacity to deliver using an alternative delivery mode.
- Prepare a report describing the effectiveness of recruitment and retention strategies for the alternatively delivered. Ideally, this report is a publication-ready manuscript prepared for peer-review.
- Submit reports presenting results of each of the short-term and longer-term evaluations and disseminate these results to appropriate community-based organizations, public health practitioners, and health care providers through medical/public health publications or other means. Ideally, these reports are publication-ready manuscripts prepared for peer-review.
- Develop, pilot-test, and share pilot-tested technical assistance products (e.g., training and program delivery videos and manuals) for public health and community program delivery providers.

Public Health Priorities

Healthy People 2030 Objectives

- A-1 Reduce the proportion of adults with provider-diagnosed arthritis who experience severe or moderate joint pain
- A-2 Reduce the proportion of adults with provider-diagnosed arthritis who experience a limitation in activity due to arthritis or joint symptoms
- A-3 Reduce the proportion of adults with provider-diagnosed arthritis who are limited in their ability to work for pay due to arthritis
- A-4 Increase the proportion of adults with provider-diagnosed arthritis who receive health care provider counseling for physical activity or exercise

CDC Health Impact-5 Initiative: NA

NCCDPHP Chronic Disease Prevention and Health Promotion Domains

This SIP aligns with NCCDPHP Domain 4: Community programs linked to clinical services and Health Equity Plan.

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 and justify an approach to address all study objectives. For each objective involving a literature review, data collection, or evaluation, describe the specific questions to be addressed and the methods used to conduct these activities. Applicants are expected to describe any activities related to data collection including questionnaire development and pilot-testing, data collection mode, sampling, recruitment, and potential analyses.

The applicant is expected to provide a detailed description of the experimental design that will be used for the evaluation. Ideally, the evaluation will be designed to detect clinically meaningful differences in effects for primary outcomes with statistical power of 80% and statistical significance of 5%. Applicants may categorize short- and longer-term outcome measures as primary (e.g., pain, physical function) and secondary and describe rationale for this categorization. The evaluation plan should identify specific outcomes (e.g., pain, physical limitations, mental health, psychosocial function, body mass index, physiologic measures [e.g., A1C, blood pressure, blood cholesterol], work loss, and health care utilization) that will be assessed, when they will be assessed, and methods used to collect these outcome data. Applicants are expected to use one of the following methods to identify people with arthritis:

- Case-finding question: Have you EVER been told by a doctor or other health professional that you have some form of arthritis, rheumatoid arthritis, gout, lupus, or fibromyalgia (24, 25);
- ICD-9-CM codes: 274, 710, 712, 713, 714, 715, 716, 719, and 729 (24); or
- Conditions in definition #2 above converted to ICD-10-CM codes.

It is expected that the study population will not be limited to a specific arthritis type and ideally will contain individuals with all of the arthritis types included in the definitions.

Target population

The target population is adults with arthritis. Additionally, at least half of the participants are expected to be drawn from at least one of the following special populations: adults age 18-64 who report moderate to severe limitations in their activities of daily living, adults age 18-64 years with low annual household incomes, or adults age 18-64 years who are rural residents.

Collaboration/Partnerships

To accomplish the SIP objectives, the applicant is expected to collaborate with at least one community-based partner organization experienced in delivery of CDC-recognized AAEBIs. Ideally, the applicant will present evidence of successful collaborations on previous community-based evaluation projects. The applicant is expected to provide letters of support and intent to collaborate from key public health partners and their affiliates (e.g., Y-USA, National Recreation and Parks Association, state and local health departments) who have implemented existing CDC recognized AAEBIs and have current AAEBI licensing agreements. Ideally, collaborators/partners have experience with research studies and can share expertise with investigators. Letters from community partners should state their specific role and activities in this project, acknowledge that they understand that this is a research study and therefore the study design may affect timing of intervention delivery, and provide evidence that they have sufficient catchment to achieve the required sample size.

Recruitment Plan

The Research Plan is expected to include a description of: 1) how they will access the target population; 2) how the investigators and community-based partner organization(s) will collaborate to recruit and retain a population of adults with arthritis that meets the target population specifications; and 3) the criteria that will be used to identify these specific populations, including the definition of limitations in activities of daily living, low socio-economic status, and rural residents. It is expected that methods to reduce attrition and strategies to overcome potential barriers to recruitment are described.

Annual Action Plan

Provide a 12-month action plan using SMART goals and objectives that includes a progressive timeline for completion of activities. Progress in achieving these milestones should be reported in progress reports and conference calls with CDC.

Evaluation Plan /Performance measurement

Provide an evaluation plan that will be used to assess project performance and progress including a detailed timeline that provides completion dates for all project activities. This timeline is expected to include the entire project period.

Dissemination Plan

- Publish findings in peer-reviewed journal or MMWRs and present findings at local and national meetings. This is expected regardless of whether intervention is effective.
- Develop and share plain language technical assistance products (e.g., training and program delivery videos and manuals) for public health and community program delivery providers.

Data Management Plan

It is expected that a standalone data management plan that addresses the 5 elements of AR-25 be submitted in Appendix A. https://www.cdc.gov/grants/additional-requirements/ar-25.html

Visit link https://www.cdc.gov/chronicdisease/programs-impact/nofo/index.htm for DMP Template and Guidance.

Translation Plan

The applicant is expected to recommend strategies for translating study findings to wide-scale dissemination of AAEBIs delivered using alternative methods. Recommendations will identify appropriate target audiences and strategies for reaching potentially hard to reach populations.

All results, findings, reports, products, or processes developed under this cooperative agreement should be shared with CDC.

Public Health Impact

Focus group work indicates that adults with arthritis prefer non-pharmacologic approaches to managing arthritis. With the 2020 COVID-19 epidemic, AAEBIs are being redesigned to overcome barriers imposed by social distancing and shelter in place. These interventions are largely being delivered online which may be barrier to some adults with arthritis, especially those with poor physical and mental health outcomes. Study results will be used to : 1) identify strategies for recruitment and retention of hard to reach populations to AAEBIs; and 2) assess whether there is sufficient evidence for wide-scale dissemination of packaged AAEBIs delivered in alternative modes. These results will advance AAEBI dissemination even in the absence of the COVID-19 epidemic.

Special Eligibility and Responsiveness

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

- Has the necessary license to use the relevant AAEBI .
    - Responsiveness Criteria: Letter (s) of support or a memorandum of agreement demonstrating access to current AAEBI licensing agreements. Evidence should be clearly labeled and placed in Appendix A of the application.

- Access to the proposed study populations for the entire study duration.
    - Responsiveness Criteria: Letter (s) of support or memorandum of agreement from collaborating organizations documenting access to the proposed population for the entire course of the research project. Evidence should be clearly labeled and placed in Appendix A of the application.

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 evidence of successful and timely completion of rigorous community-based behavioral evaluation projects (e.g., publications, reports, etc.)?

- Demonstrate experience in:
    - Using research literature to inform study design and implementation, preferably for hard to reach populations?
    - Developing, planning, and implementing chronic disease self-management research, arthritis self-management research, or public health prevention research in hard to reach populations?
    - Working with partners in priority public health settings such as health care, work sites, and communities?
    - Evaluating the impact of public health interventions?

- Has the applicant submitted letters of support or memorandum of agreements from community-based organizations that demonstrate the organizations:
    - Experience in delivering the AAEBI being investigated?
    - Access to current AAEBI licenses?
    - Understanding of the research project and its objectives?
    - Recognition that this is a research study and intervention delivery is dependent on the study design?
    - Commitment to collaborating with the applicant including explicitly stating that the applicant can collect complete data at multiple time points over the entire study period?

- Does the applicant identify and address:
    - Potential barriers to data collection resulting from the 2020 COVID-19 pandemic?
    - Any other anticipated barriers to conducting the Research Plan and how these will be addressed?

- Does the applicant:
    - Document the specific roles of each study investigator in this project?
    - Provides evidence that all investigators and staff involved in the design and execution of the study have appropriate experience to successfully conduct and complete a study that will meet the project objectives?
    - Does the applicant provide evidence that they will be able to identify and recruit adults with arthritis from hard to reach populations that meets the NOFO requirements (e.g., half of study population will be individuals with disabilities age 18-64 years, individuals of lower socio-economic status age 18-64 years, and/or rural populations age 18-64 years)?
    - Describe how arthritis will be defined and provide evidence that the study population will contain individuals will all arthritis types specified in their case definition and not limited to a population with one type of arthritis?
    - Describe how they will address barriers to recruitment of the study target population?
    - Describe their previous experience in recruitment and retention of hard to reach populations in community-based interventions?

- Provide evidence (e.g., at least 2 peer reviewed publications) that the project team includes experts in the research topic areas (as evidenced in the Research & Related Senior/Key Person Section of the SF424 (R&R))?
- Work with state and local public health and community service agencies?

Funding Preferences

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

- Diversity of target population: adults age 18-64 years who report moderate to severe limitations in their activities of daily living, adults age 18-64 years with low annual household incomes, or adults age 18-64 years who are rural residents.
- **Diversity in AAEBI Interventions.**

Research Plan Length and Supporting Material

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

Availability of Funds

It is anticipated that approximately $2.4 million is available to fund 2 Prevention Research Centers for a 3-year project period; each award is anticipated to be $1.2 million over a 3-year 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

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

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SIP 21-004: Development, Evaluation and Dissemination of an Evidence-Based Intervention to Increase Sun Safety among Outdoor Workers

Project Description

According to the U.S. Bureau of Labor Statistics, nearly half of jobs held by civilian workers require work outdoors at some point during the workday [1]. Outdoor workers are often exposed to high levels of ultraviolet (UV) radiation which increases their skin cancer risk, particularly their risk for non-melanoma skin cancers [2-4]. The Community Preventive Services Task Force recommends interventions in outdoor occupational settings to prevent skin cancer based on strong evidence of effectiveness in increasing outdoor workers sun protective behaviors and reducing sunburns? [5].

However, this recommendation is based on studies conducted among limited types of outdoor workers (specifically staff at ski resorts and outdoor swimming pools, US Postal Service letter carriers, and road workers) [5]. The corresponding peer-reviewed papers were all published in 2012 or earlier [5]. Little is known about how to implement sun-safety interventions within other prominent yet underserved and understudied outdoor work sectors and what some of the common barriers and facilitators to implementation and sustainability might be.

The purpose of this SIP is to fill this research gap through the development, evaluation, and dissemination of an evidence-based intervention to increase workplace policies and practices to support sun safety and reduce UV exposure among underserved and understudied sectors of outdoor workers.

Project Objectives and Outcomes - Specific objectives of this SIP are:

- summarize existing evidence on and resources to support sun safety among outdoor workers;
- develop an evidence-based intervention to increase workplace policies and practices to support sun safety among outdoor workers;
- evaluate implementation, use, effectiveness and scalability of the newly developed intervention; and
- disseminate the new sun-safety intervention and evaluation findings.

Expected outcomes of this SIP are:

- a summary of existing resources and publications on sun safety for outdoor workers;
- development and evaluation of a sun-safety intervention for underserved and understudied outdoor employees;
- products to support dissemination of the new intervention and corresponding evaluation results such as posters, slides, and content for the CDC website and social media; and
- presentations and peer-reviewed publications summarizing the results of the evaluation.

Public Health Priorities

Healthy People 2030 Objective

Reduce work-related skin diseases OSH-03

CDC Health Impact-5 Initiative

NA

NCCDPHP Chronic Disease Prevention and Health Promotion Domains

This SIP aligns with the NCCDPHP domain of environmental approaches. In addition, this SIP addresses a Social Determinant of Health, the conditions in the environments in which people work, which is a priority for NCCDPHP.

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:

- review and summarize the existing evidence on and resources to support sun safety among outdoor workers, develop an evidence-based sun-safety intervention for outdoor workers,
- evaluate implementation, use, effectiveness, and scalability of the newly developed intervention, and
- disseminate the new sun-safety intervention and evaluation findings.

Identification and assessment of barriers, facilitators, and needs related to implementation of organizational policies and practices to support sun safety among outdoor workers is expected to inform the development of a new intervention. The new intervention may build on an existing intervention but should be shaped and informed by the assessment.

For all assessments, applicants should describe 1) the constructs to be measured, 2) the various stakeholders (e.g., employers, employees, relevant community-based organizations), 3) the methods to be used (e.g., survey, focus groups), and 4) the anticipated timing.

Target population

The target population for this SIP is outdoor workers with 1) high levels of sun exposure on the job, 2) representative of socially and economically disadvantaged populations, and 3) low access to health information and resources. The target population should also reflect a sector of outdoor workers who are understudied in the scientific literature on occupational sun safety.

Collaboration/Partnerships

Recipients 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 beyond only outdoor workers and their employers, including but not limited to:

- Relevant community-based organization (e.g., worker organizations, non-profit groups, faith-based groups, local charity groups, immigration groups)
- New or existing partners who could facilitate dissemination activities (e.g., advocacy groups, trade associations, dermatologists, municipal governments, chambers of commerce, state and local health departments)

The recipient is also expected to work with the CDC Scientific Collaborator to explore the possibility of adding the final intervention materials to the CDC Workplace Health Program materials (https://www.cdc.gov/workplacehealthpromotion/index.html) and the National Cancer Institute's database of Research-Tested Intervention Programs (https://rtips.cancer.gov/rtips/index.do).

Applicants should provide documentation of current or planned partnerships with organizations or entities necessary to conduct the intervention and evaluation.

Recruitment Plan

Recruitment plans and approaches for each assessment should be addressed. The recipient is responsible for recruiting one or more employers of outdoor workers and a subset of their employees to participate in the study. Participating employees should have high levels of sun

exposure on the job, low wages (in the lowest 25% wage category), low access to health information and resources, and represent a sector understudied in the scientific literature on occupational sun safety.

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

The applicant's evaluation plan should describe the methods and timeline for collecting data to assess implementation, use, effectiveness, and scalability of the sun-safety intervention as well as the costs of planning and implementing the intervention.

Dissemination Plan

The applicant should describe plans to develop products to support dissemination of the new sun-safety intervention and the evaluation findings. Therecipient should disseminate the intervention through new and existing partners such as advocacy groups, trade associations, dermatologists, municipal governments, chambers of commerce, and state and local health departments. The recipient should disseminate the evaluation findings through presentations and peer-reviewed publications. If the intervention is found to be effective, the recipient is also expected to work with the CDC Scientific Collaborator to explore the possibility of adding the final intervention materials to the CDC Workplace Health Program materials (https://www.cdc.gov/workplacehealthpromotion/index.html) and the National Cancer Institute's database of Research-Tested Intervention Programs (https://rtips.cancer.gov/rtips/index.do).

Data Management Plan

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

Visit link https://www.cdc.gov/chronicdisease/programs-impact/nofo/index.htm for DMP Template and Guidance.

Translation Plan

The applicant is expected to provide details on the anticipated strategies to translate the research findings for several key audiences, including employers of outdoor workers, relevant community-based organizations, and public health researchers and practitioners. The strategies should include plans to provide practical guidance on implementation of the sun-safety intervention in various outdoor employment settings using principles of implementation science [7] and considering relevant challenges, barriers, and recommendations applicable to each intended audience.

Public Health Impact

Outdoor workers are often exposed to high levels of UV radiation which increases their skin cancer risk [2-4]. However, little is known about how to implement sun-safety interventions within many prominent yet underserved and understudied outdoor work sectors and what some of the common barriers and facilitators to implementation and sustainability might be [5]. This project will fill this outstanding research gap and could increase the availability and

implementation of evidence-based interventions to improve sun safety and reduce UV exposure among underserved and understudied sectors of outdoor workers.

Special Eligibility and Responsiveness:

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

- Access to one or more worksites and their outdoor workers to conduct the intervention is required.
    - Evidence of this access should be a letter of support or memorandum of agreement; this evidence should be placed in Appendix A of the application. In order to be deemed responsive, applicants must meet all facets of the above eligibility criteria.

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 of the project team with workplace health promotion and/or occupational risk mitigation in the form of publications or publicly available reports?
- Presence of evaluation expertise on the research team?
- Access to the study population in the form of letters of support? Specifically, does the applicant demonstrate access to outdoor workers 1) with high levels of sun exposure on the job, 2) representative of socially and economically disadvantaged populations), 3) with low access to health information and resources, and 4) who reflect a sector of outdoor workers that is understudied in the scientific literature on occupational sun safety?
- Relationships with relevant community-based organizations, in the form of letters of support, that will participate in the development, implementation, and/or dissemination of the sun-safety intervention?

Funding Preferences: None

Research Plan Length and Supporting Material

The Research Strategy Section of the Research Plan is limited to a maximum of 12 pages. Supporting material included as appendices may not exceed 10 PDF attachments, 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 $900,000 is available to fund one Prevention Research Center for a 2-year project period. The average award for the recipient is expected to be approximately $450,000 for year one. The year one ceiling is $450,000. Funding may vary and is subject to change. Funding available includes direct and indirect costs.

Research Status

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

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

Award Administration

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

References

1. Bauer A, Diepgen TL, Schmitt J. Is occupational solar ultraviolet irradiation a relevant risk factor for basal cell carcinoma? A systematic review and meta-analysis of the epidemiological literature. Br J Dermatol 2011; 165: 612?625. http://doi.org/10.1111/j.1365-2133.2011.10425.x.
2. Lucas R, McMichael T, Smith W, Armstrong B. Environmental Burden of Disease Series, No. 13. Solar Ultraviolet Radiation: Global Burden of Disease from Solar Ultraviolet Radiation; Prss-stn A, Zeeb H, Mathers C, Repacholi M, Eds.; World Health Organization: Geneva, Switzerland, 2006. Available online: http://www.who.int/uv/health/solaruvradfull_180706.pdf.
3. Schmitt J, Seidler A, Diepgen TL, Bauer A. Occupational ultraviolet light exposure increases the risk for the development of cutaneous squamous cell carcinoma: A systematic review and meta-analysis. Br J Dermatol. 2011; 164: 291?307. http://doi.org/10.1111/j.1365-2133.2010.10118.x.
4. The Community Preventive Services Task Force Skin Cancer: Interventions in Outdoor Occupational Settings. https://www.thecommunityguide.org/findings/skin-cancer-interventions-outdoor-occupational-settings.
5. The U.S. Bureau of Labor Statistics. TED: The Economics Daily. Lower-wage workers less likely than other workers to have medical care benefits in 2019. https://www.bls.gov/opub/ted/2020/lower-wage-workers-less-likely-than-other-workers-to-have-medical-care-benefits-in-2019.htm.
6. 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 21-005: Feasibility of a Model Cancer Screening Surveillance Report Using All-Payer Claims Data

Project Description

An increasing number of states maintain or have strong interest in developing an all-payer claims database (APCD), a large state database that includes medical and pharmacy claims reported

directly by insurers to states, usually as part of a state mandate.[1] APCDs include data on the insurance claims from multiple sources in a state. Although the name is all-payer, APCD coverage in a state may not be comprehensive, and the included data sources may vary by state.[2-3] A research gap is whether APCDs can be used to develop a model cancer screening surveillance report to support data-driven decisions by state cancer programs and their stakeholders.[4]

The purpose and intent of this project is to demonstrate the feasibility of a model cancer screening surveillance report that uses data from an APCD, and where the report would be designed to help state cancer programs and their stakeholders plan and evaluate health system, clinic, and community interventions to improve cancer screening. At a minimum, the model report would be expected to include preventable cancers with US Preventive Services Task Force (USPSTF) recommendations for screening, such as breast, cervical (Pap/HPV), colorectal, and lung cancer. The report also could include other cancer screening topics to be determined by the recipient.

Estimates of cancer screening at the census tract level are advantageous to better understand, plan, and evaluate interventions to improve cancer screening at the neighborhood level. Thus, an additional project objective is to evaluate the feasibility of estimates of cancer screening at the census tract level or using other small geographic areas (e.g., aggregates of census tracts) that state cancer programs and their stakeholders would recommend for interventions to improve cancer screening. To develop the census tract estimates, the recipient may combine information from the APCD with information from other data sources and use statistical modeling. To evaluate whether the results are under-estimates or over-estimates, the recipient may compare the APCD census tract estimates with existing census tract estimates available from sources such as the CDC Behavioral Risk Factor Surveillance System (BRFSS).[5]

Project Objectives and Outcomes

Applicants are expected to achieve the following project objectives and outcomes:

- **Objective 1**: Community engagement by formation of a project advisory committee that includes representatives from state cancer programs and their stakeholders to help plan and evaluate a model surveillance report on cancer screening in ambulatory care, using an APCD (or equivalent). **Outcome:** Development of a surveillance report with input from community stakeholders and that addresses community concerns.
- **Objective 2:** Analysis of the measures proposed for inclusion in the model surveillance report on cancer screening, using an APCD (or equivalent). **Outcome:** An understanding of the strengths and limitations of the measures in surveillance report.
- **Objective 3:** Statistical modeling to develop census tract (or other small area) estimates of cancer screening, using an APCD (or equivalent), and comparison of the APCD estimates with existing estimates from other data sources. **Outcome:** Geographically specific, small area estimates of cancer screening compared with at least one other data source.

State cancer programs and their stakeholders, and CDC Division of Cancer Prevention and Control programs would use the products of this research to plan and evaluate interventions to improve cancer screening.

Public Health Priorities

Healthy People 2030 Objectives

- C-02, C-04, C-06. Reduce the lung, female breast, and colorectal cancer death rates.
- C-03, C-05, C-07, and C-09. Increase cancer screening based on the most recent guidelines.

CDC Health Impact-5 Initiative: Not applicable

NCCDPHP Chronic Disease Prevention and Health Promotion Domains

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

Project Activities and Submission Requirements

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

Study design and methods

- Describe plans for how the project advisory committee and community stakeholders will be engaged to help plan and evaluate the model cancer screening surveillance report.
- Outline the proposed topics and measures to be included in the model cancer screening surveillance report. The applicants may propose new, additional, or innovative measures or topics for the surveillance report.
- Describe how the project will determine persons eligible for cancer screening, persons with new screening tests, persons with abnormal screening test results, and persons with follow-up to diagnose cancer after an abnormal screening test.
- Describe quality measures to be included in the model surveillance report.
- Describe the project team's experience with analysis of APCD claims data (or equivalent).
- Describe the APCD (or equivalent) that the project proposes to use, including details on the geographic area covered and any Data Partners to add value to the APCD model surveillance report.
- Describe proposed methods for developing small area estimates, plans for statistical modeling, and the methods for comparison of the study results with other existing data sources.

Target population

Describe the overall characteristics of the proposed study population such as sex, age, race/ethnicity, education, income level, years of study, and geographic area. The US Preventive Services Task Force (USPSTF) recommendations for cancer screening define different target populations for breast, cervical (Pap/HPV), colorectal, and lung cancer screening. For each type of cancer to be included in the model surveillance report, the target population description should include details on the anticipated number of persons that would meet the US Preventive Services Task Force (USPSTF) criteria for screening for that cancer.

Collaboration/Partnerships

Describe plans for community engagement by collaboration with representatives of state cancer programs and their stakeholders. Examples of activities for this collaboration might include discussion of whether additional data sources or data partnerships were needed for complete geographic and data coverage; input on the proposed data measures for cancer screening; and plans to evaluate the model report.

Recruitment Plan

If Data Partners will be used to facilitate access to the APCD or to add value to the APCD model surveillance report, describe how the Data Partners will be identified and recruited. This project is limited to analysis of existing computerized data collected for other purposes and is not anticipated to involve any recruitment, direct contact, or follow-up with human subjects.

Annual Action Plan

Provide an annual action plan using SMART goals and objectives to include a progressive timeline for completion of project 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 The evaluation plan should include details on how project feasibility will be determined.

Dissemination Plan

Provide a dissemination plan that describes how the results from the research will be shared with academic, practice and community audiences. It is anticipated that the applicant will prepare at least one scientific article that describes the model surveillance report and methodological challenges.

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

Visit link https://www.cdc.gov/chronicdisease/programs-impact/nofo/index.htm for DMP Template and Guidance.

Translation Plan

Provide a translation plan that describes how the results from the research will be implemented and sustained after project completion, determination of feasibility, and identification of challenges and barriers. The applicant should provide details on the anticipated strategies to translate the research findings for key audiences such as state cancer programs and their stakeholders.

Public Health Impact

Cancer screening tests can identify breast, cervical, colorectal, and lung cancer at an early stage when treatment might be more effective. The model cancer screening surveillance report could provide an applied prevention research tool to improve public health practice in communities

with disparities in cancer screening. If successful, the model surveillance report could be used by state cancer programs and their stakeholders to plan and evaluate health system, clinic, and community interventions to improve cancer screening. Success with this project also could spur development and improvement of APCDs and cancer screening surveillance reports using APCDs in other states contributing to the improved availability of information on cancer screening for public health and clinical action.

Special Eligibility and Responsiveness

Applicants must meet all special eligibility criteria in this section for the application to be deemed responsive:

- Access to All Payers Claims Data (APCD) or equivalent
    - Responsiveness Criteria: In Appendix A, the applicant must provide documentation (e.g. a current letter of support or memorandum of agreement) that the applicant will have access to the critical datasets for the study

Additional Review Criteria

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

- Does the applicant propose a rigorous study design for the proposed study topics, and identify appropriate potential data sources and Data Partners to evaluate the feasibility of a model cancer screening surveillance report?
- Has the applicant identified appropriate methods to calculate small area estimates and to compare those estimates with other data sources?
- Does the project team include the experience and expertise needed to implement the proposed project activities?
- Does the applicant propose a plan that can adequately evaluate and disseminate the project results?
- Does the plan include appropriate approaches for sustaining the project results, and for ensuring use by state cancer programs and their stakeholders?

Funding Preferences

None

Research Plan Length and Supporting Material

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

Availability of Funds

It is anticipated that approximately $1,000,000 is available to fund one Prevention Research Center for a 2-year project period. The average award for the recipient is expected to be

approximately $500,000 for year one. The year one ceiling is $500,000. 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 Institutional Review Board (IRB) approval. Applicants should provide a federal-wide assurance number for each performance site included in the project. CDC staff will not have contact with human subjects or data collected from human subjects, other than aggregate tables without identifiers provided as part of project progress reports and as part of scientific articles.

OMB/PRA

OMB/PRA is not expected to apply.

Award Administration

The CDC Project Scientific Collaborator will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards. CDC staff will serve as consultants on this project, and will provide technical assistance, as requested, on activities such as design and nature of research, co-authoring manuscripts, and dissemination of results.

References

1. Agency for Healthcare Research and Quality. All-Payer Claims Databases. Available at https://www.ahrq.gov/data/apcd/index.html
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4. Centers for Disease Control and Prevention. National Comprehensive Cancer Control Program. Available at: https://www.cdc.gov/cancer/ncccp/
5. Centers for Disease Control and Prevention. 500 Cities: Local data for better health. Available at: https://www.cdc.gov/500cities/index.htm

SIP 21-006: Increasing Genetic Counseling Referrals Among Patients At-Risk for BRCA-Associated Cancers

Project Description

Approximately 5%-10% of breast cancers are hereditary. [1,2] However, hereditary cancer syndromes increase cancer risk, cancers diagnosed at advanced stages, and cancers diagnosed at younger ages. The U.S. Preventive Services Task Force (USPSTF) recommends offering genetic counseling and testing to women who have identified at least one family member with a potentially harmful mutation in the BRCA1 or BRCA2 genes. Despite national recommendations for genetic counseling and testing among women with high risk for Hereditary Breast and Ovarian Cancer (HBOC), appropriate use of these services remains low among all women and lowest among African American women.[3-6] One study found that Black women with a

personal history of breast cancer had 53% lower odds of receiving cancer genetic services than white women with a personal history. [3] In addition, Black women are also more likely to be diagnosed with Triple Negative Breast Cancer, an aggressive form of breast cancer that is difficult to treat and associated with pathogenic BRCA mutations. [7] The most commonly reported obstacle to getting genetic services among all women was that no one had recommended these services.[8] While lack of provider recommendation for cancer genetic services is a barrier among all women, Black women have lower odds of being recommended cancer genetic services than white women. [6] Also, analysis of claims data suggests that those living in non-metropolitan areas have lower rates of utilization of BRCA genetic testing, as well as some risk management practices, than those living in metropolitan, or more urban settings. [9]

Also, BRCA mutations are implicated in more than just breast and ovarian cancers, and BRCA-related cancers affect men as well as women. For example, a significant percentage of African American men with prostate cancer also had a family history of HBOC.[10] Men with BRCA mutations have a higher risk of developing malignant abnormalities of the prostate, pancreas, breast, colon, and melanoma.[11-13] Similar to HBOC in women, BRCA mutations are associated with more advanced stages and grades, and poorer survival rates in patients with prostate cancer.[14]

The purpose of this project is to increase appropriate referrals to genetic counseling for those patients who have a family cancer history or a mutation probability score (based on a risk algorithm) indicating an increased risk of carrying a pathogenic variant associated with BRCA and assess if system-level interventions to increase access address racial/ethnic disparities in referral and utilization of cancer genetic services. It is expected that with the implementation of evidence-based changes at the health care system level,?such as automated referrals, electronic health record (EHR) enhancements, and changes in clinical processes,?this project will improve the timely identification and referral of patients at high risk for BRCA-related cancers to genetic counseling.

Project Objectives and Outcomes

Objectives

By the end of this three-year SIP project, the applicant should show clinically meaningful improvements in referrals to genetic counseling among indicated patients from population segments less likely to utilize genetic counseling in a given health system, compared to current practice by implementing at least one of the following strategies:

- Developing an EHR-alert reminding the clinician to take personal and family history and refer patients at risk for BRCA-associated cancers to genetic counseling, including the option for alternative strategies (referral to telephone- based genetic counseling and other alternative strategies).
    - Improving EHR processes for documenting outcomes of referrals and testing.
    - Embedding genetics staff in the cancer center (or as a member of the oncology care team) to improve the referral process, and address patients? concerns while the patient is present during a treatment appointment.
    - Using of patient navigators to guide patients through the referral process.
    - Exploring the role of predictive analytics to improve detection of BRCA-associated cancers among patients who may need support from a patient navigator

to follow through with the referral process, or the use of predictive analytics to guide the best implementation strategy for the health system.

- The applicant should implement a quasi-experimental or experimental intervention. The study design should allow for the assessment of differences in referral and use of genetic counseling and testing attributable to the implementation of the system intervention (this may require access to historical data or data from prior to the implementation of the intervention for the target population). Investigators may benefit from including the perspectives and input of patients and/or health care providers in the design of the intervention through a community advisory board.
- Conduct an evaluation of the intervention strategies selected to indicate if clinically meaningful improvements in referral and use of genetic counseling and testing among indicated patients in a given health system occurred, compared to current practice. The evaluation should also consider if the intervention increased referral and utilization of cancer genetic services among members of minority racial/ethnic groups compared to current practice and barriers and facilitators in the receipt of cancer genetic services. The implementation of the intervention, such as fidelity to intervention protocol, consistency of delivery, and time and costs of the intervention, should also be considered.
- Creation of an implementation tool kit or other resources for health systems to translate and adapt this intervention for their setting, to provide best practices to others, and to support dissemination among partners.

Outcomes

- New policies and procedures (e.g., reminders or clinical decision support tools) to identify patients for whom genetic counseling is indicated and to refer them to genetic counseling.
- Evaluation of the intervention and its ability to change referral patterns and utilization of cancer genetic services in a health care system and the impact of the intervention on racial and ethnic disparities in referral and utilization. In addition, the evaluation should enhance the knowledge and understanding of barriers and facilitators in the receipt of cancer genetic services.
- A tool kit or other resources to provide best practices for other health systems to translate and adapt this intervention for their settings.
- Evaluation findings disseminated through presentations and peer reviewed publications

Public Health Priorities

Healthy People 2030 Objectives

C-4 Reduce the female breast cancer death rate

CDC Health Impact-5 Initiative

This project aligns with the CDC Health Impact-5 Initiative health condition of cancer.

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.

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 and testing new strategies to increase referral and use of cancer genetic services among patients for whom genetic counseling for BRCA-associated cancers is indicated. The design of the intervention may be experimental or quasi-experimental in nature. The design should require the use of historical data or data from prior to the implementation of the intervention to detect differences in referral practices and use of cancer genetic services at the health system(s)/cancer center(s)/clinic(s) for the study population(s). In addition, expected sample size and statistical power should be discussed and calculated as part of the study design and methodology. The study should be sufficiently powered (B=80%) to detect differences in study outcomes stratified by race/ethnicity. Discussions of sample size should include estimates of the proportion of the patient population that expected to meet referral criteria for genetic counseling and testing and present by racial/ethnic group. Previous or ongoing efforts within selected health systems or at the study sites to increase referral or use of cancer genetic services should be described and assessed to clarify potential opportunities for intervention contamination. Plans to mitigate potential intervention contamination, if any, should be described.

All applicants should ensure that there is sufficient access to genetic counseling services in the health systems and clinics with whom they will be partnering so that all patients who desire genetic counseling are able to receive it within a reasonable time frame (especially if recently diagnosed with cancer) and can be received either in person or through tele-genetic services. Applicants must show that systems and clinics have a sufficient supply of genetic counselors to absorb the increased use of the service based on sample size estimates. Letter of support from partner health systems should address having sufficient capacity for the provision of genetic counseling services. In addition, applicants should consider the need for access to historical data or data from before the implementation of the intervention to determine change in use of genetic counseling and testing services in the target population.

Target population

The applicant is responsible for recruiting one or more cancer centers/health systems who are involved in obtaining and discussing family health and cancer histories, or cancer screening, diagnosis, or treatment. Cancer centers and health systems that serve racial/ethnic minority or rural communities, such as community cancer clinics, are desired. The health system should have a racially and ethnically diverse client base. The health systems or cancer centers should be able to provide the necessary data, or access to the necessary data, to assess use of and referral to genetic counseling and testing services through historical data or data from prior to the implementation of the intervention for the target population. The primary target audiences who will benefit from this project include those who are involved in obtaining and discussing personal and family health and cancer histories, or genetic counseling/testing, or involved in cancer screening /diagnosis (OB/GYN, primary care physicians, nurses, nurse practitioners, physician?s assistants).

Collaboration/Partnerships

Applicants are expected to collaborate with organizations and entities that will support the accomplishment of the objectives of this project. A community advisory board of patients and providers from the target population may also help inform the design and implementation of the intervention. Two possible collaborative partners include CDC?s Cancer Genomics Program or the National Comprehensive Cancer Control Program. The applicant is also expected to work with the CDC Scientific Collaborator to disseminate the final tool kit or other resources to provide best practices to other health systems.

Recruitment Plan

The applicant is responsible for recruiting one or more cancer centers/health systems to participate in the study. A letter of support should be included from all participating health systems or cancer centers. Health systems serving racial/ethnic minority populations or rural communities would be well suited to address the focus of the project, given that patients at institutions serving racial/ethnic minority populations or rural communities may be less likely to receive genetic counseling and testing. When selecting health systems with whom to partner, the ability to access historical data or data prior to the implementation of the intervention should be considered.

Annual Action Plan

The 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 applicants are expected to provide an evaluation plan that describes methods to assess which intervention strategies are most favorable for implementation, identify the critical elements needed for the intervention to produce appropriate referrals, assess the ability of the intervention to address racial and ethnic disparities, and which strategies best support patient-centered decision making. The evaluation should also address the implementation of the intervention, for example fidelity, consistency of delivery, costs, and time.

Dissemination Plan

The applicants are expected to develop a dissemination plan that includes: 1) presentation of findings at national conferences, 2) presentation of findings to CDC funded programs (including CDC?s Cancer Genomics Program, National Breast and Cervical Cancer Early Detection Program, National Comprehensive Cancer Control Program, and networks supported by the Comprehensive Cancer Control Branch under the Networking2Save (DP18-1808) cooperative agreement), and 3) development of a manuscript(s) for publication in a peer-reviewed scientific journal.

Data Management Plan

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

Visit link https://www.cdc.gov/chronicdisease/programs-impact/nofo/index.htm for DMP Template and Guidance.

Translation Plan

The applicants are expected to provide details on the anticipated strategy to translate their process into an implementation tool kit or other resources to provide best practices for a number of intended audiences, including health care providers and health systems, and provide practical guidance to implement the strategies in practice using principles of implementation science.[15]

Public Health Impact

This research will support the identification of effective health care system strategies to increase the number of patients being referred to genetic counseling for BRCA-associated cancers.

Identification of patients with hereditary cancer syndromes can help patients and their families make decisions regarding testing family members, initiating cancer screening on an accelerated schedule, and following other preventive and surveillance strategies (e.g., prophylactic mastectomy or salpingo-oopherectomy to prevent breast and ovarian cancer). These strategies may help prevent new cancers, increase early detection and more timely treatment, and reduce cancer mortality.

Special Eligibility and Responsiveness:

Applicant must provide documented evidence, in the form of letters of support, or memorandum of understanding from each cancer center, health system, or clinic where the intervention will be implemented. The evidence should demonstrate that the health system has agreed to participate in the study and will implement the intervention in accordance with the study protocol. Evidence should be clearly labeled and placed in Appendix A.

In order to be deemed responsive, applicants must meet all facets of the above eligibility and responsiveness.

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 to appropriately identify patients at risk for BRCA-associated cancers and refer them to genetic counseling? Does the study team have a history of conducting research on health disparities in health service utilization? Does the study team have a history of implementing system interventions?
- Does the applicant demonstrate, through a letter of support or memorandum of understanding, evidence of an existing and established partnership with a cancer center(s), health system(s), or health clinic(s)? Does the letter of support:
    - Describe the patient population served by the health system and present the demographic break down of the patient population of the health system/cancer center by race/ethnicity?
    - Present an estimate of the proportion of the patient population, stratified by race/ethnicity, that would be eligible for genetic counseling and testing services for BRCA?

    - List and briefly describe relevant previous collaborations, partnerships, or studies conducted on the patient population that focused on health disparities?
    - Indicate whether investigators at the awarded Prevention Research Center will have access to either historical data or data prior to intervention implementation on referral to and use of genetic counseling and testing services, for the target population?
    - Describe any current or on-going efforts at the health system to increase utilization of cancer genetic services (specifically for hereditary breast and ovarian cancer)?

- Does the applicant demonstrate that the participating cancer center(s), health system(s), or health clinic(s) has a diverse patient population that will allow for the meaningful assessment of racial and ethnic disparities in referral and use of cancer genetic services compared to current practices? Are sample size estimates and power calculations (with power set at 80%) stratified by race/ethnicity presented? Is the study sufficiently powered to detect differences in the outcome within racial/ethnic groups? Does the study design allow for assessing differences in referral to and use of cancer genetic services by racial and ethnic group pre- and post-intervention implementation?
- Does the study design document how historical data or data prior to the implementation of the intervention for the target study population(s) will be accessed or collected to detect changes in referrals to and use of cancer genetic services?
- Does the applicant indicate if there are previous or ongoing efforts to increase referral to or use of cancer genetic services at the partner health system? If so, does the applicant indicate if these efforts may contaminate or impact the implementation of the intervention or the evaluation of the intervention?s effects? Does the applicant describe strategies to mitigate potential intervention contamination?
- Does the applicant appropriately demonstrate how patients will be identified, e.g., using current NCCN Guidelines [16] or a mutation probability algorithm (e.g., BRCAPro, BOADICEA) to assess genetic risk and identify those who should be referred for genetic counseling? If probability prediction models are used, has their use been adequately supported?

Funding Preferences:

Study sites with both of the following characteristics:

- Study sites with racially and ethnically diverse populations that are sufficiently powered (power at 80%) to detect differences in the study outcome within racial/ethnic groups.
- Study sites with access to historical data or data prior to the implementation of the intervention to assess change in referral to or utilization of cancer genetic services.

Research Plan Length and Supporting Material

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

Availability of Funds

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

Research Status

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

OMB/PRA

OMB/PRA is not expected to apply

Award Administration

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

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SIP 21-007: Epilepsy incidence and etiology: important information for public health prevention and health promotion in the US community

Project Description

Epilepsy is a neurological disease characterized by recurring seizures (1). Approximately 1.2% of the US population (about 3.4 million people) has active epilepsy (being on antiepileptic medications and/or having had one or more seizures in the past year) (2). Information about epilepsy incidence is limited in the general U.S. population: Most publications about epilepsy incidence in U.S. populations report less recent data with short follow-up times in specific subgroups (3). A few recent studies of epilepsy incidence in large populations that addressed epilepsy risk factors and treatment (4,5) used commercial claims data in limited age groups. Therefore, assessing recent epilepsy incidence in large U.S. general populations is a research gap, especially in children, older adults, and Veterans. Filling this gap is a need described in both the 2012 Institute of Medicine (IOM) report, Epilepsy Across the Spectrum: Promoting Health and Understanding? (3), and the summary of CDC epidemiologic studies listing this gap as a research priority for the CDC Epilepsy Program (6). Except for a few known risk factors (e.g. stroke, post-traumatic brain injury, infections, genetic conditions), only a few novel risk factors have been proposed as linked to epilepsy etiology (e.g., inflammation) (7). However, even these

risk factors for epilepsy development account for only about one-half of epilepsy cases. (3).

The first goal of this study is to use recent, existing administrative claims and other data from geographically defined populations, as well as standardized definitions and methods to assess and update epilepsy incidence. The second goal is to explore social determinants of epilepsy including risk factors and protective factors that affect epilepsy incidence.

Project Objectives and Outcomes

The objectives of this study are to:

- determine the incidence of any type of epilepsy in large populations of U.S. children and adults.
- explore the association between risk factors and protective factors (e.g., socioeconomic factors or well-being/ thriving / social connection with family, friends, schools, community etc.) before epilepsy onset and newly diagnosed incident epilepsy cases.
- examine potential disparities in incidence rates of epilepsy by stratified demographic characteristics and by above risk and protective factors.

By using the existing administrative claim (8) and other data, at the end of this project, applicants are expected to provide a final report with the results for incidence and risk factors of epilepsy. Additionally, applicants are expected to develop one or more peer reviewed scientific manuscripts regarding above objectives. Overall, these findings will help to determine opportunities for public health prevention, interventions, and services for people with epilepsy in the U.S.

Public Health Priorities

Healthy People 2020 Objectives (10)

Objective AHS-7: Increase the proportion of persons who receive appropriate evidence-based clinical preventive services.

U.S Department of Health and Human Services (HHS) Strategic Plan FY 2018 ? 2022 (9)

Goal 4, Objective 4.1: improve surveillance, epidemiology, and laboratory services

CDC Health Impact-5 Initiative NA

NCCDPHP Chronic Disease Prevention and Health Promotion Domains (11)

The SIP is aligned with NCCDPHP Chronic Disease Prevention and Health Promotion Domains on Epidemiology and Surveillance.

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 proposed study should include standard case definitions, outcome measurement, methods of data collection, analysis and dissemination.

Target population

In order to get the large and geographically defined population representative data of pediatric and/or adult epilepsy to better assess the outcomes, it is expected that the study covers at least 1 million population. This population may include: 1) all age groups; 2) both sexes; 3) all race/ethnicities; 4) both rural- and urban-dwelling residents; 5) patient population with any types of epilepsy. Applicants responding to this SIP should obtain enough information for specific age groups (e.g., children and older adults) to allow incidence rates and risk or protective factors to be stratified by these characteristics. Applicant is encouraged to carry out multiple center data collections with diverse study populations.

Collaboration/Partnerships

The applicant is expected to develop or expand relationships with collaborating partners that will assist in achieving study goals. Partners such as professional medical organizations, academic networks of research organizations or clinics or other stakeholders should facilitate access to data, support the conduct of analysis, or promote dissemination

Recruitment Plan

NA

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

To successfully achieve the proposed objective and outcomes of this SIP, applicant is expected to evaluate and to determine possible critical obstacles and solutions to ensure accessing to data, identify enough sample size, analyze data and disseminate research findings.

Dissemination Plan

The applicant is expected to provide a final report with the results for incidence and risk factors of epilepsy to CDC. A dissemination plan for the results and findings, including publishing results in peer-reviewed journals 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

Visit link https://www.cdc.gov/chronicdisease/programs-impact/nofo/index.htm for DMP Template and Guidance.

Translation Plan

The applicant is expected to include a plan to translate the findings of the research into public health practice through publications and presentations, especially for those results of social disparity related to the epilepsy incidence rate.

Public Health Impact

Information about epilepsy incidence (any types from all ages) and related risk and protective factors from large, population representative pediatric and/or adult epilepsy data in the U.S. will provide invaluable information for academic researchers, advocacy groups, and other government agencies to help better guide interventions or services for preventing epilepsy, treating and rehabilitating people with epilepsy, and minimizing their health disparities and adverse outcomes.

Special Eligibility and Responsiveness

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

- Evidence of access to study populations and/or specified data source
    - The applicant must provide documentation, e.g. a letter of support or memorandum of agreement, demonstrating evidence of access to the study population and existing administrative claims and other data relevant for the project, necessary to carry out the proposed study.
    - The evidence must be clearly labeled and placed in Appendix A of the application.

- Evidence of expertise in epilepsy
    - The applicant must provide evidence that the project team includes experts in epilepsy research, as evidenced in the Research & Related Senior/Key Person Section of the SF424 (R&R).
    - The evidence must be clearly labeled and placed in Appendix A of the application.

Additional Review Criteria

Besides 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 special interest project will be considered in the determination of scientific merit and priority score:

Does the applicant:

- identify and confirm access to an existing data set to be used to accomplish the study objectives?
- describes an existing data set covering the population at risk for all ages and representing at least 1 million population?
- provide evidence of successful experience working on the studies of epilepsy incidence.

Does the applicant have experience:

- in the diagnosis and the treatment of epilepsy patients.
- in conducting surveillance and epidemiologic research.
- in conducting studies of standard definitions or the criteria for epilepsy case ascertainment.
- in designing education materials and outreaching to community or professional groups.

Funding Preferences

Geographic diversity of study sites (i.e., multiple study sites) and study populations (i.e., diverse study populations).

Research Plan Length and Supporting Material

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

Availability of Funds

It is anticipated that approximately $600,000 is available to fund 1 Prevention Research Center for a 3-year project period. The average award for recipient is expected to be approximately $200,000 for year one. The year one ceiling is $200,000. Funding may vary and is subject to change. Funding available includes direct and indirect costs.

Research Status

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

OMB/PRA

OMB/PRA is not expected to apply

Award Administration

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

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SIP 21-008: Examining approaches to improve care and management of people with lupus

Project Description

Lupus is a chronic, autoimmune disease that can damage any part of the body. Lupus is more common among women of childbearing age (ages 15 to 44 years). [1] The symptoms of lupus include, but are not limited to, joint pain, fever, fatigue, kidney trouble, and rashes. [2,3] Estimates of the number of Americans with lupus varies but range as high as 1.5 million.[4,5] About 9 out of 10 diagnoses of lupus are in women ages 15 to 44.[1] Lupus raises the risk of coronary artery disease, osteoporosis, and kidney disease.[6,7] African-American women are three times more likely to have lupus than white women.[8] Lupus is also more common in Hispanic, Asian, and Native American and Alaskan Native women.[9] African-American and Hispanic women usually get lupus at a younger age and have more severe symptoms, including kidney problems, than women of other groups.[8,9] The cause of lupus is still being determined but may include the environment, hormones, and immune problems. Common methods for managing lupus symptoms include lowering stress, exercise, eating healthy food, and getting good sleep.

The CDC currently funds several lupus registries [10] to support public health research on lupus. These registries collect data on treatment history, health care access, and natural history (i.e., severity, morbidity, mortality, etc.) of cohort members. The registries house state-of-the-art clinical, patient-reported, and biospecimen lupus repositories. High-impact research investigations are conducted to advance understanding of racial, ethnic, and socioeconomic disparities in lupus.

The purpose of this SIP is to investigate prevention research topics that can improve care and management of adults with lupus. CDC is interested in prevention research in one or more topics including : 1) Examining psychosocial characteristics associated with mortality and/or patient-

reported outcomes (e.g., physical functioning, general health, mental health, pain, and social functioning), including adverse childhood experiences, work loss, and other measures of socio-economic deprivation, self-reported experiences of racism, 2) the effectiveness of physical activity on improving lupus outcomes, 3) effectiveness of counselling for physical activity among individuals with lupus, and 4) effectiveness of a Chronic Disease Self-Management Program in improving lupus outcomes.

Project Objectives and Outcomes

The outcome of this project is greater foundational knowledge for future development of approaches and actions for clinical- and self-management of lupus. The project objectives are to assess behavioral and psychosocial factors that may impact health, functioning and other patient reported outcomes for people with lupus. Further prevention research is needed to both identify these factors and to determine whether and how these factors can be addressed to improve health care management and outcomes for people with lupus. Behavioral, psychosocial and self-management approaches have been shown to be effective for people with other conditions such as arthritis and epilepsy, but prevention research is needed to confirm this for people with lupus.

Public Health Priorities

Healthy People 2020 Objectives

This program addresses the ?Healthy People 2020? focus areas of Health Services, Health-Related Quality of Life and Well-Being, physical activity, and comorbidities.

Project Activities and Submission Requirements

It is expected that activities will include a literature review, identification of an approach to further study the topic, and a detailed research plan that will obtain results within the funding timeline. Applications submitted in response to this SIP should present a discussion of the topic of interest and implications for improving care and outcomes for people with Lupus, proposed research plan to further investigate the topic, any products that might be developed, and plans for dissemination.

Study design and methods

The applicant should describe and explain in detail the study design and methods regarding study variables and analyses including the following:

- Study design and study population
- Methods for assessing how you plan to address the study objectives
- The data sources that will be used
- The role of partners that will be involved in this research project and include letters of support from the key collaborators.
- Plans to develop any patient, provider or communications products from this project
- Plans to disseminate the findings of this research project through publications, presentations, and active engagement with state and community partners, as well as other stakeholders.

Target population

Applicant should clearly describe the target population of lupus cases. What is their geographic location and race/ethnicity? For example, are the cases drawn from an existing registry or other data source?

Collaboration/Partnerships

It is expected that this applied research will be done in collaboration with relevant local, state or national public health partners (e.g., public health agencies, national organizations, epidemiologists, community-based organizations) to promote this work and to ensure that the project will be relevant to people with lupus. The applicant should describe whether and how partners will be engaged. Letter of support should outline these collaborations.

Recruitment Plan

The applicant should clearly describe a recruitment plan appropriate to the proposed approach. If a cohort of people with lupus is planned, the applicant should describe, for example, whether this is through access to an existing registry, identification of people with lupus through medical records, or access through a local or national lupus organization. The applicant should describe the approach to contacting potential participants.

Annual Action Plan

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

Evaluation Plan /Performance measurement

Applicants are expected to develop an evaluation and performance management plan. Plan should include SMART project goals and objectives, a plan for performance monitoring, and plans to remediate any anticipated barriers**.**

Dissemination Plan

The applicant is expected to develop a dissemination plan for the project including publications, presentations, and other communications materials to support the dissemination of study findings to national, state, and local organizations involved in lupus research and public health, and to engage partners and stakeholders to disseminate information and provide support to local communities ensuring that those that work with the target population are aware of these findings.

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

Visit link https://www.cdc.gov/chronicdisease/programs-impact/nofo/index.htm for DMP Template and Guidance.

Translation Plan

The applicant should describe how the proposed study, approach, and products (publications, presentations and other products) has implications for improving care and outcomes for people with lupus. Proposed written deliverables (e.g., publications and presentations) should

demonstrate that the recipient has assessed how the research can be translated to inform public health practice and should include implications for implementation.

Public Health Impact

This SIP builds on prior knowledge from the scientific literature and experience from other funded work. The proposed research will improve understanding of how psychosocial characteristics, physical activity, counseling for physical activity, and self-management may impact lupus outcomes. Public health professionals can use these findings to develop approaches to potentially intervene and improve outcomes among adults with lupus.

Special Eligibility and Responsiveness

None

Additional Review Criteria

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

- **Specifically for research topic 1 (Examining psychosocial characteristics associated with mortality and/or patient-reported outcomes (e.g., physical functioning, general health, mental health, pain, and social functioning), including adverse childhood experiences, work loss, and other measures of socio-economic deprivation, self-reported experiences of racism),** does the applicant propose methods sufficient to assess how psychosocial characteristics are associated with mortality and patient-reported outcomes in adults with lupus?
- Does the applicant show their experience collaborating with public health and other partner organizations that will be involved in this project?
- Does the applicant identify appropriate partners to accomplish the goals/objectives of the study?

Funding Preferences

None

Research Plan Length and Supporting Material

The Research Strategy Section of the Research Plan is limited to a maximum of 12 pages. Supporting material included as appendices may not exceed 10 PDF attachments, with a maximum of 30 pages total. 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 up to three (3)** Prevention Research Center for a 2-year project period contingent on availability of funds. The average award per recipient for year one is expected to be approximately $250,000. The year one ceiling

is $275,000. Funding may vary and is subject to change. **Funding available includes direct and indirect costs.**

Research Status

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

OMB/PRA

OMB/PRA is not expected to apply

Award Administration

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

References:

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SIP 21-009 Mental Health of Mothers Study (MHOMS) and Substance Use Evaluation Network

Project Description

Mental health conditions like depression, anxiety, substance use disorder, and severe mental illness, are common conditions affecting pregnant and postpartum women, and they have devastating effects on women, children, and families. [1-3] An estimated 1 in 7 women will experience a new episode of depression during pregnancy or postpartum, [4] an estimated 18% of women experience postpartum anxiety, [5] and an estimated 6.3% of women experience both postpartum depressive symptoms and anxiety.[5] The American College of Obstetricians and Gynecologists (ACOG), the United States Preventive Services Task Force (USPSTF), and the Council on Patient Safety in Women?s Care recommend universal screening of pregnant and postpartum women for depression and anxiety symptoms using a standardized, validated tool, paired with systems in place to provide a range of treatment or referral options.[6-8]

Massachusetts Child Psychiatry Access Program for Moms (MCPAP for Moms) implemented a program to provide the complete care pathway, which includes screening, assessment, triage and referral, treatment access, and treatment engagement.[9] Similar state perinatal psychiatric access programs have emerged, including seven recently funded by Health Resources and Services Administration (HRSA) projects (Florida, Kansas, Louisiana, Montana, North Carolina, Rhode Island, and Vermont).[10] These programs are designed to capture aggregate process and programmatic data (e.g., number of women screened), but not individual-level outcomes.

This SIP builds upon and extends the recent work funded by Division of Reproductive Health (DRH), Program in Support of Mom (PRISM, DP 15-005), which is a collaboration with the University of Massachusetts (UMass) that compares depression outcomes and treatment rates between the PRISM intervention (enhanced standard of care) and Massachusetts state access program (MCPAP for Moms, i.e., usual care). Dissemination of the UMass work has ignited interest and replication across the country, resulting in a network of state access programs called Lifeline4Moms. The purpose of this SIP is two-fold: 1) conduct new applied research with clinical sites enrolled in state access programs to examine pregnant and postpartum women?s mental health outcomes, care, and inequities; and 2) serve as the coordinator for **the Mental Health of Mothers Study (MHOMS) and Substance Use Evaluation Network** (?network?), which will be comprised of representatives from state access programs. The coordinator will provide leadership, implement a data platform, and coordinate with clinical sites enrolled in state access programs within the network to conduct applied research, evaluate outcomes, and answer the research question.

Project Objectives and Outcomes

The purpose of this SIP is to fund one PRC to both conduct research and function as a ?network coordinator? to examine individual-level maternal mental health outcomes and care, overall and by subpopulations??. Objectives include:

- Facilitate sustainable collaborations with the network to improve generalizable knowledge about individual mental health and substance use outcomes and care.
- Develop or identify an existing data platform to capture individual-level symptomology and treatment engagement outcomes through pregnancy and postpartum periods.

- Conduct an applied research study with one or more clinical sites enrolled in state access programs within the network to examine variation in individual-level treatment and health outcomes of women with perinatal anxiety, severe mental illness, and substance use disorder, including examination of diversity among subpopulations (e.g., race/ethnicity, sociodemographic status, rural/urban residence);
- Analyze and describe outcomes of interest overall and by subpopulations, which may include screening results, mental health symptomology, diagnoses, substance use, suicidal ideation and attempts, deaths, treatment uptake and adherence, provider satisfaction, and feasibility.

Public Health Priorities

This project addresses four Healthy People 2020 Focus Areas: Maternal, Infant, and Child Health, Mental Health and Mental Disorders, Substance Abuse, and Social Determinants of Health.

Healthy People 2020 Objectives

- MICH-6: Reduce maternal illness and complications due to pregnancy (complications during hospitalized labor and delivery)
- MHMD-4: Reduce the proportion of persons who experience major depressive episodes (MDEs)
- MHMD-9: Increase the proportion of adults with mental health disorders who receive treatment
- MHMD-11: Increase depression screening by primary care providers
- SA-8.1: Increase the proportion of persons who need illicit drug treatment and received specialty treatment for abuse or dependence in the past year
- AHS-6.4: Reduce the proportion of persons who are unable to obtain or delay in obtaining necessary prescription medicines.

CDC Health Impact-5 Initiative

NA

NCCDPHP Chronic Disease Prevention and Health Promotion Domains

This SIP addresses health equity and data modernization which align with two NCCDPHP domains: health system interventions to improve the effective delivery and use of clinical and other preventive services; and strategies to improve community-clinical linkages.

Project Activities and Submission Requirements

Applications should present a Research Plan that addresses the following requirements:

- Engage and manage a geographically diverse network of state access programs through facilitated monthly calls and other communication strategies
- Facilitate experiential learning by coordinating and/or providing interactive peer-learning education for the network;
- Propose a research approach/design that is appropriate to capture necessary data components to answer the research question and includes a Data Management Plan;

- Provide subject matter expertise and leadership to members of the network in implementing the complete care pathway (see Introduction) for mental health and/or substance use disorders;
- Collect multi-clinical site, patient-level data to follow women through pregnancy and postpartum and capture individual-level symptomology and treatment engagement outcomes, including engagement with perinatal mental health state access programs.

Study design and methods

Applications should present a plan that addresses the following:

- How the applicant will engage, support, and monitor individual-level symptomology, treatment, and health outcomes data collection overall and by subpopulations from one or more clinical sites that are enrolled in state access programs in the network throughout the duration of the project;
- How the applicant will conduct an applied research study to evaluate variation in perinatal depression, anxiety, severe mental illness, and substance use disorder on treatment engagement and other individual-level maternal outcomes, including examination of differences by subpopulations;
- A detailed 12-month action plan that uses SMART goals and objectives and includes a description of activities and a progressive timeline for completion of activities.

Target population

The target population that will benefit from this SIP is pregnant and postpartum women.

Collaboration/Partnerships

Collaborations will include clinical sites and state perinatal psychiatric access programs (i.e., network members) to build capacity for research with individual patient-level outcome data, and professional clinical organizations such as the American College of Obstetricians and Gynecologists to facilitate dissemination of results and promote best practices from the network.

Recruitment Plan

Applicants should include a description of the proposed approach for identifying, engaging, and working with one or more clinical sites enrolled in state perinatal psychiatric access programs in the network that will contribute diversity (i.e., racial/ethnic, socioeconomic, and rural/urban) to the overall study population and that will contribute data to a data platform.

Annual Action Plan

Applicants are expected to provide a 12-month action plan that uses SMART goals and objectives and includes (at a minimum) a description of activities and a progressive timeline for completion of activities.

Evaluation Plan /Performance Measurement

The anticipated goal of the evaluation plan is to monitor that the research is progressing according to the stated timeline. The plan is expected to include, but not be limited to, time-oriented performance measures, responsible party, and source of information to evaluate/assess progress toward project outcomes.

Dissemination Plan

The applicant is expected to provide a dissemination plan, which at a minimum will describe publications in peer-review journals and other strategies for disseminating results of the project to academic, health care practices, and community audiences. Additionally, the dissemination plan should address how technical assistance products will be shared.

Data Management Plan

This SIP involves the generation or collection of public health data. The applicant is expected to provide a stand-alone data management plan that addresses the five elements of AR-25 must be submitted (https://www.cdc.gov/grants/additional-requirements/ar-25.html).

Visit link https://www.cdc.gov/chronicdisease/programs-impact/nofo/index.htm for DMP Template and Guidance.

Translation Plan

The applicant is expected to provide a translation plan that summarizes findings for a number of intended audiences, including health care providers and health systems, and provide practical guidance to implement the strategies in practice using principles of implementation science. The funded recipient should consider relevant types of communication (e.g., webinar, fact sheet, toolkit, talking points) to properly translate research findings into practice

Public Health Impact

Alongside universal depression screening, ACOG, USPSTF, and the Council on Patient Safety in Women?s Care all advocate for a systems of care approach to integrate the complete care pathway into practices.[6-8] Perinatal mental health state access programs that incorporate an on-call perinatal psychiatrist or facilitation of referral to community services may support this recommendation. They may improve provider confidence, screening assessment skills, treatment plans, and general coordination of care across providers, and as a result of this increase in support, providers may be more comfortable initiating a depression screening and managing referral and treatment. If clinic engagement with state access programs is shown to be effective in screening women, managing symptoms, and improving treatment uptake, this will inform implementation of these programs in states.

Special Eligibility and Responsiveness

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

- The institution must demonstrate previous or current relationships/collaborations with state perinatal psychiatric access programs.
    - Responsiveness Criteria: Evidence of this criteria can be demonstrated through Letters of Support or Memoranda of Understanding.

NOTE: Applications that do not meet the eligibility requirements stated in this section will be deemed as not responsive and therefore will not be entered into the review process.

Additional Review Criteria

In addition to the standard review criteria (Significance, Approach, Innovation, Investigators, and Environment), the following review criteria will be considered in the determination of scientific merit and the priority score:

- Does the applicant demonstrate experience in providing implementation support to states with emerging or existing perinatal psychiatric access programs, including technical assistance in tailoring screening and treatment engagement to the needs of the state?
- Does the applicant demonstrate experience working with state access programs that have diverse populations with regard to race/ethnicity, socioeconomic status, rural/urban residence?
- Does the applicant provide evidence that the project team includes experts in the research topic area for perinatal mental health and substance use disorders and 4+ years of experience with implementing the complete care pathway?
- Does the applicant demonstrate the ability to facilitate implementation of a multi-site, clinical data platform and experience collecting individual-level data from clinical sites?
- Does the applicant demonstrate experience coordinating and/or managing similar multi-site, collaborative research or evaluation initiatives?
- Does the applicant demonstrate experience in evaluating outcomes of longitudinal cohorts?

Funding Preferences

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

Diversity of populations represented in the network of state access programs (e.g., race/ethnicity, socioeconomic status, rural/urban residence)

Research Plan Length and Supporting Material

The Research Strategy Section of the Research Plan is limited to a maximum of 12 pages. Supporting material included as appendices may not exceed 10 PDF attachments, 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 $930,000 will be available to fund one Prevention Research Center for a 3-year project period. The average award is expected to be approximately $310,000 for year one. The year one ceiling is $310,000. Funding may vary and is subject to change.

Research Status

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

OMB/PRA

OMB/PRA is not expected to apply.

Award Administration

CDC Project Scientist/Scientific Collaborator will serve as consultants on this project, and will provide technical assistance, as requested, in developing and carrying out project activities. co-authoring manuscripts, and dissemination of results. CDC will not be directly engaged with participants nor will CDC receive identifiable information.

References

1. Yonkers, K.A., S. Vigod, and L.E. Ross, Diagnosis, pathophysiology, and management of mood disorders in pregnant and postpartum women. Obstet Gynecol, 2011. **117**(4): p. 961-77.
2. Deave, T., et al., The impact of maternal depression in pregnancy on early child development. BJOG, 2008. **115**(8): p. 1043-51.
3. Grote, N.K., et al., A meta-analysis of depression during pregnancy and the risk of preterm birth, low birth weight, and intrauterine growth restriction. Arch Gen Psychiatry, 2010. **67**(10): p. 1012-24.
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9. Byatt, N., et al., Perinatal depression care pathway for obstetric settings. Int Rev Psychiatry, 2019: p. 1-19.
10. Health Resources and Services Administration (HRSA), HRSA awards over $12M for maternal & child mental health programs. 2018, U.S. Department of Health & Human Services.

SIP 21-010: Engagement of Community Health Workers to Reduce Racial Discrimination and Improve Hypertension Management

Project Description

Hypertension (HTN) contributes to morbidity, disability, and mortality in the US, with disparities in incidence, prevalence, and self-management among people from racial and ethnic minority groups compared to non-Hispanic White persons. [1] These disparities in HTN are linked to social determinants of health (SDoH) ? the conditions in which we are born, live, learn, work, play, worship, and age that are shaped by structural policies and practices. Because of these linkages, disparities in HTN are health inequities.

Poor HTN-related outcomes are correlated with racial discrimination. Racial discrimination is both a SDoH itself as well as a major driving force of other SDoH that are correlated with poor HTN-related outcomes (e.g., people with lower incomes, without health insurance, experiencing

poverty, etc.). Additionally, there is a clear dose-response relationship between racial discrimination and psychological disorders. [2-3] Both psychosocial stressors and consistent discriminatory experiences increase risk for HTN, as well as reduce effort towards self-management activities. [4] To reduce racial inequities in HTN management, public health interventions are needed that address self-management practices, mental wellbeing, and discriminatory experiences and barriers. [5]

Community engagement is a key strategy of public health interventions that aim to reduce health inequities. It is the process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the well-being of those people. [6] For several decades, community health workers (CHWs) have been working to improve community engagement by building connections among communities, health care systems, and social services. [7] Although there is a lot of diversity among CHWs (e.g., job titles, roles, certification), a common feature among them is that they are frontline public health workers with a deep understanding of the community served. They are trusted members of the community and are expert at engaging community members, particularly the most vulnerable, such as those experiencing homelessness, older adults who are isolated, etc. While there is robust evidence of CHWs? impact on the prevention or management of various chronic diseases, there is a lack of evidence of effectiveness among interventions designed to improve HTN through CHWs? community-engaged strategies/approaches that aim to reduce racial discrimination.

Historically, processes and outcomes in CHW programs have been measured in many ways by many programs and initiatives, making it challenging to combine data from across programs to make a strong case for the value of what CHWs do, and the health and social outcomes they achieve. [8] The field also needs validated indicators contributing to the evidence base for CHWs as agents of change in community engagement interventions and documenting these efforts? direct and/or indirect pathways to improving HTN outcomes.

The purpose of this special interest project (SIP) is to build necessary research evidence and validate indicators for community engagement with CHWs in order to reduce racial discrimination and improve the wellbeing and management of HTN among racial and ethnic minority groups disproportionately affected by HTN.

Project Objectives and Outcomes

The objective of this project is to develop, implement, and evaluate a community engagement intervention that engages CHWs in core roles to improve HTN among racial and ethnic minority groups through the reduction of community-level racial discrimination and barriers.

Applicant will determine if a community engagement intervention with CHWs results in reducing community-level racial discrimination and barriers and subsequently increasing HTN management; CHW engagement; community member wellbeing; and psychological empowerment. Findings will help the division develop research-based interventions and strategies and validate evaluation indicators.

Public Health Priorities

Healthy People 2030 Objectives:

- Heart Disease and Stroke (HDS-01, HDS-04, HDS-05),
- Mental Health and Mental Disorders (MHMD-04),

- Health Communication (HC/HIT-04, HC/HIT-R01),
- Community (ECBP-D07), and
- Health Care Access and Quality (AHS-08)

CDC Health Impact-5 Initiative
This SIP:

- targets the public health impact focusing on ?Social Determinants of Health? and ?Changing the Context? from the CDC?s HI-5 Initiative (https://www.cdc.gov/policy/hst/hi5/index.html) through a community-wide approach.
- aligns with the following health conditions that the HI-5 interventions address: anxiety and depression, blood pressure, and cardiovascular disease.

NCCDPHP Chronic Disease Prevention and Health Promotion Domains

- Domain 1. Epidemiology and surveillance
- Domain 2. Environmental approaches that promote health and support and reinforce healthful behaviors
- Domain 4. Strategies to improve community-clinical linkages

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

Study Design and Methods
Applicant should describe the proposed theoretical framework, strategies, core CHW roles, activities, partnerships, and evaluation designs and methods that will be used to address the five Stages of Intervention (listed below) for this SIP. Considerations for each stage are provided.

Stage 1. 1) Conduct Community-level Assessment of Prevalence and Incidence of: a) HTN-Related Disparities b) HTN-Related Inequities and c) Racial Discriminatory Attitudes, Behaviors, Beliefs, and Barriers; and 2) Select Evidence-based Strategies

- How CHWs who work in the community of interest, and other key stakeholders, will be invited to participate in the planning process, and their specific role(s)
- How attitudes, behaviors, beliefs, and barriers in the community that reflect racial discrimination will be documented by CHWs to provide evidence of the existing problem
- How stakeholder engagement and problem documentation will inform the selection of evidence-based strategies that engage CHWs in core roles [9] to improve HTN management by addressing racial discriminatory attitudes, beliefs, behaviors, and barriers at the structural and individual levels
- How health equity-related approaches (e.g., popular education, [10] community-based participatory approach, racial equity, intersectionality) will be used to develop and implement the intervention

Stage 2. Conduct Community Members? Assessment of HTN Management, Mental Wellbeing, and Psychological Empowerment

- How community members who are at high risk for or have HTN in targeted communities will be recruited to assess their: management of HTN; access and utilization of health and

social services; healthy lifestyle behaviors; racial discriminatory experiences; racial discriminatory barriers; mental wellbeing; and psychological empowerment

Stage 3. Implement Intervention that Improves the Management of HTN by Reducing/Dismantling Racial Discriminatory Attitudes, Behaviors, and Beliefs at the Structural and Individual Levels through Community Engagement facilitated by CHWs

- How findings from Stage 1 will link the intervention targeting racial discrimination
- How CHWs will be engaged to implement effective evidence-based strategies and activities

Stage 4. Implement Intervention on Addressing Mental Wellness and Psychological Empowerment while Linking to Appropriate Resources and Services

- How CHWs will be engaged to use their core roles in strategies and activities that document and reduce the impact of racial discrimination on mental wellbeing and psychological empowerment
- How CHWs will be engaged to implement strategies and activities that bring awareness to community members of available and appropriate social and clinical services, linking community members to services, and following up to identify barriers encountered that prevented receipt of services that impact HTN

Stage 5. Process Evaluation and Outcome Evaluation

- How CHW common indicators [8] will be used and validated to evaluate engagement processes and outcomes
- How community-level discriminatory attitudes, behaviors, beliefs, and barriers will be reassessed
- How community members from Stage 2 will be reassessed for Stage 2 baseline outcomes

Target population
Applicant are expected to describe the population prioritized for this project concentrating on racially diverse communities disproportionally affected by HTN. Applicant must identify a community that includes a marginalized population (Black/African American, American Indian/Alaska Native, Native Hawaiian/Pacific Islander, Asian, Hispanic, and/or Immigrant populations). Participants contributing data to the intervention and evaluation portion of this project will be adults aged 18 years or older. Depending on proposed methods and strategies for each stage of the intervention, qualitative and quantitative data collection components must consider sample size needed to meet stated objectives.

Collaboration/Partnerships
Applicants are expected to describe collaboration/partnerships with groups that have a deep understanding of the community?s needs, history, context, energies, and resources to effectively assist in the planning and carrying out of strategies and activities to meet the objectives of this project. Collaborators/partners are expected to have expertise in community engagement, CHWs, understanding systemic racism, mental wellness and the related health system, and health promotion.

Recruitment Plan
Applicants are expected to describe plans to recruit evaluation participants as part of the study

design and methods section. Recruitment plans for each data collection component should consider precautions to ensure CHWs and participants reflect characteristics of the community they represent.

Annual Action Plan
Applicants are expected to provide a 12-month action plan using SMART goals and objectives to develop a progressive timeline for completion of activities. The annual plan should reflect evidence-based or promising activities for community engagement facilitated by CHWs, for example:

- Facilitating a community forum or town event on racism to conduct assessments to better understand targeted communities and to choose strategies that best fit the community?s needs, history, context, energies, and resources;
- Creating partnership/collaborations with existing community efforts; and/or
- Coordinating a coalition of leaders from diverse communities and from local media groups to discuss how they can work together to address the way people from different cultural and ethnic backgrounds address the health-related racial discrimination.

Evaluation Plan /Performance Measurement
Applicants are expected to describe an evaluation plan that meets SMART goals, including a logic model for the intervention, and propose strong study designs and methods for the baseline evaluation, process evaluation, and outcome evaluation. This includes testing and validating evaluation indicators.

Dissemination Plan
Applicants are expected to develop a dissemination plan that will, at minimum, publish and present the results of findings publicly, prepare a detailed report of findings for dissemination, and notify/educate appropriate health professionals, organizations, and/or professional societies about the results of the study. 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

Visit link https://www.cdc.gov/chronicdisease/programs-impact/nofo/index.htm for DMP Template and Guidance.

Translation Plan: Applicants are expected to develop a translation plan summarizing finding for audiences including health care providers and health systems and provide practical guidance to implement the strategies in practice using principles of implementation science. The translation plan needs to include lessons learned and promising practices that are effective, scalable, and sustainable after funding period.

Public Health Impact: This SIP will begin to develop research evidence and validated indicators for improving HTN by addressing racial inequity and discrimination in policies, structures, and processes through CHW engagement. Project findings may help to inform the development, implementation, and evaluation of effective, scalable community engagement interventions to address racial discrimination as a social determinant of health to management of chronic diseases, improve mental health, and access to services.

Special Eligibility and Responsiveness: None

- Additional Review Criteria

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

- Does the applicant propose a rigorous study design and identify appropriate potential data sources and adequate sample sizes to accomplish the required project objective?
- Does the applicant demonstrate evidence of successful experience with recruitment and retention of racial and ethnic minority groups disproportionately affected by HTN?
- Does the applicant provide evidence of project team experience and history developing, implementing, and evaluating community engagement interventions with CHWs; racial discrimination; and
- Does the applicant demonstrate successful experience working with collaborators/partners in addressing community-level and community-based interventions for HTN management, CHWs, community engagement, and/or racial **discrimination?**

Funding Preferences
None

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

Availability of Funds
It is anticipated that up to $400,000 is available to fund one Prevention Research Center(s) for a 2-year project period. The average award per recipient is expected to be approximately $150,000 for year one. The year one ceiling is $200,000. Funding may vary and is subject to change. Funding available includes direct and indirect costs.

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

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

Award Administration

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

dissemination of results. CDC staff may be co-authors on manuscripts. However, CDC staff will not have contact with human subjects or data collected from human subjects.

References

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Questions from Potential Applicants for NOFO DP21-004 "Health Promotion and Disease Prevention Research Centers PRC: 2021 SIPS" and CDC Responses

Pre-application Questions and Responses from January 14, 2021: Q1 to Q22

Q1. Do the award ceiling amounts include only direct costs or both direct and indirect costs?

Response to Q1. The ceiling amounts include both the direct and indirect costs for all SIPs.

Q2. Budget Preparation: Can you please confirm the anticipated start date for SIPS through this NOFO?

Response to Q2. The start date for the 2021 SIPs awarded is September 30, 2021.

Questions on Primary PI (PRC PI), CO-PI, SIP PI and Level of Effort:

Q3. Should LOI and grant submission, list the PI of the overall PRC or the PI of the SIP?

Q4. Would the primary PI be the PRC PI and then we also list the SIP PI as the PI of the

SIP? Or is there some other way that we need to list it?
Q5. The RFA states that the PRC PI of record, must be listed as the SIP PI on the SIP application. Additional PIs are permitted but would be referred to as a Co-PI. How much, if any % effort is required for the PRC PI of record?

Responses to Q3-Q5. The LOI should include the name of the primary PRC PI.
The application must be submitted under the primary PRC PI (Core PI of Record). The SIP PI may be listed as a Co-PI. The SIP project may be led by more than one PI whom would all be listed as Co-PIs if they are not the primary PRC PI. On the Notice of Award (NOA), recipients will only see the PRC Core PI, as the PI of record.
There is no requirement for the PRC PI of record to have a percent of effort listed for submission of a SIP proposal. Note: The SIP PI should be listed as a Co-Investigator with clarification in the budget justification noting that the SIP PI will lead the SIP Project.

Q6. The NOFO (pg 12) states "The PRC PI/PD of record, as listed on the Notice of Award, must be listed as the SIP PD/PI on the SIP application." Please clarify.

Response to Q6: The name, EIN and DUNS of the SIP application must correspond with the application under the Core application for DP19-001.

Q7. If the PRC PI will have 0% effort, and there will be a SIP Co-PI - do we need to include a multi-PI plan?

Response to Q7. There is no need for a multi-pi plan if the PRC PI will have no % effort on the SIP project.

Q8. What does "list both and clarify in justification" mean? Are you saying that the application is submitted listing both as primary PIs? or still the PRC PI as primary PI and the other PI as a Co-PI.

Response to Q8. List the primary PI (Core PI of record) as the application PI. The SIP PI should be listed as a Co-Investigator with clarification in the budget justification noting that the SIP PI will lead the SIP Project.

Q9. We have submitted an RO1 proposal to NIH already. We plan to revise the current proposal, minimizing the overlap. Would such a proposal be appropriate for this RFA at CDC?

Response to Q9. The federal requirements are that an applicant may not have the same project under review by multiple organizations at the same time. Applicants will need to evaluate if submitted proposals have sufficient difference between the proposals so there is no overlap.

SIP-002:
Q10. SIP-002: with the revision to the award ceiling, to be clear, you will EITHER award ONE grant for up to 600k total, OR 2 grants for up to 300k total. Does this put people applying with the 600k ceiling at a competitive disadvantage (because they have to more

comprehensive and/or be reviewed as clearly better than any TWO of the applications applied for with the 300k total - so if there is even one project of equal or better score than the 600k award single application, the 600k application would fail.) Does CDC have any recommendation about whether applicants should strongly consider one or the other of the award ceilings in anticipation of competing applications?

Response to Q10: The year one ceiling for SIP21-002 is $300,000. It is anticipated that approximately $600,000 is available to fund up to 2 PRCs for a 2-year project period. Funding may vary and is subject to change. **Funding available includes direct and indirect costs.** T**he year one award ceiling amount** for this SIP will be revised from $150,000 to $300,000 in the amended NOFO. Funding is anticipated for up to two awards. There is no advantage or disadvantage either way of applying.

Q11. SIP-002 makes it clear that there is the expectation of collaboration with public health partners - can you elaborate on A. what is considered a public health partner/agency (can it include groups that have members in the alcohol industry but who are doing public policy research and may have access to, for example, sales data or data about what retailers are doing), B. would an advisory board (for assistance with development and review of measures, findings, assistance with dissemination) suffice, would data made publicly available from public health organizations (like data from NIH) suffice, or need these be more active partnerships with these organizations as part of data collection/analysis efforts?

Response to Q11: The role of the partners and collaborators will vary depending on the project. It is expected that the research will be done with public health partners. Partner examples are listed in the NOFO but not explicitly defined. It would vary depending on the project proposed.

SIP 21-003:

Q12. Under "Project Objectives and Outcomes" (on page 59 of 106) it states, "The two projects will evaluate…." And then later, "Applicants can apply for both activities (A , B or A and B), but can only be funded for one project." However, nowhere else in the SIP description are the A, B activities noted nor is there a description of more than one project. Please clarify what is meant by these statements".

Response to Q12: The NOFO has been amended and language in SIP21-003 has been revised. See Section VIII "Other Information" , SIP21-003 in which the project description and project objectives have been edited to reflect one project.

Q13. For SIP 21-003, would an online, livestream version of an AAEBI be an acceptable alternative delivery mode if tested in the target population that is identified in the RFA?

Response to Q13: Yes, it would. It may be considered a barrier if someone has to only be available at a certain time to view the live stream.

Q14: SIP 003 - It states 50% of participants must be aged 18-64 (and part of 1 of 3 special populations). Does this mean participants over the age of 64 can be included (provided they

don't make up over half of the sample)?

Response to Q14: Yes, it does.

Q15: For SIP 21-003, regarding the additional eligibility requirements, are designers of AAEBIS and their virtual adaptations eligible to apply?

Response to Q15: Yes. The special eligibility and responsiveness requirements for SIP21-003 are listed on pages 62-63 of the NOFO, and state that the applicant must provide documentation that it has the "necessary license to use the relevant AAEBI". The applicant must also provide documentation showing "access to the proposed study populations for the entire study duration." Evidence should be demonstrated through letters of support or memorandums of agreements, documenting access to current AAEBI licensing agreement and access to the proposed study population for the duration of the research project.

SIP21-005

Q16: For SIP 21-005 are there specific criteria for what constitutes an all-payers claims database (ACPD)? Are all categories of ACPDs considered equal?

Response to Q16: No. SIP 21-005 does not provide specific criteria for what constitutes an "all-payers claims database. (APCD)" and does not specify that the study database be a specific category of APCD (e.g., existing; in implementation; strong interest; existing with voluntary submission, existing voluntary effort).

In development of proposals for SIP 21-005, key questions to consider are whether the proposed database will be able to successfully address the Project Objectives (listed on pages 72-73 of the NOFO) and whether the investigator will be able to meet the Specialty Eligibility and Responsiveness criteria (page 75 of the NOFO). On page 75 of the NOFO regarding "Access to All Payers Claims Data (APCD)" or equivalent, the applicant must provide documentation (e.g. a current letter of support or memorandum of agreement) that the applicant will have access to the critical datasets for the study." SIP 21-005 does include wording at several places to indicate some flexibility will be allowed in the definition of "all-payers claims database". Example 1: page 72 of SIP 21-005, indicates: "An increasing number of states maintain or have strong interest in developing an all-payer claims database (APCD), a large state database that includes medical and pharmacy claims reported directly by insurers to states, usually as part of a state mandate.[1] APCDs include data on the insurance claims from multiple sources in a state. Although the name is "all-payer", APCD coverage in a state may not be comprehensive, and the included data sources may vary by state. [Reference 2-3]". Example 2: Project Objectives on page 72-73 of NOFO, which uses the phrase "APCD (or equivalent)" at several places. See also at page 72: "To develop the census tract estimates, the recipient may combine information from the APCD with information from other data sources and use statistical modeling." That is, this project is not necessarily limited to "administrative billing claims" as the only data source. Other data sources may be appropriate to include in the proposal, such as information from electronic medical records.

Page 76 of the NOFO (references: item 2), shows a state map with the categories of

ACPDs. This is the All-Payer Claims Database Council. Interactive State Report Map. 2009-2020. University of New Hampshire, the All-Payer Claims Database Council, and the National Association of Health Data Organizations. Available at: https://www.apcdcouncil.org/state/map.

Q16a. SIP 21-005 - Do all four cancers have to be included in the project or just one or two of the cancer types listed?

Response to Q16a: Inclusion of all four cancers is not mandatory, but SIP 21-005 includes the phrase "at a minimum" that strongly suggests that proposals should include all four cancers --- breast, cervical (Pap/HPV), colorectal, and lung cancer.

Page 72 of the NOFO states: "At a minimum, the model report would be expected to include preventable cancers with US Preventive Services Task Force (USPSTF) recommendations for screening, such as breast, cervical (Pap/HPV), colorectal, and lung cancer. The report also could include other cancer screening topics to be determined by the recipient."

Q17: For SIP 21-005 regarding the APCD geographical coverage, should it include all payers or a subset of all state's payers?

Response to Q17: SIP 21-005 does not provide specific criteria for geographic coverage. See Study design and methods" on page 74 of SIP 21-005, which indicates proposals should "Describe the APCD (or equivalent) that the project proposes to use, including details on the geographic area covered and any Data Partners to add value to the APCD model surveillance report." See also on page 73 of SIP 21-005: "Objective 3: Statistical modeling to develop census tract (or other small area) estimates of cancer screening, using an APCD (or equivalent), and comparison of the APCD estimates with existing estimates from other data sources." The quality of the estimates for cancer screening from the "APCD (or equivalent)" depends on the extent that the study area has complete community-level coverage of cancer screening by all providers in the proposed study area.

SIP 21-008

Q18: SIP21-008 states that CDC is interested in prevention research in one or more topics and lists 4 topics. In addition to the standard review criteria used to evaluate research applications, the first criterion refers to the applicant's proposal of methods that are sufficient to assess how psychosocial characteristics are associated with mortality and patient-reported outcomes in adults with lupus. Is it intended that [research] topic 1 (Examining psychosocial characteristics) be one of the selected topics?

Response to Q18: The additional review criteria listed on page 92 for SIP21-008 ("Does the applicant propose methods sufficient to assess how psychosocial characteristics are associated with mortality and patient-reported outcomes in adults with lupus?") should refer specifically to the first proposed research topic (Examining psychosocial characteristics associated with mortality and/or patient-reported outcomes (e.g., physical functioning, general health, mental health, pain, and social functioning), including adverse childhood experiences, work loss, and other measures of socio-economic deprivation, self-reported experiences of racism).

For SIP21-008, “additional review criteria” will be amended as follows:

> *Specifically for research topic 1 (Examining psychosocial characteristics associated with mortality and/or patient-reported outcomes (e.g., physical functioning, general health, mental health, pain, and social functioning), including adverse childhood experiences, work loss, and other measures of socio-economic deprivation, self-reported experiences of racism), does the applicant propose methods sufficient to assess how psychosocial characteristics are associated with mortality and patient-reported outcomes in adults with lupus?*

SIP 21-009

Q19: For SIP 21-009 would proposing to develop and pilot an approach for examining the impact of Access Programs on individual-level factors be responsive? This would be in the context of other aims focused on identifying a data platform and describing outcomes of interest.

Response to Q19 . It is up to the applicant to propose what they think is feasible project given the available funding.

Q20. Is it ok to recruit or enroll individual providers as clinical sites or do we have to enroll an entire practice/organization?

Response to Q20 The SIP does not specify; it is up to the applicant’s discretion.

Other Questions from Potential Applicants sent to Research Contact listed in NOFO:

SIP21-001

Q21. The RFP states that the demonstration project should take place in school-based sites. In <name of state> and likely other states, OST programming utilizes a 'hybrid model' which means programs are at a school setting/building, a community site (e.g., YMCA or Boys and Girls Club) or at a childcare center. Is it acceptable for our proposal to include these other types of sites (beyond school sites)?

Response to Q21: We recognize that many communities have OST programs in a variety of settings, all of which may have strong relationships with local schools/the school district and play an important role in supporting child wellbeing. That said, the NOFO section about Target Population clearly states that “This SIP focuses on existing multipurpose OST programs offered to K-12 students on the school site". The applicant can consider including these other types of sites as part of the dissemination plan.

Q22. Can CDC speak to the 'scaling up' goals related to starting with a demonstration project and further disseminating OST strategies? Our project team would like more information on this to better understand how to best situate the demonstration project research design. How many students would be needed for a successful demonstration project (e.g, suggestions beyond statistical power)?

Response to Q22: The SIP mentions the possibility of scaling the approach in the section on Public Health Impact, which describes future implications should the intervention prove to be effective. The SIP is not asking for the applicant to scale up the intervention within the demonstration period.
In the Evaluation Plan/Performance Measurement section, applicants are asked to identify (and report on) both outcome measures and implementation indicators. Information that would be valuable in determining scalability includes information about program characteristics, program delivery characteristics (e.g., resources involved for implementation), and staff satisfaction with the intervention. That is, information that can help answer feasibility and fit questions, like, "what does a program need to have in place to do this"? To want to do this?
The plan should include both outcome and implementation indicators, potentially including.

- Participant demographics and how closely they reflect school or district demographics
- Program characteristics (e.g., staff: youth ratio, staff turnover, total enrollment/size, types of PA, staff training and experience level, participation in federal meal or snack programs etc.)
- Program delivery characteristics
- Resources involved in implementing an integrated approach
- Site level policy/practice adoption and implementation.
- Staff instructional practices and reported facilitators and barriers to implementation
- Youth outcomes, using validated measures, related to physical activity, self-efficacy to eat nutritious foods, program engagement and SEL opportunities.

Q23. In <name of state>, our public-school system includes 4-year-old kindergarten (and often times 3-year-old kindergarten). The RFP states K-12. Is it acceptable for our project team to include a site that serves 4k?

Response to Q23: We recognize that the NOFO does not explicitly define "K" in K-12. Our focus is on school-aged youth. The Participant Recruitment section of SIP21-001, states that "Applicants are expected to describe their plan to recruit school-based OST program(s) and school-aged program participants (e.g. e.g., elementary, middle, and/or high-school students). If the school-based OST program is of mixed ages in a way that makes it infeasible to solely focus on school-aged program participants, it's OK to include this site. Standalone 3-K or 4-K OST programs should **not** be recruited for participation as they will not include school-aged program participants

Q24. In the special eligibility requirements, we see the requirements of expertise, experience and publication track record. Is it acceptable to use an academic advisory board in addition to a small team of Co-Is to cover these eligibility requirements? If our project is based more in the nutrition/food access realm, is it required that we have an expert in physical activity on our project team?

Response to Q24: The applicant is **required** [See Special Eligibility/Responsiveness Criteria] to "provide demonstrated prior experience (i.e., reports, publication) conducting and/or evaluating interventions with K-12 school or OST settings". The "Additional Review Criteria" represent other application attributes that the review panel will consider as part of their overall deliberations: these are not eligibility requirements. The item you reference, "Evidence of project team expertise in physical activity" falls into this category of 'additional review criteria' (i.e., not a requirement).

Q25. Application Submission: Please advise what should be entered in ASSIST for box 4c. We entered our information into ASSIST per the guidance in the RFA and received an error message.

Response to Q25: Applicants may leave the box blank (4c). If the applicant has a Grant Tracking number from an earlier submission, that number goes in this box. The NOFO will be amended, and the instructions for the SF424 fields 4a., 4b., and 4c. will be corrected as follows:

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