

Centers for Disease Control and Prevention

NATIONAL CENTER FOR INJURY PREVENTION AND CONTROL

Rigorous Evaluation of Policies for their Impacts on the Primary Prevention of Multiple Forms of Violence

RFA-CE-24-034

12/01/2023

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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 Injury Prevention and Control

Notice of Funding Opportunity (NOFO) Title

Rigorous Evaluation of Policies for their Impacts on the Primary Prevention of Multiple Forms of Violence

Activity Code

Research Grant

Notice of Funding Opportunity Type

Reissue of CE-21-001

Agency Notice of Funding Opportunity Number

RFA-CE-24-034

Assistance Listings Number(s)

93.136

Category of Funding Activity

HL - Health

NOFO Purpose

The Centers for Disease Control and Prevention (CDC), National Center for Injury Prevention and Control (NCIPC) is soliciting research proposals to expand the evidence base for policy approaches for the primary prevention of multiple forms of violence experienced by children, youth, and adults. Policies that promote the social and economic well-being of populations and address community characteristics associated with violence have the potential to not only reduce rates of multiple forms of violence, including the five forms that are the focus of this

announcement: child abuse and neglect, youth violence, community violence, intimate partner violence (including teen dating violence), and sexual violence, but also impact health equity. To advance CDC's commitment to achieving health equity, the intent is to support applications that investigate policies that address social and structural conditions to reduce the disproportionate burden of violence experienced by some groups and communities. Applications should empirically examine the health equity implications of selected policies on population(s) disproportionately impacted by violence.

Amendment 1: Update the maximum total project funding per award over the project period.

Key Dates

Publication Date:

To receive notification of any changes to RFA-CE-24-034, 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:

11/01/2023

Although a letter of intent is not required, is not binding, and does not enter into the review of an application, the information that it contains assists NCIPC with planning for scientific and technical merit peer review.

Application Due Date:

12/01/2023

12/01/2023

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 11:59 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:
03/24/2024
This is an estimated date.

Secondary Review:
05/01/2024
This is an estimated date.

Estimated Start Date:
09/30/2024
This is an estimated date.

Expiration Date:
06/01/2024

Required Application Instructions

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

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

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

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

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

Executive Summary

The Centers for Disease Control and Prevention (CDC), National Center for Injury Prevention and Control (NCIPC) is soliciting research proposals to expand the evidence base for policy approaches for the primary prevention of multiple forms of violence experienced by children, youth, and adults. Policies that promote the social and economic well-being of populations and address community characteristics associated with violence have the potential to not only reduce rates of multiple forms of violence, including the five forms that are the focus of this announcement: child abuse and neglect, youth violence, community violence, intimate partner violence (including teen dating violence), and sexual violence, but also impact health equity. To advance CDC’s commitment to achieving health equity, the intent is to support applications that investigate policies that address social and structural conditions to reduce the disproportionate burden of violence experienced by some groups and communities. Applications should empirically examine the health equity implications of selected policies on population(s) disproportionately impacted by violence.

Mechanism of Support: The funding mechanism for this Notice of Funding Opportunity (NOFO) will be a cooperative agreement (U-01).

Funds Available and Anticipated Number of Awards: CDC/NCIPC intends to commit up to $700,000 in FY 2023 to fund up to two (2) applications. Awards issued under this NOFO are contingent upon availability of funds and a sufficient number of meritorious applications.

Budget and Project Period: The maximum award amount will be $350,000 per award for the first 12-month budget period. This includes both direct and indirect costs.

Applicants may request a project period of up to three (3) years. The maximum total project funding is **$1,050,000** (direct and indirect) per award, over the project period. The project period is expected to be 09/30/2024 to 09/29/2027. The total award will depend upon the project quality, duration, and cost proposed.

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. Eligibility Information 1. Eligible Applicants* are eligible to apply.

Eligible Project Directors/Principal Investigators (PDs/PIs): CDC does not make awards to individuals directly. 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. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply.

Applications in which the contact Eligible PD/PI meets NIH Early Stage Investigator (ESI) status, as verified via the NIH Determination of Investigator Status process, **and** whose application has a meritorious peer review score, may be considered for prioritization during the second level of review (see *Section V. Application Review Information 4. Review and Selection Process*). For the contact PD/PI Determination of Investigator Status:

Prior to application submission, PD/PIs are encouraged to verify and/or enter the date of their terminal research degree or the end date of their post-graduate clinical training in their eRA Commons Profile to ensure the correct identification. NIH systems will automatically calculate the status of each investigator and display it within their eRA Commons personal profile. The ESI status of the PD/PIs on any R01 or R01 equivalent application will be flagged at time of submission. Investigators should make sure their status is correctly marked in their profile. If your status is incorrect, please contact the NIH eRA Service Desk.

Number of PDs/PIs: An application may name more than one PD/PI; their names must appear on the face page of the application. However:

- One (1) principal investigator must be designated as the contact PD/PI for all correspondence related to the application.
- All PD/PIs must include their eRA Commons Identification in the Credential Field of the Senior/Key Person Profile Component of the SF-424 (R&R) Application Package.

- Institutions/organizations proposing multiple PDs/PIs must visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF-424 (R&R) Application Guide.

Number of Applications: Eligible applicant organizations may submit more than one application to this NOFO, provided that each application is scientifically distinct. However, applicant institutions can submit only one application with the same contact PD/PI. Only one application per contact PD/PI will be funded under this announcement. If two or more applications from the same contact PD/PI are received for this NOFO, the only application that will be submitted for review will be the last application received based on the document's time and date stamp in Grants.gov (https://www.grants.gov). The applicant must ensure that duplicate applications are withdrawn prior to the application review date.

Additionally, applicant institutions submitting applications with essentially the same proposed research to two or more CDC/ATSDR NOFOs will not be funded under more than one NOFO.

Application Type: NEW

Special Date(s)
A pre-application teleconference call will be conducted on October 30, 2023, to address questions from prospective applicants regarding NOFO RFA-CE-24-034. The call will begin at 2:00PM Eastern Standard Time (EST) and end at 3:00PM Eastern Standard Time (EST), or sooner if all questions are addressed. Questions and answers from the discussion will be included in an amended NOFO approximately 3 weeks after the call.

Participant Access Information:

- Call Date: October 30, 2023
- Call Start Time: 2:00PM Eastern Standard Time (EST)
- Call End Time: 3:00PM Eastern Standard Time (EST)
- Call Leader: **Candis Hunter, Scientific Program Official**
- Toll-Free Number: 1-866-600-6035
- Use Passcode 23198543# when prompted

Section I. Funding Opportunity Description

Statutory Authority
Section 301 (a) [42 U.S.C. 241(a)] of the Public Health Service Act, and Section 391 (a) [42 U.S.C. 280 b (a)] of the Public Health Service Act, as amended.

1. Background and Purpose

Background

Violence is a significant public health problem in the United States and disproportionately impacts some groups and communities (e.g., racial/ethnic minority persons, people with disabilities, tribal populations, sexual and gender minority persons) due in part to differences in social and structural conditions that affect health and safety. In 2020, approximately 1.4 million

non-fatal assault-related injuries occurred in the United States, and in 2021, and in 2021 an estimated 26,031 homicides occurred in the United States (CDC, 2023). Research shows high lifetime burden of violence in the United States: approximately 47.3% of women and 44.2% of men have experienced contact sexual violence, physical violence, and/or stalking by an intimate partner in their lifetime (Leemis et al., 2022). While violence affects all communities, some communities are at disproportionate risk for multiple forms of violence. For example, counties with the highest poverty rates, including high unemployment and mortgage foreclosure rates, have increased risks of firearm homicides and incidence of child abuse and neglect, respectively (Kegler et al., 2022; Frioux, Wood, Fakeye, Luan, Localio, & Rubin, 2014); individuals with disabilities experience higher rates of intimate partner violence, sexual violence, and child victimization compared to people without disabilities (e.g., Basile et al., 2016, Breiding & Amour, 2015, Jones et al., 2012); and American Indian/Alaska Native and non-Hispanic Black persons are more likely to experience four or more adverse childhood experiences (ACEs) compared to non-Hispanic White persons (Merrick et al., 2019) as well as higher rates of firearm homicide (Kegler et al., 2022).

Violence is linked to poor mental and physical health and has adverse impacts on educational attainment and employment (Arseneault at al., 2006; Felitti et al., 1998; Fowler et al., 2009; Gilbert et al., 2015; Hillis et al., 2016; Jennings et al., 2012; Menard et al., 2002; Metzler et al., 2016; Shonkoff et al., 2016). Violence can also erode the sense of safety and security essential to the well-being of families and disrupt social services (Mercy et al., 2002). The economic burden of violence is substantial, costing the United States billions of dollars each year in medical, criminal justice, and other costs (CDC, 2020; Peterson, et al., 2018a; Peterson et al., 2018b; Peterson et al., 2017).

Using a public health approach, NCIPC is committed to supporting research that rigorously evaluates prevention strategies to reduce the burden of violence and inequities across groups. The social and structural conditions in which people are born, grow, live, work and age can be shaped by the distribution of resources, which is influenced in part by policies. Social and structural determinants (e.g., concentrated poverty, structural racism, high rates of unemployment, limited access to high-quality education and /or affordable, high-quality child care) contribute to health inequities, including differences in health status seen across population groups (Solar & Irwin, 2010; Yearby, 2020). Multiple forms of violence share risk and protective factors that accumulate throughout childhood and adolescence and into adulthood (CDC, 2016; Wilkins et al., 2014). Despite the known interconnections among different forms of violence, and relevance of social and structural conditions that can contribute to violence, more research is needed to identify prevention strategies that address common underlying factors and have cross-cutting impacts on reducing multiple forms of violence.

Policy interventions that address social determinants of health have the potential to reach a large number of people and make substantial improvements to population health and reduce inequities (Frieden, 2010; Lorenc et al., 2013). Social and structural conditions and the risk for violence can be affected by federal, state, local, tribal, or organizational policies. Policy is defined as a law, regulation, procedure, administrative action, incentive, or voluntary practice of governments and other institutions (see http://www.cdc.gov/stltpublichealth/policy). Rather than policies that target characteristics of individuals or individual behaviors (e.g., social-emotional learning, increasing severity of punishment for alcohol offenses), social and structural policies focus on contextual or environmental factors that promote population health and well-being (e.g., laws

around where alcohol can be sold or advertised) as fundamental drivers of public health problems such as violence (Blankenship et al. 2006; Link & Phelan, 1995; Hoffman, 2009)). Rigorous policy evaluation gauges whether changes in outcomes of interest can be attributed to a policy and builds the evidence base for the effectiveness of policy approaches. Information on using evaluation to inform CDC's policy process can be found on the CDC website (https://www.cdc.gov/policy/analysis/process/docs/UsingEvaluationtoInformCDC'sPolicyProcess.pdf).

Purpose

The Centers for Disease Control and Prevention (CDC), National Center for Injury Prevention and Control (NCIPC) is soliciting research proposals to expand the evidence base for policy approaches for the primary prevention of multiple forms of violence experienced by children, youth, and adults. Policies that promote the social and economic well-being of populations and address community characteristics associated with violence have the potential to not only reduce rates of multiple forms of violence, including the five forms that are the focus of this announcement: child abuse and neglect, youth violence, community violence, intimate partner violence (including teen dating violence), and sexual violence, but also impact health equity. To advance CDC's commitment to achieving health equity, the intent is to support applications that investigate policies that address social and structural conditions to reduce the disproportionate burden of violence experienced by some groups and communities. Applications should empirically examine the health equity implications of selected policies on population(s) disproportionately impacted by violence.

Healthy People 2030 and other National Strategic Priorities

NCIPC is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2030."This funding announcement addresses the "Healthy People 2030" focus areas of injury and violence prevention. Specific Healthy People core objectives addressed in this NOFO include:

- Reduce intimate partner violence-IVP-D04
- Reduce contact sexual violence- IVP-D05
- Reduce homicides –IVP-09
- Reduce nonfatal physical assault injuries – IVP-10
- Reduce physical fighting among adolescents – IVP-11
- Reduce gun carrying by adolescents – IVP-12
- Reduce firearm-related deaths – IVP-13
- Reduce nonfatal firearm-related injuries – IVP-14
- Reduce child abuse and neglect deaths - IVP-15
- Reduce nonfatal child abuse and neglect - IVP-16
- Reduce adolescent sexual violence by anyone – IVP-17
- Reduce rate of minors and young adults committing violent crimes – AH-10
- Reduce the rate of adolescent and young adult victimization from violent crimes – AH-R11
- Reduce work-related assaults- OSH-05

This NOFO is aligned with CDC Injury Center's research priorities to evaluate the effectiveness of policies or community-level change strategies designed to enhance the economic and social environment to reduce multiple forms of violence and ACEs throughout the lifespan. For additional information about the CDC injury research priorities, see https://www.cdc.gov/injury/researchpriorities/index.html.

This funding announcement supports CDC CORE Health Equity Goals to embed health equity principles in the design, implementation, and evaluation of its research, data, surveillance, and intervention strategies. For more information about CDC CORE Health Equity Goals, see https://www.cdc.gov/healthequity/core/index.html.

Public Health Impact

The proposed research is expected to expand the evidence base for the effectiveness of federal, state, local, tribal, and/or organizational policies on the primary prevention of multiple forms of violence and the reduction in inequities in rates of violence across population groups. Policy approaches which address the social and structural conditions contributing to violence related inequities have the potential to reach many individuals and may have cross-cutting, population-level impacts on inequities in multiple forms of violence affecting children, youth, and adults. The primary prevention of violence and addressing inequities in violence risk are critical to the health and prosperity of the United States.

Relevant Work

NCIPC is the nation's leading public health authority on violence and injury prevention. CDC's approach involves three elements: a focus on prevention, a science-driven approach to identify risk and patterns, and multidisciplinary collaboration to address the problem and keep people safe, healthy, and productive. NCIPC's Division of Violence Prevention has prevention resources for action or technical packages to help states and communities take advantage of the best available evidence to prevent violence and ACEs (https://www.cdc.gov/violenceprevention/communicationresources/pub/technical-packages.html).

The strategies and approaches in the violence prevention resources or technical packages represent different levels of the social ecology with efforts intended to impact individual behaviors as well as the relationship, family, school, community, and societal factors that influence risk and protective factors for violence. NCIPC's research priorities (https://www.cdc.gov/injury/researchpriorities/index.html) and the Division of Violence (DVP) Prevention's Strategic Vision (https://www.cdc.gov/violenceprevention/pdf/Strategic_Vision.pdf) support the need for evaluating the effectiveness of prevention strategies that lack rigorous evaluation research. In addition, NCIPC's research priorities and DVP's Strategic Vision highlight the need to evaluate the efficacy and effectiveness of approaches across all levels of the social ecology and to expand evidence for population(s) that experience a disproportionate burden of violence.

Prior CDC NOFOs that have supported rigorous evaluations of policies for their impacts on multiple forms of violence include:

- RFA-CE-18-002 (*Evaluation of Policies for the Primary Prevention of Multiple Forms of Violence*) - https://www.grants.gov/web/grants/view-opportunity.html?oppId=297311

- RFA-CE-21-001 (*Rigorous Evaluation of Policies for their Impacts on the Primary Prevention of Multiple Forms of Violence*) - https://www.grants.gov/web/grants/view-opportunity.html?oppId=329352

Examples of previously-funded policy evaluation research and descriptions of violence prevention initiatives that address multiple forms of violence are available on NCIPC's website: http://www.cdc.gov/injury/ https://www.cdc.gov/violenceprevention/publichealthissue/fundedprograms/research-awards.html.

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2. Approach

The objective of this research funding opportunity is to support rigorous evaluations of previously or currently implemented federal, state, local, tribal and/or organizational policies that address social and/or structural conditions for their effectiveness in the primary prevention of multiple forms of violence and to reduce inequities in rates of violence affecting specific populations of children, youth, and adults in the United States. The proposed research must evaluate the impact of at least one selected policy on measures of at least two of these five forms of violence: child abuse and neglect, youth violence, community violence, intimate partner violence (including teen dating violence), and sexual violence. **Applications that do not propose to evaluate the impact of at least one selected policy on measures of at least two of these five forms of violence: child abuse and neglect, youth violence, community violence, intimate partner violence (including teen dating violence), and sexual violence do not meet the scientific intent of this NOFO. These applications will not be recommended for funding consideration during the NCIPC second level review (see *Section V. Application Review Information*).**

Applications that propose to examine only violence prevalence/incidence, inequities, cost-effectiveness, or other research questions without also measuring the policy impact on at least two different forms of violence do not meet the scientific intent of this NOFO. These applications will not be recommended for funding consideration during the NCIPC second level review (see *Section V. Application Review Information*).

Applications should empirically examine the health equity implications of selected policies on population(s) disproportionately impacted by violence. **Applications that do not propose to evaluate previously or currently implemented federal, state, local, tribal and/or organizational policies that address social and/or structural conditions for their effectiveness in the primary prevention of multiple forms of violence, as evidenced in the Research Strategy section of the application's research plan, will be considered nonresponsive and will not be forwarded for peer review**.

The results of the policy evaluations funded by this opportunity are expected to expand the existing evidence base for the primary prevention of violence and the reduction of inequities in rates of violence. To support comprehensive prevention efforts, policies that seek to reduce inequities (e.g., child development accounts, conditional cash transfer programs, child tax credit) are strongly encouraged. Policy approaches that have already been rigorously evaluated for their impact on violence outcomes must demonstrate how the proposed research would expand the

evidence base (e.g., additional violence outcomes or inequities, innovative methodology, multi-policy analysis) that aligns with the intent of this NOFO.

Policy Selection: The application must clearly describe the policy to be evaluated, how the policy impacts the social or structural conditions, what has been learned from previous research, and how the proposed rigorous evaluation will contribute to the evidence-base. In addition, it will be critical to describe methods for empirically studying populations disproportionately impacted by violence and the policy implications for improving equity. The proposed evaluation may build upon a previous non-rigorous evaluation in order to extend the evidence base for the policy's impact on multiple forms of violence. Applicants are encouraged to propose evaluations of previously or currently implemented policies with promising or undetermined evidence of impacts on multiple forms of violence and policies that are designed to reduce inequities. Promising policies include those with evidence for impacts on risk and protective factors common to multiple forms of violence but have not yet been rigorously evaluated for the primary prevention of violence outcomes (e.g., Basile et al., 2016; David-Ferdon et al., 2016; Fortson et al., 2016; Niolon et al., 2017). Policy strategies that have not been evaluated or have not been rigorously evaluated with an experimental or quasi-experimental design are considered to have undetermined effectiveness (Puddy & Wilkins, 2011**).**

This NOFO is not intended to support new policy implementation. The policy selected for evaluation must have been implemented prior to the proposed period of evaluation (though it may or may not be ongoing). **Applications proposing to rigorously evaluate policies that have not been enacted and implemented at the time the application is submitted, as evidenced by lack of inclusion of the dates of the enactment and implementation of the policy in the Research Strategy section of the application's research plan, will not be recommended for funding consideration during the NCIPC second level review (see *Section V. Application Review Information*).**

Applications proposing to engage in advocacy efforts designed to enact laws, regulations, administrative actions, or incentives will not be recommended for funding consideration during the NCIPC second level review (see *Section V. Application Review Information*). Additional information about anti-lobbying restrictions for CDC recipients is available at: https://www.cdc.gov/grants/additional-requirements/ar-12.html.

CDC's prevention resources for action or technical packages to prevent child abuse and neglect, youth violence, community violence, intimate partner violence, and sexual violence present examples of promising policies, many of which have demonstrated impacts on risk and protective factors for violence but have not yet been evaluated for their impact on the primary prevention of multiple violence outcomes (see: https://www.cdc.gov/violenceprevention/communicationresources/pub/technical-packages.html#technicalPackages and https://www.cdc.gov/violenceprevention/communityviolence/prevention.html). Risk factors include, but are not limited to, income inequality, neighborhood poverty, diminished economic or employment opportunities, and poor neighborhood cohesion. Protective factors include, but are not limited to, community connectedness, coordination of resources and services among community agencies, and economic security for individuals and families. For more information on shared risk and protective factors for violence see: https://www.cdc.gov/violenceprevention/pdf/connecting_the_dots-a.pdf. **Applicants may**

propose evaluations of previously or currently implemented policy strategies that do not yet have evidence of impact on risk and protective factors or on violence outcomes, or that have demonstrated impacts on risk and protective factors for violence but not on violence outcomes.

Examples of policies that fall into broad approaches aligned with CDC's prevention resources for action, or technical packages, are the following--- universal basic income programs, public assistance reform in childcare, policies that strengthen work-family supports, land use and zoning, and policies that improve economic and/or social opportunity for youth and young adults. This list is not exhaustive and is intended to serve as examples of policies. Applicants may propose to evaluate policies not listed. These policies have the potential to prevent multiple forms of violence, regardless of whether they were originally designed to prevent or reduce violence. Some policies have evidence that they prevent and reduce one form of violence; however, additional rigorous evaluation is needed to ascertain whether the policies have cross-cutting effectiveness in the primary prevention of multiple forms of violence. The intent of this NOFO is to support rigorous evaluation of policies that address social and structural conditions to prevent multiple forms of violence and reduce inequities in rates of violence across population subgroups.

Considerations for Policy Selection: Proposals should help expand and advance the understanding of policies that impact multiple forms of violence and that have not yet been rigorously evaluated. Recent investments in rigorous policy evaluation by CDC are advancing what is known about how policies can prevent violence (e.g., Assini-Meytin et al., 2023; Dalve et al., 2022; Edmonds et al., 2022; Klevens at al., 2017; Kovski et al., 2022; Letourneau et al., 2022; McGinty et al., 2022; Moe et al., 2020; Moe et al., 2022; Rostad et al., 2020(a); Rostad et al., 2020(b); also see: https://www.cdc.gov/violenceprevention/publichealthissue/fundedprograms/research-awards.html). Examples of policies and other interventions that have been or are currently being rigorously evaluated for preventing violence outcomes include, but are not limited to, Earned Income Tax Credit (EITC); Medicaid expansion; Permit to Purchase policies; Supplemental Nutrition Assistance Program; Women, Infants, and Children; Unemployment Insurance; bystander intervention strategies; business improvement districts; Crime Prevention through Environmental Design (CPTED) and greening. Applications proposing to evaluate such policies must describe how the proposed research is innovative and advances what is already known, including but not limited to a rigorous examination of health equity implications**.**

As a public health agency, CDC focuses on public health responses to violence prevention. While public health agencies may collaborate with law enforcement agencies to implement violence prevention strategies, **applications that propose to evaluate criminal justice policies or perform criminal justice research, as evidenced in the Research Strategy section of the application's research plan, will be considered nonresponsive and <u>will not</u> be forwarded for peer review.**

Examples of criminal justice policies and research include, but are not limited to, those that involve or affect the policies, programs, or practices of law enforcement and the criminal and civil courts (e.g., policing, arrest, trial, sentencing, incarceration, mandated intervention and treatment strategies).

Research funded under this announcement is intended to focus on evaluation of policy approaches for the primary prevention of multiple forms of violence. Public health strategies may be characterized in terms of three levels of prevention: primary prevention approaches, which aim to prevent violence before it occurs; secondary prevention approaches, which focus on the more immediate responses to violence, such as emergency services or treatment immediately following violence; and tertiary prevention approaches, which focus on long term care, such as rehabilitation/reintegration and mitigation of trauma and long-term disability associated with violence. Applicants should propose to evaluate the impact of a policy on the **primary prevention** of at least two of the five different forms of violence (child abuse and neglect, youth violence, community violence, intimate partner violence, and sexual violence) that are the focus of the funding announcement. Applicants may propose to examine secondary prevention effects as supplemental analyses, but the primary prevention of at least two forms of violence must be the focus of the evaluation**.**

Applications proposing to evaluate a policy for its impact only on the secondary prevention of violence (e.g., violence-related treatment in an emergency department; address/treat individuals after violence occurs) or tertiary prevention of violence (e.g., long-term care or rehabilitation) without also evaluating the policy's impact on the primary prevention of at least two forms of violence do not meet the scientific intent of this NOFO. These applications will not be recommended for funding consideration during the NCIPC second level review (see *Section V. Application Review Information*).

For the purposes of this NOFO, a distinction is made between community-based strategies and federal, state, local, tribal or organizational policy. **Community-based strategies** are implemented in community settings but address individual-, peer-, or other proximal relationship and family-level factors (e.g., conflict resolution skills, parenting skills, personal attitudes, knowledge about violence, bystander behaviors). **Federal, state, local, tribal or organizational policy strategies** typically seek to affect community or societal risk and protective factors, such as the climate or processes within the defined community (e.g., Dahlberg & Krug, 2002). Communities are defined as formal or informal organizations or geographical settings in which social relationships occur (e.g., neighborhoods, cities, states, etc.; Dahlberg & Krug, 2002). Communities may include any defined population with shared characteristics, risk/protective factors, and potential for exposure to the policy. Applicants are expected to evaluate policies that have the potential to affect social and structural conditions to reduce inequities in rates of violence across population groups. Activities that are instituted as the result of a policy and are being evaluated for their impact on individual-, peer- or family-factors (e.g., state policy requiring teacher training and proposal is evaluating changes in teachers' identification of dating violence) are evaluations of a community-based strategy. **Applications that propose to evaluate a community-based strategy that addresses change in individual-, peer-, or family-level factors rather than change in social or structural community conditions do not meet the scientific intent of this NOFO. These applications will not be recommended for funding consideration during the NCIPC second level review (see *Section V. Application Review Information*).**

Theory of Change: Applicants are expected to submit a narrative Theory of Change (TOC). The TOC describes the causal processes through which a previously or currently implemented federal, state, local, tribal or organizational policy is expected to result in change in at least two forms of violence and reductions in inequities in violence across population groups of interest

(e.g., Leviton et al., 2010; Lipsey, 1993; W. K. Kellogg Foundation, 2004). If more than one policy is to be evaluated, applicants should clearly explain whether the same TOC applies to all policies in relation to the specific outcomes that will be measured, and if not, applicants should provide specific TOCs for each policy evaluated. In their description of the TOC, applicants should:

- Describe the federal, state, local, tribal or organizational policy to be evaluated, including details about when the policy was enacted and implemented, and justification that the timeframe of the policy's implementation allows for rigorous evaluation of impact on multiple forms of violence.
- Describe the level of policy implementation and intended reach (e.g., population(s), geographic region) and level of evaluation that are appropriate. For example, a local policy should be evaluated at the local level only. A state policy could be evaluated at the state or local levels. A federal policy could be evaluated at national, state or local levels.
- If the policy has already been or is currently being evaluated for impacts on violence, the applicant should discuss the gaps being addressed in the proposed research and describe how the proposed work is innovative and advances what is already known.
- Demonstrate, through the TOC:
    - How the policy could affect rates of at least two of the five forms of violence that will be the focus of the evaluation (e.g., child abuse and neglect, youth violence, community violence, intimate partner violence, sexual violence),
    - How the proposed measures of violence outcomes (and potential risk and protective factors, if also proposed for measurement) would validly and reliably demonstrate the hypothesized changes, and
    - How the policy has the potential to reduce inequities in rates of violence across the population in the study.

Research Design: This funding opportunity is intended to support evaluations that are designed to detect whether any measured changes in multiple forms of violence can be attributed to the selected policy. To this end, applicants are expected to employ the most rigorous research design feasible to examine the impact of previously or currently implemented federal, state, local, tribal, or organizational policies on two or more forms of violence and inequities in rates of violence affecting specific populations in the United States. For the purpose of this announcement, rigorous evaluation designs include those that utilize experimental (i.e., randomized controlled trials) or quasi-experimental designs (e.g., comparative interrupted time series design, event study, stepped wedge, designs using propensity-score matching). Because a policy must have been previously or is currently implemented and may have been implemented outside the control of the investigators, applicants must propose to utilize an appropriately matched comparison group or other design that would maximize the ability to make causal inferences from the findings. Applicants are expected to provide a justification that the proposed design and data analysis plans (including, but not limited to, attention to statistical power and baseline measures) are appropriate for evaluating the impacts of the strategy. Applicants may propose mixed-methods approaches that include additional qualitative analyses to explore the equity implications of quantitative findings about how a policy impacted violence outcomes. For example, applicants with community partners may propose to conduct in-depth interviews or

focus groups to further explore how the selected policy may work to close or widen existing inequities in violence burden across population(s).

This announcement is not intended to support an evaluation of a larger multi-level strategy where the policy is only one of the strategies that will be evaluated. A multi-level strategy could be one that addresses community risk factors via policy change in combination with one or more components, such as programs that address individual- or family-level factors. Evaluation of a multi-level strategy makes it difficult to attribute effects to a single federal, state, local, or organizational policy (e.g., Matthay et al., 2021).

Innovation in methodology to evaluate policies is highly encouraged. If an applicant proposes to evaluate more than one policy, each policy must be evaluated for its impact on two or more of the four main forms of violence that are the focus of this NOFO and inequities across population(s) of interest. The two (or more) violence outcomes may be the same for each policy evaluation or they may be different. The applicant should describe how the evaluation design would disentangle impacts that might be due to each of the selected policies and allow conclusions to be drawn about how any observed changes in violence outcomes can be attributed to each policy. If proposing to compare the impact of multiple policies on multiple forms of violence, applicants must propose to utilize an appropriately matched comparison group or other design that would maximize the ability to make causal inferences from the findings for each policy separately and/or to capture interactive effects of a multi-policy environment. If an applicant proposes an additional qualitative component to the research study, the applicant must clearly articulate how the proposed work would complement quantitative evaluation findings and propose rigorous qualitative methods to address the specified research objectives.

Applicants are asked to indicate in the applications Abstract what NCIPC Research Priority (https://www.cdc.gov/injury/researchpriorities/index.html) the research proposal intends to address.

Data collection, acquisition, and analysis

Applicants must identify and describe appropriate data sources and provide evidence of their ability to acquire and/or collect data of sufficient quantity and quality to conduct the proposed research within the three-year project period. Applications should clearly describe and justify the proposed sampling methods, sample size, power estimates, and data collection methods for the primary outcome(s), at a minimum, and other proposed secondary outcomes and subgroup analyses. The timeline for data acquisition (requests for extant data and or primary data collection) must be specified. Numerous data sources can be used for the outcome data, including hospital and emergency department data, emergency medical services (EMS) data law enforcement data, self-report data, and other sources of data. In addition, administrative data from relevant agencies and survey data collected prior to or in the context of the evaluation are potential sources. Appropriate data sources will vary by the proposed research approach and outcome measures.

Protection of Human Subjects and Personally Identifiable Information

The Research Strategy section of the application is expected to clearly describe the type, source, access to, and protections of the data and human subjects participating in the study. Access to non-publicly available, previously collected data must be clearly described in the Research

Strategy and documented with a signed Data Sharing Agreement or Letter of Support. Access to publicly available, previously collected data must be clearly described in the Research Strategy.

Protection of previously collected data includes, but is not limited to, protection of personally identifiable information from loss and/or misuse.

The application is expected to identify each performance site that will be conducting human subjects research and include the FWA number for the applicant institution and each performance site. Research conducted with more than one institution will be expected to use a single Institutional Review Board (sIRB) to conduct the ethical review required by HHS regulations. See *Section IV. Application and Submission Information, 10 Funding Restrictions, Human Subjects* for details.

Objectives/Outcomes

The primary goal of this research is to support the rigorous evaluation of the impact of a previously or currently implemented federal, state, local, tribal and/or organizational policy **that addresses social or structural conditions** for their effectiveness in the primary prevention of multiple forms of violence and to reduce inequities in rates of violence affecting specific populations of children, youth, and adults in the United States. **Applicants should propose to evaluate the effectiveness of the selected policy on at least two of the five different forms of violence.** Violence outcomes include, but are not limited to:

- Child abuse and neglect

  Outcomes include physical abuse, sexual abuse, emotional abuse, and/or neglect of needs such as housing, food, clothing, education, and/or medical care among children

- Youth violence

  Outcomes include bullying, cyber-bullying, physical fighting, assault, weapon use, and homicide among youth ages 10-24 years

- Community violence

  Outcomes include violence-related behaviors, injuries, and deaths experienced within communities, including all forms of youth violence and other assaults or fights among groups and shootings in public places

- Intimate partner violence

  Outcomes include stalking, physical violence, psychological aggression (including coercive tactics), and sexual violence by a current or former intimate partner (i.e., spouse, boyfriend, girlfriend, dating partner or ongoing sexual partner)

- Sexual violence

  Outcomes include attempted or completed forced or alcohol/drug facilitated penetration of victims (i.e., rape), being made to penetrate someone else, non-physical pressured unwanted penetration (e.g., sexual coercion), unwanted sexual contact (e.g., fondling),

and non-contact unwanted sexual experiences (e.g., verbal harassment, voyeurism) by anyone. These examples are not an exhaustive list.

Applicants must also propose analyses to investigate the policy's impact on inequities in violence in population(s) that are disproportionately impacted by violence (e.g., racial/ethnic minority persons, people with disabilities, tribal populations, and sexual and gender minority persons). Equity-related outcomes include, but are not limited to:

- Aspects of policy implementation (e.g., exposure to, distribution, timing, and uptake) across population(s) disproportionately impacted by violence
- Stratified analyses examining the differential impacts of the policy approach across population(s) disproportionately impacted by violence
- Analyses investigating potential unintended consequences of the policy approach on population(s) disproportionately impacted by violence

Innovation is encouraged in the identification of data sources for measuring relevant policy characteristics, covariates, and violence outcomes included in the proposed evaluation. Selection of appropriate data sources will be informed by the selected policy approach(es), violence outcomes, and evaluation design. Applicants must identify the data sources that are appropriate for the measurement of violence outcomes that align with the level at which the policy is hypothesized to prevent violence (e.g., federal, state, local, tribal, or organizational).

The use of existing data sources may strengthen an evaluation plan if the data are of high quality, exist for the time period on which the policy evaluation is focused, and provide the ability to compare violence measures in a manner that aligns with the level at which the policy is enacted. Existing data sources may include administrative data from various governmental agencies and survey data collected through governmental and non-governmental research projects. Other potential sources of outcome data include, but are not limited to, violence-related mortality data; police records of community arrests for violent crimes including homicide, physical assault, physical assault of a partner, sexual assault, and rape; violent school incidents including bullying (e.g., aggregated to the school or system level); violent injury-related hospital or emergency department data (e.g., aggregated by community and disaggregated by age); violence-related intake rate for juvenile detention facilities; workplace violence-related insurance claims; hospital or emergency services data related to physical or sexual assault; and number of substantiated reports of child abuse and neglect. Alternatively, or in addition to existing data sources, applicants may propose to expand an existing dataset (e.g., baseline data or data for a limited number of geographic areas from a previous project), and/or initiate primary data collection for the purposes of this research project. Applicants should describe how any new data collection will be conducted and all proposed analyses completed within the project period. The proposed processes, partnerships, and resources required to accomplish data collection and management would need to be clearly detailed.

Supplemental analyses are not required but are encouraged. Any supplemental analyses undertaken would complement the primary prevention aims of the rigorous policy evaluation rather than be the research focus. Applicants may propose to investigate risk and protective factors that may be mediators or moderators of the association between the policy and multiple forms of violence. Mediating factors help explain the mechanism or process through which an exposure leads to an outcome. Moderating factors qualify the impact of an exposure on an outcome (Baron & Kenny, 1986). Applicants may propose to examine aspects of policy

implementation when feasible to inform future economic and comparative effectiveness evaluations of the policy strategy. Applicants are encouraged to be innovative in the identification of data sources that allow for supplemental analyses.

Target Population

This announcement is intended to expand the evidence base for the effectiveness of previously or currently implemented federal, state, local, tribal and/or organizational policies in preventing multiple forms of violence and to reduce inequities in rates of violence affecting specific populations of children, youth, or adults in the United States. The intent is to support investigations of policies that address social and structural conditions contributing to inequities in violence experienced by some groups and communities, including but not limited to racial/ethnic minority persons, people with disabilities, tribal populations, and sexual and gender minority persons. Individuals of all ages may be affected by the policies selected for rigorous evaluation through the funded research. Families, communities, and society-at large may benefit since policies have the potential to prevent multiple forms of violence and impact population-level health.

Collaboration/Partnerships

It is expected that for all applications, the applicant organization and contact PI will provide the scientific and technical leadership necessary to conduct the proposed research throughout the entire project period. It is expected that the proposed research work plan described in the Research Strategy section of the application and the SF-424 Research and Related Budget will demonstrate the applicant organization’s leadership and involvement throughout the entirety of the project period. The applicant organization cannot serve as a “pass through" to fund another entity to conduct the majority of the research or provide the scientific or technical leadership necessary to complete the proposed research project.

NCIPC recognizes the importance of community collaborations and community-centered research to complete the proposed work. Applicants are strongly encouraged to seek and include the meaningful involvement of communities, including state and/or local health departments, local governmental agencies and/or businesses, community-based organizations and communities disproportionately impacted by violence in all phases of the development and conduct of the proposed research, and in the translation and dissemination of research results. This can include strong partnerships with community members with lived experience who participate in all phases of the research (e.g., developing study methods, collecting data, interpreting results, and disseminating findings).

Partnerships between the applicant institution and outside entities may be necessary or advantageous to complete the proposed work.

The Research Strategy section of the application is expected to clearly describe the roles and responsibilities of each research team member individually and each participating entity. This includes describing how the partnership will allow the applicant to complete the proposed work.

In particular, the Research Strategy section must clearly describe all planned data sources and the partnerships that are in place to assure data access for all proposed analyses to be completed within the project period. The Research Strategy section of the application must clearly describe the nature and extent of the proposed partnership, including the roles and responsibilities of the Principal Investigator(s) and of the outside entities or partner agencies, the existing working

relationship, the nature and extent of the involvement to be provided by the applicant institution and outside entity, and how the partnership will ensure implementation of the proposed evaluation.

The roles and responsibilities described for each partnering entity must be substantiated with a signed Data Sharing Agreement, Letter or Support (LOS), or Memorandum of Understanding (MOU), and be included in the Letter of Support section of the application. The Data Sharing Agreement, Letter of Support (LOS), or Memorandum of Understanding (MOU) must describe the partner's commitment of resources, time, and personnel to the proposed research.

Applications that do not include a signed Data Sharing Agreement, Letter of Support, or Memorandum of Understanding from each partnering entity may not be recommended for funding (see *Section V. Application Review Information, 4 Review and Selection Process*).

Applications will be evaluated during peer review on:

- The extent to which the Research Strategy section clearly describes the roles and responsibilities of each partner involved in data collection and/or the effectiveness evaluation.
- The extent to which the Research Strategy clearly describes the existing working relationships between the applicant institution and all partner organizations.
- The extent to which the Research Strategy clearly describes the involvement of work each partner is willing to complete, including data access for all proposed analyses, if applicable, to ensure the success of the proposed research within the proposed project period.
- The extent to which the relationships and activities of the partnerships described in the Research Strategy, are documented by a signed Data Sharing Agreement, Letter of Support, or Memorandum of Understanding that clearly delineates the intent and capabilities of each partnership.

It is incumbent on the applicant to clearly describe each contribution of each partnership to the proposed research in the Research Strategy and document the intent and capabilities of each partnership with a signed Data Sharing Agreement, Letter of Support, or Memorandum of Understanding.

This NOFO seeks diversity among applicant institutions, research investigators, and partnering organizations to ensure researcher experience and research outcomes are applicable and beneficial to all segments of our population and social ecology. Applicant organizations from or conducting research in collaboration or partnership with institutions that have a demonstrated record of or historical commitment to serving underrepresented students, including racial and ethnic minorities, individuals from disadvantaged backgrounds and individuals with disabilities may be considered during the second level of review (see *Section V. Application Review Information, 4. Review and Selection Process*). Applicants may indicate this the Research Strategy of their application.

This NOFO encourages the inclusion of early-stage investigators as members of the SF-424 Senior/Key Personnel research team to help build experience and expertise in violence prevention research.

Applications should demonstrate that the research staff have the necessary skills and experience to ensure quality and timeliness of proposed activities. The participation of students and other researchers-in-training is encouraged. Applicants planning to incorporate training and/or mentorship roles into their research activities should describe the plans for the recruitment, training, and supervision of trainees/mentees and the ongoing quality assurance of their scientific products.

Evaluation/Performance Measurement

Most of the application should be dedicated to describing the policy approach proposed for rigorous evaluation, the evaluation plan, and measurement of key variables. In addition, the degree to which a funded project meets its goals will be aided by a detailed project workplan and timeline, accompanied by discussion of how unanticipated delays or adverse events of any kind will be handled. Applicants must also evaluate and document performance during each stage of the project. The application is expected to include a clear description of relevant performance measures, including process and outcome measures that are applicable to the project design. Potentially relevant performance measures include data collection and/or acquisition; database development, cleaning and management; data analyses and dissemination; staff recruitment and training; study participant recruitment and retention; partnership building and/or collaborations; and other activities required to conduct the evaluation. Regularly scheduled comparison of the project's progress to the performance measures would be expected in order to monitor and document whether the project is progressing as planned and in a timely manner, and whether the research activities are of high scientific quality.

Translation Plan

The application is expected to describe how results from the proposed research will be disseminated. Research findings should be disseminated through publications, including articles in peer reviewed scientific journals, and "Research Briefs" for diverse audiences (e.g., policy makers, public health programs, community groups), as well as presentations at professional conferences and in institutional and community-based venues. Applicants are strongly encouraged to work with communities disproportionately impacted by violence to design a dissemination plan.

Funded recipients will be required to attend at least one reverse site visit in Atlanta with CDC/NCIPC staff during the duration of performance to review their progress and findings and to discuss opportunities for widespread dissemination of their research achievements and lessons learned. This travel must be reflected in the grantee's budget in their application submitted in response to this NOFO.

3. Funding Strategy

N/A

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:
$2,100,000

Anticipated Number of Awards:
2
Awards issued under this NOFO are contingent on the availability of funds and submission of a sufficient number of meritorious applications.

Award Ceiling:
$350,000
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.
If you are successful and receive a Notice of Award, in accepting the award, you agree that the award and any activities thereunder are subject to all provisions of 45 CFR Part 75, currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:
00 (State governments)

01 (County governments)

02 (City or township governments)

04 (Special district governments)

05 (Independent school districts)

06 (Public and State controlled institutions of higher education)

07 (Native American tribal governments (Federally recognized))

08 (Public housing authorities/Indian housing authorities)

11 (Native American tribal organizations (other than Federally recognized tribal governments))

12 (Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education)

13 (Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education)

20 (Private institutions of higher education)

22 (For profit organizations other than small businesses)

23 (Small businesses)

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

99 (Unrestricted (i.e., open to any type of entity above), subject to any clarification in text field entitled "Additional Information on Eligibility")

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

Nonprofits (Other than Institutions of Higher Education):

Nonprofits (Other than Institutions of Higher Education)

Other:

Faith-based or Community-based Organizations

Regional Organizations

Bona Fide Agents: A Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If applying as a bona fide agent of a state or local government, a legal, binding agreement from the state or local government as documentation of the status is required. Attach with "Other Attachment Forms."

Federally Funded Research and Development Centers (FFRDCs): FFRDCs are operated, managed, and/or administered by a university or consortium of universities, other not-for-profit or nonprofit organization, or an industrial firm, as an autonomous organization or as an identifiable separate operating unit of a parent organization. A FFRDC meets some special long-term research or development need which cannot be met as effectively by an agency's existing in-house or contractor resources. FFRDC's enable agencies to use private sector resources to accomplish tasks that are integral to the mission and operation of the sponsoring agency. For more information on FFRDCs, go to https://gov.ecfr.io/cgi-bin/searchECFR.

2. Foreign Organizations

Foreign Organizations **are not** eligible to apply.

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

For this announcement, applicants may not include collaborators or consultants from foreign institutions. All applicable federal laws and policies apply.

3. Additional Information on Eligibility

Please see Section III. Eligibility Information

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

It is the applicant's responsibility to ensure that the application meets all responsiveness criteria listed in this section. Applications that do not meet all of the following Responsiveness criteria will be considered nonresponsive and will not be forwarded for peer review. There must be an overall match between the proposed research objectives as described in the applicant's abstract and the research objectives of this announcement as described in Section I under the heading, "Objectives/Outcomes." The following criteria are required for responsiveness:

1. Application must propose to evaluate the impact of a **previously or currently implemented federal, state, local, tribal and/or organizational policy that addresses social and/or structural conditions for their effectiveness in the primary prevention of multiple forms of violence**.
    - **Applications that do not propose to evaluate previously or currently implemented federal, state, local, tribal and/or organizational policies that address social and/or structural conditions for their effectiveness in the primary prevention of multiple forms of violence, as evidenced in the Research Strategy section of the application's research plan, will be considered nonresponsive and will not be forwarded for peer review.**
2. The application does not propose to evaluate approaches that are solely under the influence or control of the criminal justice system.
    - **Applications that propose to focus on criminal justice policies or perform criminal justice research, as evidenced in the Research Strategy section of the application's research plan, will be considered nonresponsive and will not be forwarded for peer review.**

3. Applicants must include required documentation that meets the following PI/Co-PI requirements.
    a. **The SF-424 Biographical Sketch for the PI or Co-Investigator(s) must include documentation of expertise in the area of substance use, substance use disorders, or overdose that is reflected in the application's research strategy section.** The knowledge, experience, and expertise necessary to conduct this research and achieve proposed objectives must be documented with at least one first-authored, peer-reviewed publication as defined by the NIH National Library of Medicine in the relevant area of substance use, substance use disorders, or overdose, or by serving as a principal investigator on a research grant in substance use, substance use disorders, or overdose. Experience requirements may be demonstrated through the combined experiences of a Principal and Co-Principal Investigator (if applicable). The citation of the relevant publication(s) or research experience must be clearly identified (by bold text or highlight) in the appropriate SF 424 Biographical Sketch.
    b. **Applications that do not include documentation to meet this PI/co-PI requirement will be considered non-responsive and <u>will not</u> be forwarded for peer review.**

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 Unique Entity Identifier (UEI) number in order to begin each of the following registrations.

PLEASE NOTE: Effective April 4, 2022, applicants must have a Unique Entity Identifier (UEI) at the time of application submission. The UEI replaced the Data Universal Numbering System (DUNS) and is generated as part of SAM.gov registration. Current SAM.gov registrants have already been assigned their UEI and can view it in SAM.gov and Grants.gov. Additional information is available on the GSA website, SAM.gov, and Grants.gov-Finding the UEI.

- (Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: NCAGE Tool / Products / NCS Help Center (nato.int).
- System for Award Management (SAM) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, SAM.gov.
- Grants.gov
- eRA Commons

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

All Senior/Key Personnel (including Program Directors/Principal Investigators (PD/PIs) must

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

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

All applicant organizations **must obtain** a Unique Entity Identifier (UEI) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The UEI number is a twelve-digit number assigned by SAM.gov. An AOR should be consulted to determine the appropriate number. If the organization does not have a UEI number, an AOR should register through SAM.gov. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a UEI number.

Additionally, 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.gov 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 SAM.gov and the SAM.gov Knowledge Base.

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

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.

Eligible applicant organizations may submit more than one application to this NOFO, provided that each application is scientifically distinct. However, applicant institutions can submit only one application with the same contact PD/PI. Only one application per contact PD/PI will be funded under this announcement. If two or more applications from the same contact PD/PI are received for this NOFO, the only application that will be submitted for review will be the last application received based on the document's time and date stamp in Grants.gov (http://www.grants.gov). The applicant must ensure that duplicate applications are withdrawn prior to the application review date.

Additionally, applicant institutions submitting applications with essentially the same proposed research to two or more CDC/ATSDR NOFOs will not be funded under more than one NOFO. Institutions submitting multiple applications with essentially the same proposed research to this announcement will not be funded more than once.

Section IV. Application and Submission Information

1. Address to Request Application Package

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

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

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

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

2. Content and Form of Application Submission

Applicants must use FORMS-G application packages for due dates on or before January 24, 2023 and must use FORMS-H application packages for due dates on or after January 25, 2023.

Application guides for FORMS-G and FORMS-H application packages are posted to the How to Apply - Application Guide page.

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

Please use the form and instructions for SF 424 (R&R) FORMS-H for applications due on or after January 25, 2023.

3. Letter of Intent

Due Date for Letter Of Intent 11/01/2023

11/01/2023
Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows NCIPC staff to estimate the potential review workload and plan the review. By the date listed above and in *Part 1. Overview Information*, prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed research
- Description (one-two paragraphs) of the proposed research including a description of the proposed research objectives
- Name, address, and telephone number of the contact PD/PI
- Name(s) of all other Senior/Key Personnel

- Name(s) of participating institutions
- Number and title of this funding opportunity

The letter of intent should be sent electronically to:

Aisha Wilkes
Scientific Review Official
Extramural Research Program Operations
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention (CDC)
Email: bki6@cdc.gov

4. Required and Optional Components

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

5. PHS 398 Research Plan Component

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

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

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

Other Research Plan Sections

5. **Vertebrate Animals**
6. **Select Agent Research**

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

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

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

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

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

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

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

Applicants must use FORMS-G application packages for due dates on or before January 24, 2023 and must use FORMS-H application packages for due dates on or after January 25, 2023.

Application guides for FORMS-G and FORMS-H application packages are posted to the How to Apply - Application Guide page.

Please use the form and instructions for SF424 (R&R) FORMS-H for applications due on or after January 25, 2023.

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.

The three 'not publicly available' publications will count towards the ten PDF documents allowed in the appendix. The five appendices described below for the Research Plan supporting materials will also count towards the 10 PDF documents allowed in the appendix. The total number of pages in the appendix may not exceed 25 pages.

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 25 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 at .How to Apply - Application Guide.

Applicants must use FORMS-G application packages for due date on or before January 24, 2023 and must use FORMS-H application packages for due dates on or after January 25, 2023.

Application guides for FORMS-G and FORMS-H application packages are posted to the How to Apply - Application Guide page.

Please use the form and instructions for SF424 (R&R) FORMS-H for applications due on or after January 25, 2023.

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 12/01/2023

12/01/2023
Electronically submitted applications must be submitted no later than 11:59 p.m., ET, on the listed application due date.

10. Funding Restrictions

Expanded Authority:

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

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

Public Health Data:

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

Data Management Plan:

Fulfilling the data-sharing requirement must be documented in a Data Management Plan (DMP) that is developed during the project planning phase prior to the initiation of generating or collecting public health data and must be included in the Resource Sharing Plan(s) section of the PHS398 Research Plan Component of the application.

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

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

Human Subjects:

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

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

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

11. Other Submission Requirements and Information

Risk Assessment Questionnaire Requirement

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

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

When uploading supporting documentation for the Risk Questionnaire into this application package, clearly label the documents for easy identification of the type of documentation. For example, a copy of Procurement policy submitted in response to the questionnaire may be

labeled using the following format: Risk Questionnaire Supporting Documents _ Procurement Policy.

Duplication of Efforts

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

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

Application Submission

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

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

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

Important reminders:

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

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

The applicant organization must ensure that the UEI 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 (https://www.cdc.gov/about/organization/mission.htm), all applications submitted to the CDC in support of public health research are evaluated for scientific and technical merit through the CDC peer review system.

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

Scored Review Criteria
Reviewers will consider each of the review criteria below in the determination of scientific merit and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

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

- To what extent will the successful completion of the proposed research advance current knowledge of the effectiveness of policy strategies for the primary prevention of multiple forms of violence (including child abuse and neglect, youth violence, community violence, intimate partner violence, and sexual violence) and reduce social and/or structural inequities?
- To what extent will the proposed project inform strategies to decrease health inequities and build the evidence-base for policies that address the social and structural conditions that impact rates of violence?
- To what extent will the proposed project address the needs of specific populations and communities experiencing disproportionate burden of violence?

Does the application propose to evaluate the following approaches that will not be considered for funding at the second level of review?

- Applications that propose to examine only violence prevalence/incidence, inequities, cost-effectiveness, or other research questions without also measuring the policy impact on at least two different forms of violence.
- Applications proposing to rigorously evaluate policies that have not been enacted and implemented at the time the application is submitted.
- Applications proposing to engage in advocacy efforts designed to enact laws, regulations, administrative actions.
- Applications proposing to evaluate a policy for its impact only on the secondary prevention of violence (e.g., violence-related treatment in an emergency department; address/treat individuals after violence occurs) or tertiary prevention of violence (e.g., long-term care or rehabilitation) without also evaluating the policy's impact on the primary prevention of at least two forms of violence.
- Applications that propose to evaluate a community-based strategy that addresses change in individual-, peer-, or family-level factors rather than change in social or structural community conditions.
- Applications that do not propose to evaluate the impact of at least one selected policy on measures of at least two of these five forms of violence: child abuse and neglect, youth violence, community violence, intimate partner violence (including teen dating violence), and sexual violence.

Investigator(s)

Are the PD/PIs, collaborators, and other researchers well suited to the project? Have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

- To what extent do the PI and/or Co-I or other members of the research team have prior experience conducting etiological research or evaluation of prevention strategies for each of the forms of violence being examined by the proposed research?
- To what extent do the PI and/or Co-I and other members of the research team have prior and diverse experience and knowledge in conducting rigorous evaluations of policy strategies consistent with that proposed in the evaluation?

- To what extent is there evidence of past collaboration between the proposed research team and external partners to support the success of the proposed research and demonstrated expertise working with populations disproportionately impacted by violence?
- To what extent does the application demonstrate that the research team has the skills, experience, and sufficiently devoted time to complete the proposed activities within the 3-year project period?
- To what extent does the application incorporate first time and early-stage investigators as members of the Senior/Key Personnel research team to help build experience and expertise in violence prevention research?

Innovation

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

- To what extent does the proposed research demonstrate a reasonable potential of meeting the purpose and Research Objectives of this NOFO?
- If the policy has been previously evaluated for primary violence-related outcomes, does the proposed research address a particular gap in the literature (i.e., outcomes that have not previously been addressed) such that it will not be duplicative of previous or current research?
- Is the Theory of Change explicitly identified and clearly explained in the application, including details on the enactment and implementation of the policy at the federal, state, local, tribal, or organizational levels?
- To what extent is the proposed policy evaluation of two or more forms of violence well-supported by the Theory of Change?
- To what extent is the proposed research innovative (e.g., propose use of novel data sources and/or methodology to address research questions) and offer reasonable potential of meeting the purpose and Research Objectives of this NOFO?

Approach

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

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

- To what extent does the proposed research describe an appropriate and rigorous evaluation strategy for assessing effectiveness of the proposed policy for the primary

prevention of multiple forms of violence (i.e., child abuse and neglect, youth violence, community violence, intimate partner violence, sexual violence) through an experimental or quasi-experimental design?

- To what extent does the proposed policy for evaluation have sufficient theoretical support to suggest that it may be effective in reducing rates of victimization and/or perpetration of multiple forms of violence (i.e., child abuse and neglect, youth violence, community violence, intimate partner violence, and/or sexual violence)?
- Is the description of the level of policy implementation (i.e. national, state, local, tribal, and/or organizational) appropriately matched to the proposed evaluation and available data?
- Is the timeframe of the policy's implementation and degree to which it has been enacted appropriate for rigorous evaluation of impact on multiple forms of violence?
- To what extent does the applicant propose an evaluation design that will determine the effectiveness of the proposed policy on two or more violence outcomes?
- To what extent does the study assess the health equity implications of selected policy or policies on population(s) disproportionately impacted by violence (e.g., racial/ethnic minority persons, people with disabilities, tribal populations, sexual and gender minority persons)?
- Does the applicant appropriately anticipate, conceptualize, and measure the intended and potential unintended outcomes and the effects of threats to internal and external validity relevant to the study proposed?
- Does the applicant demonstrate the ability to access the necessary data for the evaluation of the proposed policy? Are these data appropriate for documenting the effects of the policy and likely to show the expected changes in the time available?
- Are the violence outcomes, risk or protective factors, and proposed moderators or mediators to be examined clearly described, validly measured, and appropriate according to the Theory of Change (TOC)?
- Does the applicant propose a study with adequate sample size to test the proposed hypotheses, if applicable? To what extent does the application specify how recruitment strategies will be sufficient to achieve the projected sample size, if applicable? Are appropriate strategies proposed to assure sample retention and adequate statistical power over time, if applicable?
- If an applicant is proposing to evaluate multiple policies, to what extent does the applicant propose to evaluate each policy for its independent impact on reducing rates of two or more violence outcomes (i.e., child abuse and neglect, youth violence, community violence, intimate partner violence, and/or sexual violence)?

Environment

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

- Does the applicant provide a description of the duties, percentage-of-time commitments, and responsibilities of project personnel including clear lines of authority and supervisory

capacity over the behavioral, administrative, data management, and statistical aspects of the research?

- To what extent are the relationships and activities of the partnerships necessary to the project, specifically the intent and capabilities of each partnership, documented by a signed Data Sharing Agreement, Letter of Support, or Memorandum of Understanding?
- 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?
- If the application involves collaborations or partnerships, to what extent does the research strategy provide evidence of collaboration or partnership throughout the application?
- To what extent does application propose to work collaboratively and in equitable partnership with communities disproportionately impacted by violence *in selecting policies for evaluation?*
- To what extent does the application describe working collaboratively and in equitable partnership with communities disproportionately impacted by violence *to create a plan for disseminating findings?*

2. Additional Review Criteria

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

Protections for Human Subjects

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

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

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

Inclusion of Women, Minorities, and Children

When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of

children. For additional information on review of the Inclusion section, please refer to the policy on the Inclusion of Women and Racial and Ethnic Minorities in Research (https://www.cdc.gov/women/research/index.htm) 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.

Applications from Foreign Organizations
N/A

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

New additional requirement: CDC requires recipients for projects and programs that involve data collection or generation of data with federal funds to develop and submit a Data Management

Plan (DMP) for each collection of public health data.

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

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

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

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

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

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

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

Budget and Period of Support
Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research. The applicant can obtain budget preparation guidance for completing a detailed justified budget on the CDC website, at the following Internet address: https://www.cdc.gov/grants/applying/application-resources.html. Following this guidance will also facilitate the review and approval of the budget request of applications selected for award.

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 only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review), 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.

1. Consideration for meritorious applications that contribute to a diverse mix of approaches in proposed research to rigorously evaluate effectiveness of policies for reducing drug use and overdose as evidenced by the Research Strategy section of the application's research plan.
2. Consideration for applications that examine the impact of policies on inequities in population(s) disproportionately impacted by violence.
3. Consideration for meritorious applications that contribute to a geographic balance of proposed projects, as evidenced by the congressional district of the applicant organization, to broaden the distribution of awards.
4. Consideration for applicant organizations from or conducting research in collaboration or partnership with institutions that have a demonstrated record of or historical commitment

to serving underrepresented students, including racial and ethnic minorities, individuals from disadvantaged backgrounds and individuals with disabilities. Applicants may indicate this in the Research Strategy section of their application.

5. Consideration of research conducted in collaboration/ partnership with the community, as evidenced by the Letters of Support section of the application. This may include state and/or local health departments, local governmental agencies and/or businesses, and community-based organizations.
6. Consideration for applications including signed Data Sharing Agreements, Letters of Support, or Memorandum of Understanding for each partnership described in the Research Strategy section of the application clearly describing the support to be provided to conduct the proposed research.
7. Consideration for applications in which the contact Eligible PD/PI meets NIH Early Stage Investigator (ESI) status, as verified by the NIH Determination of Investigator Status process.

Exclusion from funding consideration, regardless of the scientific or technical merit of the proposed project, as evidenced by the Research Strategy section of the application's research plan:

- Applications that propose to examine only violence prevalence/incidence, inequities, cost-effectiveness, or other research questions without also measuring the policy impact on at least two different forms of violence.
- Applications proposing to rigorously evaluate policies that have not been enacted and implemented at the time the application is submitted.
- Applications proposing to engage in advocacy efforts designed to enact laws, regulations, administrative actions.
- Applications proposing to evaluate a policy for its impact only on the secondary prevention of violence (e.g., violence-related treatment in an emergency department; address/treat individuals after violence occurs) or tertiary prevention of violence (e.g., long-term care or rehabilitation) without also evaluating the policy's impact on the primary prevention of at least two forms of violence.
- Applications that propose to evaluate a community-based strategy that addresses change in individual-, peer-, or family-level factors rather than change in social or structural community conditions.
- Applications that do not propose to evaluate the impact of at least one selected policy on measures of at least two of these five forms of violence: child abuse and neglect, youth violence, community violence, intimate partner violence (including teen dating violence), and sexual violence.

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 UEI, SAM Registration, and Transparency Act requirements. If the application is under consideration for funding, HHS/CDC will request "just-in-time" information from the applicant as described in the HHS Grants Policy Statement (https://www.hhs.gov/sites/default/files/grants/grants/policies-

regulations/hhsgps107.pdf).

PLEASE NOTE: Effective April 4, 2022, applicants must have a Unique Entity Identifier (UEI) at the time of application submission. The UEI is generated as part of SAM.gov registration. Current SAM.gov registrants have already been assigned their UEI and can view it in SAM.gov and Grants.gov. Additional information is available on the GSA website, SAM.gov, and Grants.gov-Finding the UEI.

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

If you receive an award, you must follow all applicable nondiscrimination laws. You agree to this when you register in SAM.gov. You must also submit an Assurance of Compliance (HHS-690). To learn more, see the HHS Office for Civil Rights website.

AR-1: Human Subjects Requirements

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

AR-3: Animal Subjects Requirements

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-17: Peer and Technical Reviews of Final Reports of Health Studies – ATSDR

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

AR-22: Research Integrity

AR-24: Health Insurance Portability and Accountability Act Requirements

AR-25: Data Management and Access

AR-26: National Historic Preservation Act of 1966

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

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

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

AR-31: Research Definition

AR-32: Appropriations Act, General Provisions

AR-33: United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern

AR-36: Certificates of Confidentiality

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

Organization Specific ARs:
AR-8: Public Health System Reporting Requirements
AR-15: Proof of Non-profit Status
AR 23: Compliance with 45 C.F.R. Part 87

The full text of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards, 45 CFR 75, can be found at: https://www.ecfr.gov/cgi-bin/text-idx?node=pt45.1.75

To view brief descriptions of relevant CDC requirements visit:
https://www.cdc.gov/grants/additionalrequirements/index.html

Additional CDC Award Requirements

The following Additional Requirements, some of which emphasize and expand upon those above, will be required for all recipients funded under this NOFO.

All award recipients under this NOFO will be required to complete pre-registration of the research project(s) using publicly available platforms or ClinicalTrials.gov as applicable, consistent with the National Science Foundation's open science principles. The platform for intended pre-registration should be described in the Research Plan at the time of application.

All award recipients under this NOFO will be required to make data publicly available within 30 months of completing data collection, this includes making source code available to the public, and ensuring open access to research publications consistent with the National Science Foundation's open science principle.

The CDC will follow established implementation schedules and procedures for making grant awards under this NOFO in accordance with HHS and CDC Policy for Grant Program Administration and CDC Policy for Peer Review of Research and Scientific Programs to ensure that these awards support ideologically and politically unbiased research projects.

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: https://www.plainlanguage.gov/.

Employee Whistleblower Rights and Protections Employee Whistleblower Rights and Protections: All recipients of an award under this NOFO will be subject to a term and condition that applies the requirements set out in 41 U.S.C. § 4712, "Enhancement of contractor protection from reprisal for disclosure of certain information" and 48 Code of Federal Regulations (CFR) section 3.9 to the award, which includes a requirement that recipients and subrecipients inform employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. § 4712. For more information see: https://oig.hhs.gov/fraud/whistleblower/.

Copyright Interests Provision This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. Pursuant to applicable grant regulations and CDC's Public Access Policy, Recipient agrees to submit into the National Institutes of Health (NIH) Manuscript Submission (NIHMS) system an electronic version of the final, peer-reviewed manuscript of any such work developed under this award upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. Also at the time of submission, Recipient and/or the Recipient's submitting author must specify the date the final manuscript will be publicly accessible through

PubMed Central (PMC). Recipient and/or Recipient's submitting author must also post the manuscript through PMC within twelve (12) months of the publisher's official date of final publication; however, the author is strongly encouraged to make the subject manuscript available as soon as possible. The recipient must obtain prior approval from the CDC for any exception to this provision.

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

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

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

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

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

Non-compliance with this Policy may result in suspension, limitation, restriction or termination of USG-funding, or loss of future USG funding opportunities for the non-

compliant USG-funded research project and of USG-funds for other life sciences research at the institution, consistent with existing regulations and policies governing USG-funded research, and may subject the institution to other potential penalties under applicable laws and regulations.

Data Management Plan(s)

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

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

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

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

4. Cooperative Agreement Terms and Conditions

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Part 75, and other HHS, PHS, and CDC grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial CDC programmatic involvement with the recipients is anticipated during the performance of the activities. Under the cooperative agreement, the HHS/CDC purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly

with the award recipients in a partnership role; CDC Project Officers are not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the recipients for the project as a whole, although specific tasks and activities may be shared among the recipients and HHS/CDC as defined below.

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

- Complying with the responsibilities for the Extramural Investigators as described in the Policy on Public Health Research and Nonresearch Data Management and Access https://www.cdc.gov/grants/additional-requirements/ar-25.html
- Designing and conducting research to address the described research objectives of this cooperative agreement.
- Undertaking any data collection solely to meet the applicant's research needs. Retaining custody of and exercising primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and CDC policies.
- Partnering effectively with any outside entities expected to participate in the proposed research. Such partnerships should be well-defined and documented by letters of support or Memoranda of Understanding detailing the nature and extent of involvement.
- Establishing goals and objectives that are realistic, measurable, and time- oriented for all phases of the project.
- Developing a research protocol involving human subjects for Institutional Review Board (IRB) review and approval by all cooperating institutions participating in the research project, including CDC if applicable.
- Assuring that IRB approvals are current for research involving human subjects for all participating sites.
- Considering suggestions from CDC on the design and implementation of research and the analysis, interpretation, and dissemination of study findings.
- Developing, designing, and piloting research protocols and instruments; recruiting participants; and conducting appropriate data management procedures.
- Analyzing data and disseminating findings in peer-reviewed journals and presentations at scientific conferences and other meetings.
- Requesting consultation and technical assistance from CDC, as needed. Considering suggestions from CDC on the design and implementation of research and the analysis, interpretation, and dissemination of study findings.
- Collaborating with CDC in translating and disseminating research findings.
- Participating in an initial kick-off meeting with CDC by phone or in Atlanta.
- Participating in one reverse site visit with CDC in Atlanta on an annual basis to review the project's progress with CDC scientists and staff.
- Developing and implementing a plan for sharing research resources and data with other collaborating partners, the agency, the public, and scientific community. The PI is responsible for developing and updating a data management plan that identifies the level of data access and plans for data sharing.

CDC staff will work collaboratively with the PIs/PDs, as described below:

- Assist 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 https://www.cdc.gov/grants/additional-requirements/ar-25.html
- Provide suggestions for refining research protocols (e.g., for sampling, recruitment, assessment, and data management).
- Participate in the analysis, interpretation, and dissemination of study findings (may include co-authorship of peer-reviewed manuscripts and scientific presentations). CDC will not initiate or direct data collection, own or manage the data, require the use of a specific methodological approach, or disseminate findings as part of an official CDC report. Monitoring and evaluating the scientific and operational accomplishments of the project through conference calls, site visits, and review of technical reports. Provide ongoing suggestions as needed to ensure project success.
- Collaborate with the grant recipient to ensure human subjects assurances are in place as needed.
- As necessary, collaborate in the development or amendment of a research protocol involving human subjects for Institutional Review Board (IRB) review by all collaborating institutions, including CDC if applicable.
- Obtain IRB approvals as required by CDC when CDC is engaged in research involving human subjects. If applicable, the CDC IRB will review the protocol initially and on an annual basis until the project is complete.
- Monitor and evaluate the scientific and operational accomplishments of the project through conference calls, site visits, and review of technical reports.
- Provide ongoing suggestions as needed to ensure project success.
- The agency Scientific Program Official (SPO) and CIO program director will be responsible for the normal scientific and programmatic stewardship of the award. The SPO will be named in the award notice.

Areas of Joint Responsibility include:

- The grant recipient and CDC will agree upon and establish a schedule for regular phone calls to discuss ongoing research project progress.

The recipient agrees that upon award, their application and the summary of reviewers' comments will be shared with the CDC staff, who will provide support as described above. Recipient organization will retain custody of and have primary rights to the information, data, and software developed under this award, subject to U.S. Government rights of access consistent with current HHS/CDC policies.

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).

Technical Review and Summary Statement Response Requirements
Recipients will be required to electronically submit a response to the peer reviewers' comments and/or concerns, as documented in the Summary Statement, within 30 days of the notification of their initial award. Recipients will also be required to electronically submit a response to any progress concerns or areas for improvement noted on their annual Technical Review within the time period specified in the annual award continuation notice.

Annual Report Requirements
Recipients will be required to electronically submit an Annual Report within 90 to 120 days before the end of the current budget period.

A. Submission of Reports

The Recipient Organization must submit:

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 (**Reporting | Grants | CDC) is required and must be submitted to the Payment Management System accessed through the FFR navigation link in eRA Commons or directly through PMS **within 90 days after the budget period ends.**
3. **A final progress report**, invention statement, equipment/inventory report, and the final FFR are required **90 days after the end of the period of performance.**

B. Content of Reports

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

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

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

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

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

    - How will the scientific findings be translated into public health practice or inform public health policy?
    - How will the project improve or effect the translation of research findings into public health practice or inform policy?

- How will the research findings help promote or accelerate the dissemination, implementation, or diffusion of improvements in public health programs or practices?
- How will the findings advance or guide future research efforts or related activities?

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

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

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

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

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

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

- Update of Data Management Plan: The DMP is considered a living document that will require updates throughout the lifecycle of the project. Investigators should

include any updates to the project's data collection such as changes to initial data collection plan, challenges with data collection, and recent data collected. Applicants should update their DMP to reflect progress or issues with planned data collection and submit as required for each reporting period.

- Additional Reporting Requirements:

- The Annual Report should include:
  - A description of the completion status of each Specific Aim and/or research objective or milestone for the budget period.
  - A complete list of the publications planned or completed to date - including status (e.g., published [include reference], in review, under development).
  - A description of any changes made in the use of human subjects or IRB approval status.

A description of any changes made in the Data Management Plan. Award recipients funded under this NOFO will be required to use NCIPC's Data Management Plan Template, OMB NO: 0920-1301 to make revisions to the DMP as required during the award's project period

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 budget period. 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.

Additional resources on the Payment Management System (PMS) can be found at https://pms.psc.gov.

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 period of performance. 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).

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

is independent of Grants.gov and may be done at any time.

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

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

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

6. Termination

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

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

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

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

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

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

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

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

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

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

2) Quarterly Report: The recipient must quarterly submit a report on the amount of foreign taxes charged by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant. This report shall be submitted no later than two weeks following the end of each quarter: April 15, July 15, October 15 and January 15.

3) Terms: For purposes of this clause:

“Commodity” means any material, article, supplies, goods, or equipment;

“Foreign government” includes any foreign government entity;

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

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

5) Contents of Reports: The reports must contain:

a. recipient name;

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

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

d. reporting period;

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

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

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

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

Section VII. Agency Contacts

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

Application Submission Contacts

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

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

Scientific/Research Contact

Candis Hunter, PhD, MSPH, REHS/RS
Scientific Program Official
Extramural Research Program Operations
National Center for Injury Prevention and Control (NCIPC)
Email: NCIPC_ERPO@cdc.gov

Peer Review Contact

Aisha Wilkes

Scientific Review Official
Extramural Research Program Operations
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention (CDC)
Email: bki6@cdc.gov

Financial/Grant Management Contact(s)

Angie Willard
Grants Management Officer
CDC Office of Grants Services
Telephone: 770-488-2863
Email: aen4@cdc.gov

Manal Ali
Grants Management Officer
CDC Office of Grants Services
Telephone: 770-488-2706
Email: hf08@cdc.gov

Section VIII. Other Information

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

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

Authority and Regulations

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

Successful recipients may be permitted expanded authorities in the administration of this award as provided for in the Code of Federal Regulations, Title 2, Subtitle A, Chapter II, Part 200, Subpart D, §200.308(d)(4). Specific authorities granted will be detailed in the official Notice of Award document.

Application Submission Process

Applications must be successfully submitted and complete all validation actions prior to 11:59 PM U.S. Eastern Time of the application due date for this NOFO. Applicants are encouraged to submit the application in ASSIST three (3) business days before the stated due date to provide sufficient time to correct any errors. If post-submission errors are identified during the validation process, the errors must be corrected and the application must be re-submitted in ASSIST prior to 11:59 PM U.S. Eastern Time of the application due date. 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.

Applicants who encounter problems when submitting their applications must attempt to resolve them by contacting the NIH eRA Service desk and the Grants.gov Contact Center. See Section IV. Application and Submission Information, 9 Submission Dates & Times for contact

information.

General Information
All applications submitted for this NOFO must be responsive to the specific requirements and objectives of this NOFO and must be submitted as a new application through www.grants.gov.

All applicants are advised to carefully review the responsiveness requirements and instructions on how applicants must document responsiveness in *Section III. Eligibility Information 5. Responsiveness* of this NOFO