

Centers for Disease Control and Prevention

NATIONAL CENTER FOR INJURY PREVENTION AND CONTROL

Rigorously Evaluating Primary Prevention Strategies for Intimate Partner Violence and Sexual Violence

RFA-CE-25-031

12/02/2024

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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

Rigorously Evaluating Primary Prevention Strategies for Intimate Partner Violence and Sexual Violence

Activity Code

Applications in response to this Notice of Funding Opportunity (NOFO) will be funded using the U01 activity code for a research cooperative agreement.

Notice of Funding Opportunity Type

New

Agency Notice of Funding Opportunity Number

RFA-CE-25-031

Assistance Listings Number(s)

93.136

Category of Funding Activity

HL - Health

NOFO Purpose

This NOFO seeks proposals aimed at building the evidence base for the primary prevention of intimate partner violence, including teen dating violence, and/or sexual violence. This funding opportunity will support rigorous outcome evaluations of promising practice-based prevention

approaches that are currently being implemented by state, tribal, and/or local organizations that address intimate partner violence and/or sexual violence. This includes, but is not limited to, organizations that receive funding under CDC's Rape Prevention and Education Program and CDC's DELTA AHEAD program. By promising practice-based approaches we mean programs, policies, or practices that can demonstrate the following:

- Evidence of implementation in the field for a minimum of two years and
- Collection of prior data demonstrating one or more of the following:
    - Positive implementation-related outcomes (e.g., data demonstrating reach, fidelity, availability, and/or acceptability of the approach) ***and/or***
    - Collection of outcome monitoring data before and after implementing the approach that demonstrate positive changes in intimate partner violence, sexual violence, or established risk and protective factors for intimate partner violence and/or sexual violence

Research on promising practice-based prevention approaches will evaluate the effectiveness of approaches that already have traction within the field but have not been rigorously evaluated. As a result, this research can build the evidence for approaches that are feasible to implement by practitioners and acceptable to communities. Research aimed at building evidence at the community- or societal-levels is of particular interest. In addition, research aimed at building evidence for populations and communities that experience inequitable risk for intimate partner violence and/or sexual violence is of particular interest, including approaches that address social determinants of health.

This NOFO intends to cover a four (4) year period of performance to complete a full-scale rigorous evaluation. This research can address critical research gaps and expand the evidence base for effective programs, policies, and practices that prevent intimate partner violence and/or sexual violence. The availability of a broader range of evidence-based approaches will help address risk and protective factors across all levels of the social ecology. Implementing comprehensive prevention approaches can help move the field towards reductions in intimate partner violence and sexual violence at the population level (DeGue et al., 2012).

There are two CDC Injury Center Notice of Funding Opportunities (NOFOs) that address intimate partner violence and sexual violence:

- "*Formative Research of Community-led Primary Prevention Approaches to Address Elevated Risk of Intimate Partner Violence & Sexual Violence"* (**CE-25-032**) and
- "*Rigorously Evaluating Primary Prevention Strategies for Intimate Partner Violence and Sexual Violence*" (**CE-25-031**).

The purpose of NOFO **CE-25-032** is to build the evidence base for the primary prevention of intimate partner violence (IPV) and/or sexual violence (SV) in communities experiencing elevated risk of IPV and/or SV. **NOFO CE-25-032 seeks proposals to support formative research of prevention approaches that address inequities in IPV and/or SV**. Formative research is the process that occurs *prior* to a large-scale rigorous evaluation. Therefore, this funding opportunity intends to build the pipeline of prevention approaches for communities experiencing elevated risk of IPV and/or SV that will be ready for future rigorous evaluations.

The purpose of this NOFO **CE-25-031** is to rigorously evaluate primary prevention approaches for IPV and/SV that can **demonstrate existing capacity and readiness for a full-scale rigorous outcome evaluation**. Specifically, NOFO **CE-25-031** funds rigorous outcome evaluations of promising primary prevention approaches that are currently being implemented by state, tribal, and/or local organizations that address IPV and/or SV. Unlike NOFO **CE-25-032**, the proposed full-scale rigorous evaluation of the selected approach is not required to focus on populations at elevated risk of IPV and/or SV, though it is strongly encouraged. Research on prevention approaches being implemented at the community- or societal-level are also strongly encouraged, including approaches that address social determinants of health.

Key Dates

Publication Date:
To receive notification of any changes to RFA-CE-25-031, 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:
11/01/2024

Application Due Date:
12/02/2024
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:
03/04/2025
This date is an estimate.

Secondary Review:

05/05/2025
This date is an estimate.

Estimated Start Date:
09/30/2025

Expiration Date:
02/03/2025

Required Application Instructions

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

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

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

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

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

Executive Summary

Purpose

This NOFO seeks proposals to support research aimed at building the evidence base for the primary prevention of intimate partner violence, including teen dating violence, and/or sexual violence. This funding opportunity will support rigorous outcome evaluations of promising practice-based prevention approaches that are currently being implemented that address intimate partner violence and/or sexual violence. By promising practice-based approaches, we mean programs, policies, or practices that can demonstrate the following:

- Evidence of implementation in the field for a minimum of two years and
- Collection of prior data demonstrating one or more of the following:
    - Positive implementation-related outcomes (e.g., data demonstrating reach, fidelity, availability, and/or acceptability of the approach) ***and/or***
    - Collection of outcome monitoring data before and after implementing the approach that demonstrate positive changes in intimate partner violence, sexual violence, or established risk and protective factors for intimate partner violence and/or sexual violence.

Research to evaluate promising practice-based prevention approaches that are perceived to be effective but have not been rigorously evaluated will increase the evidence for intimate partner violence and/or sexual violence prevention approaches that have traction within the field and are, therefore, feasible to implement by practitioners and acceptable to communities. Research aimed at building evidence at the community- or societal-levels is of particular interest. In addition,

research aimed at building evidence for populations and communities that experience inequitable risk for intimate partner violence and sexual violence is of particular interest under this announcement, including research on approaches that address social determinants of health.

This funding opportunity intends to cover a four (4) year period of performance to complete a full-scale rigorous evaluation that can address critical research gaps and expand the evidence base for effective programs, policies, and practices that prevent intimate partner violence and sexual violence. The availability of a broader range of evidence-based approaches will help move the field towards implementation of effective, multilevel approaches that address risk and protective factors across all levels of the social ecology and hold promise for reducing intimate partner violence and sexual violence at the population level (DeGue et al., 2012).

Mechanism of Support

The funding mechanism for this Notice of Funding Opportunity (NOFO) will be a [Research Cooperative Agreement (U-01)].

Funds Available and Anticipated Number of Awards
CDC/NCIPC intends to commit up to $1,500,000 in FY 2025 to fund up to three (3) applications. Awards issued under this NOFO are contingent upon availability of funds and a sufficient number of meritorious applications.

Budget and Period of Performance
The maximum award amount will be $500,000 per award for the first 12-month budget period. This includes both direct and indirect costs. An applicant may request a period of performance of up to four years. The maximum total project funding amount is $2,000,000 (including both direct and indirect costs) over the expected period of performance, with a maximum of $500,000 per award per year. The period of performance for this award is expected to run from 9/30/2025 to 9/29/2029.

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)

The CDC does not award individuals directly. Individuals possessing the necessary skills, knowledge, and resources to conduct proposed research should collaborate with their institutions to submit a support application. Underrepresented racial and ethnic groups, as well as individuals with disabilities, are especially encouraged to apply.

For applications where the contact PD/PI qualifies as an NIH Early Stage Investigator (ESI), as confirmed through the NIH Investigator Status determination process, and has a commendable peer review score, prioritization may occur during the second level of review (refer to Section V. Application Review Information 4. Review and Selection Process). Regarding the determination of Investigator Status for the contact PD/PI:

Before submitting an application, PD/PIs should confirm or update the date of their terminal research degree or the conclusion of their post-graduate clinical training in their eRA Commons Profile for accurate identification. NIH systems will automatically determine each investigator's status and reflect it in their eRA Commons personal profile. The ESI status for PD/PIs on any R01 or equivalent application will be indicated at submission. Investigators must ensure their status is accurately represented in their profile. If the status is incorrect, they should reach out to 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
Organizations eligible to apply may submit multiple applications to this NOFO, as long as each is scientifically distinct. However, institutions may only submit one application per contact PD/PI. Only one application for each contact PD/PI will receive funding under this announcement. If multiple applications from the same contact PD/PI are submitted, only the most recent one, based on the time and date stamp at www.grants.gov, will be considered for review. It is the applicant's responsibility to withdraw any duplicate applications before the review date.

Institutions that submit applications proposing essentially the same research to two or more CDC/ATSDR NOFOs will not receive funding for more than one.

Application Type
NEW

Special Date(s)
A pre-application teleconference call will be conducted on 10/24/2024 to address questions from prospective applicants regarding NOFO RFA-CE-25-025. The call will begin at 2:00pm Eastern Standard Time (EST) and end at 2:50 pm Eastern Standard Time (EST), or sooner if all questions are addressed. Questions and answers from the discussion will be included in a supplemental document on grants.gov approximately 2-3 weeks after the call.

Participant Access Information:

- Call Date: October 24, 2024
- Call Start Time: 2:00pm Eastern Standard Time (EST)
- Call End Time: 2:50pm Eastern Standard Time (EST)

- Call Leader: Joyce Dieterly, Scientific Program Official
- Webinar Link: https://cdc.zoomgov.com/j/1614969586?pwd=bnIwWEo3WVJrUVNXYmlGQStGTU5FUT09
- Webinar ID: 161 496 9586
- Passcode: 6S9^ixQ!
- Call-In Numbers:
    - +1 646 828 7666 US (New York)
    - +1 646 964 1167 US (US Spanish Line)
    - +1 669 254 5252 US (San Jose)
    - +1 551 285 1373 US (New Jersey)
    - +1 415 449 4000 US (US Spanish Line)
    - +1 669 216 1590 US (San Jose)
- Dial-In Passcode: 19123744

Application Materials
See Section IV.1 for application materials.

Hearing Impaired
Telecommunications for the hearing impaired are available at: TTY: 1-888-232-6348.

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

Intimate partner violence and sexual violence are significant public health problems that affect millions of people in the United States (Leemis et al., 2022; Basile et al., 2022). Intimate partner violence (including teen dating violence) is committed by a current or former intimate partner. A partner may be a spouse, boyfriend/girlfriend, dating partner, or ongoing sexual partner. (Breiding et al., 2015). Intimate partner violence includes:

- physical violence
- sexual violence
- stalking
- psychological aggression including coercive tactics.

Almost 1 in 2 women (47.3% or 59 million) and more than 2 in 5 men (44.2% or 52.1 million) in the United States reported any contact sexual violence, physical violence, and/or stalking victimization by an intimate partner at some point in their lifetime (Leemis et al., 2022).

Sexual violence can be perpetrated by anyone. For example, perpetrators of sexual violence may include, but not be limited to friends/acquaintances, current or former intimate partners, family members, strangers, or persons in positions of power, authority, or trust. The CDC defines sexual

violence as a sexual act that is committed or attempted by another person without freely given consent of the victim or against someone who is unable to consent or refuse (Basile, Smith, Breiding, Black, & Mahendra, 2014), including:

- forced or alcohol/drug facilitated penetration of the victim (i.e., rape)
- making a victim penetrate a perpetrator or someone else (i.e., being made to penetrate)
- non-physically pressured unwanted penetration (i.e., sexual coercion)
- unwanted sexual touching that does not involve penetration (e.g., groping, grabbing sexual body parts)
- unwanted non-contact acts of a sexual nature (e.g., verbal sexual harassment, tech-facilitated sexual violence)
- sex trafficking (i.e., the recruitment, harboring, transportation, provision, obtaining, patronizing, or soliciting of a person for the purpose of a commercial sex act)

Approximately 33.5 million women and 4.5 million men in the United States report a lifetime experience of completed or attempted rape (Basile et al., 2022). In addition, 54.3% of women (approximately 67.8 million) and 30.7% of men (approximately 36.2 million) have experienced some form of contact sexual violence in their lifetime (Basile et al., 2022).

The field has made progress in building the evidence-base for intimate partner violence and sexual violence prevention. However, many important gaps remain. To help address the gap between what is known and what is being implemented in communities, the CDC's Division of Violence Prevention has developed Prevention Resources for Action that outline the best available evidence. These resources include examples of programs, policies, and practices with impact on risk and protective factors for intimate partner violence and sexual violence. Most effective programs are implemented specifically in school-based settings. Limited evidence exists for approaches that can be implemented in community settings, such as businesses or workplaces, youth-serving organizations, or faith-based institutions. Research is needed to expand the evidence base for prevention approaches that can be implemented in diverse settings.

Furthermore, many of the evidence-based approaches focus on teaching healthy relationship skills and encouraging bystander behavior to address individual and relationship factors. The field needs research on policies, programs, and practices that can be implemented at the community- and societal-level of the social-ecological model. For example, limited evidence exists for effective policy-based prevention approaches for intimate partner violence and sexual violence.

Challenges exist in the uptake, implementation, and sustainability of primary prevention approaches and underscore the importance of research that evaluates practice-based approaches (Smith et al., 2018). These challenges are especially salient in communities and among populations that experience inequitable risk for violence. Additional research is needed to identify effective trauma-informed and culturally responsive prevention approaches, including approaches that address social and structural determinants of health. 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. Examples of social and structural determinants of health are concentrated poverty, structural racism, high rates of unemployment, limited access to high-quality education, and affordable, high-quality childcare. These contribute to health inequities, including differences in health status seen across population groups (Solar &

Irwin, 2010; Yearby, 2020). Building evidence for these types of approaches can support efforts to address inequities in risk for intimate partner violence and/or sexual violence. Communities require a broader and more comprehensive set of effective programs, policies, and practices that allow them to select approaches to meet their unique needs. The availability of a broad range of evidence-based approaches will also help address risk and protective factors across all levels of the social ecology. Implementing comprehensive prevention approaches can help move the field towards reductions in intimate partner violence and sexual violence at the population level (DeGue et al., 2012).

The CDC's National Center for Injury Prevention and Control (NCIPC) has published research priorities for intimate partner violence and sexual violence prevention (https://www.cdc.gov/injury-violence-prevention/programs/research-priorities.html). These priorities include evaluating innovative or promising prevention approaches to expand the evidence base on what works to prevent intimate partner violence and sexual violence. Research funded under this announcement is expected to add to the limited existing evidence base and address immediate and divergent needs in the field. Specifically, research funded under this announcement will rigorously evaluate promising practice-based prevention approaches for their impact on intimate partner violence and/or sexual violence outcomes. Promising practice-based approaches are programs, policies, or practices that have the following:

- Evidence of implementation in the field for a minimum of two years by a state, tribal, or local organization that addresses prevention of intimate partner violence and/or sexual violence. This includes, but is not limited to, organizations that receive funding under CDC's Rape Prevention and Education Program and CDC's DELTA AHEAD program.
- Collection of prior data demonstrating one or more of the following:
    - Positive implementation-related outcomes (e.g., data demonstrating reach, fidelity, availability, and/or acceptability of the approach) ***and/or***
    - Collection of outcome monitoring data before and after implementing the approach that demonstrate positive changes in intimate partner violence, sexual violence, or established risk and protective factors for intimate partner violence and/or sexual violence.

Research on promising practice-based prevention approaches will evaluate the effectiveness of prevention approaches that already have traction within the field but have not been rigorously evaluated. As a result, this research can build the evidence for approaches that are feasible to implement by practitioners and acceptable to communities.

For the purposes of this announcement, *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 program, policy, or practice.

In addition, the following definitions are provided to distinguish between *community-based approaches* and *community-level approaches*:

- *Community-based approaches* are implemented in community settings and aim to change individual, peer, family, and other proximal relationship factors. Examples of these

factors include conflict resolution skills, parenting skills, personal attitudes, knowledge about violence, bystander behaviors.

- *Community-level approaches* are defined as approaches that address the characteristics of ***settings*** that increase or buffer against the risk for violence, particularly the social, economic, and environmental characteristics of neighborhood, school, workplace, and other organizational settings (Dahlberg, 2018), as indicated by the outer levels of the social ecological model (DeGue, Hipp, & Herbst, 2016).

Research aimed at building evidence for ***community-level approaches*** is of particular interest under this announcement. Programs, policies, or practices that are designed to address one or more of the outer layers of the social ecological model (https://www.cdc.gov/violence-prevention/about/index.html) are strongly encouraged. However, both *community-based approaches* and *community-level approaches* are eligible for evaluation under this announcement.

This announcement also strongly encourages research on programs, policies, or practices that address the needs of populations and communities experiencing inequitable risk for intimate partner violence and/or sexual violence.

Identifying the needs, barriers, and supports that are necessary for preventing violence within populations and communities that face heightened risk has the potential to inform prevention efforts and produce greater impacts. Limited evidence exists for program implementation within diverse populations. Rigorous evaluation of approaches that have been tailored to meet the needs of populations experiencing inequitable risk can address important gaps in the evidence.

Populations experiencing inequitable risk include, but are not limited to:

- racial/ethnic minority persons
- people with disabilities
- undocumented immigrants
- asylum seeking and refugee populations
- tribal populations
- rural communities and other geographically underserved areas
- sexual and gender minority persons
- people experiencing poverty and/or housing instability
- people who exchange sex

Public health approaches are often characterized in terms of the timing of prevention.

- *Primary* prevention approaches aim to prevent violence before it occurs.
- *Secondary* prevention approaches focus on the more immediate responses to recent violence, such as victim treatment or arrest strategies.
- *Tertiary* prevention approaches focus on long-term care after violence has occurred, such as rehabilitation/reintegration, attempts to lessen trauma or reduce the long-term disability associated with violence.

Research funded under this announcement is intended to focus specifically on rigorous evaluation of ***primary* prevention approaches**.

Most existing evidence-based programs are designed for group-based delivery in school-, college-, or university-based settings. For the purposes of this announcement *school-based prevention approaches* refer to programs, policies, and practices implemented in K-12 schools, colleges, or university-based settings. The intent of this NOFO is to broaden the evidence beyond school-based prevention approaches and focus on programs, policies, and practices implemented in other diverse settings or environments. For example, other diverse settings or environments may include, but are not limited to, neighborhoods, community-based organizations, businesses or workplaces, faith-based organizations, and youth-serving organizations. Applicants proposing to rigorously evaluate school-based prevention approaches will be considered nonresponsive.

References:

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Smith, L. S., & Wilkins, N. (2018). Mind the gap: approaches to addressing the research-to-practice, practice-to-research chasm. *Journal of Public Health Management and Practice, 24*, S6-S11.

Smith, L. S., Wilkins, N., Marshall, S. W., Dellapenna, A., Pressley, J. C., Bauer, M., ... & Green, K. (2018). The power of academic-practitioner collaboration to enhance science and practice integration: injury and violence prevention case studies. *Journal of Public Health Management and Practice, 24*, S67-S74.

Solar O, & Irwin A. (2010). A conceptual framework for action on the social determinants of health. Social Determinants of Health Discussion Paper 2 (Policy and Practice). Geneva, Switzerland: World Health Organization.

Yearby, R. (2020). Structural racism and health disparities: Reconfiguring the social determinants of health framework to include the root cause. *Journal of Law, Medicine & Ethics, 48*(3), 518-526.

Healthy People 2030 and other National Strategic Priorities

This research addresses the health promotion and disease prevention objectives of “Healthy People 2030”, including the focus area of injury and violence prevention. For more information, see https://health.gov/healthypeople.

The objectives of this funding announcement also align with goals of the first-ever “U.S. National Plan to End Gender-Based Violence: Strategies for Action” released by the White House. For additional information on the "U.S. National Plan to End Gender-Based Violence: Strategies for Action" see https://www.whitehouse.gov/wp-content/uploads/2023/05/National-Plan-to-End-GBV.pdf.

Public Health Impact

Intimate partner violence, including teen dating violence, and sexual violence are significant public health problems that are associated with adverse physical and mental health conditions. The proposed research will add to the limited existing literature on effective approaches for the primary prevention of intimate partner violence and/or sexual violence. By preventing intimate

partner violence and sexual violence, the overall health of individuals can be improved. Specifically, research funded under this announcement will rigorously evaluate a diverse set of approaches that address immediate and divergent needs in the field. These approaches have the potential to reach many people and could significantly reduce morbidity and mortality associated with intimate partner violence and sexual violence.

Relevant Work

For more than 30 years, NCIPC has been the nation's leading public health authority on violence and injury prevention. NCIPC's approach involves three elements:

- Focus on prevention
- Science-driven approach to identify risk and protective factors, and
- Multidisciplinary collaboration to address the problem and keep people safe, healthy and productive

The research focus of this NOFO is informed by and will inform future updates to NCIPC Division of Violence Prevention's Prevention Resources for Action, formerly known as "technical packages." These resources help states and communities take advantage of the best available evidence to prevent violence (https://www.cdc.gov/violenceprevention/communicationresources/pub/resource-for-action.html). The strategies and approaches in the Prevention Resources for Action represent different levels of the social ecology. This includes 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.

This work aligns with NCIPC's research priorities (https://www.cdc.gov/injury/priorities/index.html) and the Division of Violence Prevention's Strategic Vision (https://www.cdc.gov/injury/divisions-offices/about-division-of-violence-prevention.html#cdc_about_cio_priorities-priorities) to:

- Evaluate the effectiveness of programs, policies, and practices that have substantial uptake in practice but lack evaluation research evidence
- Evaluate the efficacy and effectiveness of programs, policies or practices across all levels of the social ecology
- Expand evidence for populations that experience a disproportionate risk for intimate partner violence and/or sexual violence.

A detailed list of previously funded research awards is available on NCIPC's website: https://www.cdc.gov/violenceprevention/fundinghub/fundedprograms/research-awards.html. Additional descriptions of violence prevention initiatives supported by NCIPC are available at: http://www.cdc.gov/injury/.

NCIPC also provides funding for implementation of primary prevention efforts that address intimate partner violence and sexual violence at the state and local level. Under the Rape Prevention and Education (RPE) Program, CDC funds health departments in all 50 states, the District of Columbia, Puerto Rico, and four U.S. territories. RPE recipients work with rape crisis centers, state sexual assault coalitions, and others to advance sexual violence prevention. A list of current RPE recipients and state sexual assault coalitions are available at: http://www.cdc.gov/violenceprevention/rpe/states.html.

CDC also provides funding for state domestic violence coalitions through the Domestic Violence Prevention Enhancement and Leadership Through Alliances (DELTA): Achieving Health Equity through Addressing Disparities (AHEAD) program. The purpose of DELTA AHEAD is to decrease risk factors and increase protective factors related to intimate partner violence. Additional information on the DELTA AHEAD program and a list of current recipients are available at: https://www.cdc.gov/intimate-partner-violence/programs/index.html

2. Approach

Strategy Focus: Promising Practice-based Primary Prevention Approaches

Research funded under this announcement will rigorously evaluate promising practice-based programs, policies, or practices for their impact on intimate partner violence and/or sexual violence outcomes. Promising practice-based approaches are defined as programs, policies, or practices that can demonstrate the following:

- Evidence of implementation in the field for a minimum of two years by state, tribal, or local organization(s) that address prevention of intimate partner violence and/or sexual violence
- Collection of prior data demonstrating one or more of the following:
    - Positive implementation-related outcomes (e.g., data demonstrating reach, fidelity, availability, and/or acceptability of the approach) ***and/or***
    - Collection of outcome monitoring data before and after implementing the approach that demonstrates positive changes in intimate partner violence, sexual violence, or established risk and protective factors for intimate partner violence and/or sexual violence.

Applicants who are not a state, tribal, or local organization responsible for implementation of the proposed practice-based prevention approach must partner and collaborate with one or more state, tribal, or local organizations that are currently implementing the approach. Eligible partner organizations include, but are not limited to, organizations that receive funding under CDC's Rape Prevention and Education Program and CDC's DELTA AHEAD program. These partner organizations should be actively involved in the planning and implementation of the proposed research. See the Collaboration/Partnership section for the requirements to document the partnership in the application.

Strategy Scope

This Notice of Funding Opportunity (NOFO) intends to cover a four (4) year program plan to complete a full-scale rigorous evaluation of a *primary* prevention program, policy, or practice for intimate partner violence and/or sexual violence. Secondary or tertiary prevention approaches are not of interest under this announcement.

Research aimed at building evidence at the community- or societal-levels is of particular interest. In addition, research aimed at building evidence for populations and communities that experience inequitable risk for intimate partner violence and/or sexual violence is of particular interest, including approaches that address social and structural determinants of health. The research results are expected to add to the limited existing literature on effective approaches for primary prevention of intimate partner violence and sexual violence. In particular, the results are

expected to expand the evidence base for effective programs, policies, and practices that can be implemented outside of school-based settings.

Primary Prevention Approaches Eligible for Evaluation and Related Requirements.

Examples of potential programs, policies, and practices that could be evaluated for effects on intimate partner violence and/or sexual violence outcomes, include:

- Approaches that leverage technology and online spaces (e.g., digital apps, social media, etc.) to enhance prevention for both technology-facilitated violence and violence perpetrated in person
- Policies and other community- or societal-level approaches impacting social norms in society, communities/neighborhoods, and other novel or innovative settings (e.g., bars, workplaces)
- Policies to strengthen economic supports for families (e.g., comparable worth policies, access to affordable quality childcare, livable wage policies, paid family and medical leave)
- Programs aimed at strengthening household financial security (e.g., microfinance, financial literacy, job skills training programs)
- Programs aimed at strengthening leadership and opportunities for adolescent girls, such as community-based organizations that build adolescent girls' confidence, job readiness, and marketability
- Efforts that improve safety and monitoring in neighborhood or community settings by enhancing and maintaining the physical characteristics of settings (e.g., increased lighting, abandoned building and vacant lot remediation, creating green space, sponsoring community events that bring residents together)
- Policies to improve organizational settings and create a healthy organizational climate to reduce violence (e.g., sexual harassment policies)
- Efforts focused on addressing community-level risks through environmental approaches that change, enact, or enforce laws, regulations, or organizational policies or other characteristics of the community (e.g., alcohol-related policies)

The examples above are not an exhaustive list. This announcement is particularly interested in research focused on gathering evidence at the community or societal levels. Research that aims to build evidence for populations and communities disproportionately affected by intimate partner violence and/or sexual violence is of special interest, especially approaches that address social determinants of health.

Approaches that are NOT eligible for evaluation.

Most existing evidence-based programs are designed for group-based delivery in K-12 school-, college-, or university-based settings. The intent of this NOFO is to broaden the evidence beyond school-based prevention approaches. The Specific Aims section of the application must demonstrate that the proposed program, policy, or practice to be evaluated is not a school-based prevention approach and will not be implemented in a K-12 school, college, or university-based setting.

Applications must demonstrate that rigorous evaluation of the selected approach will expand on, and not replicate, modify, or adapt, the existing evidence base in intimate partner violence and/or

sexual violence prevention. The following programs, policies, or practices have been identified as having existing evidence of effectiveness for preventing intimate partner violence and/or sexual violence perpetration in a rigorous evaluation and are NOT eligible for evaluation under this NOFO:

- *Safe Dates*
- *Dating Matters®: Strategies to Promote Healthy Teen Relationships*
- *Families for Safe Dates*
- *Shifting Boundaries - Building Level Intervention*
- *GreenDot*
- *RealConsent*
- *Coaching Boys into Men*
- *Bringing in the Bystander*
- *Second Step*
- *Expect Respect Support Groups*
- *The Fourth R: Strategies for Healthy Teen Relationships*
- *Prevention and Relationship Enhancement Program*
- *ePREP*

Additionally, several programs, policies, or practices aimed at preventing intimate partner violence and/or sexual violence are currently being evaluated under existing CDC-funded initiatives and are NOT eligible for this NOFO. A list of CDC-funded research awards focused on intimate partner violence, teen dating violence, and/or sexual violence prevention can be generated at https://www.cdc.gov/violenceprevention/fundinghub/fundedprograms/research-awards.html.

The Specific Aims section of the application must demonstrate that the proposed prevention program, policy, or practice is not a criminal justice approach (e.g., community policing, arrest strategies). The application must also demonstrate that the proposed prevention approach is not solely surveillance and/or etiological research. Surveillance and/or etiological research includes research examining the prevalence or correlates of behavior with the intent to uncover the causes or correlates of violence.

In summary, to be responsive to this funding opportunity, the prevention program, policy, or practice must meet the following criteria:

- Focus on the **primary prevention** of intimate partner violence and/or sexual violence
- Have evidence of implementation in the field for a minimum of two years by a state, tribal, or local organization that addresses intimate partner violence and/or sexual violence
- Have evidence of data demonstrating one or more of the following:
    - Prior positive implementation-related outcomes (e.g., data demonstrating reach, fidelity, availability, and/or acceptability of the approach) and/or
    - Collection of outcome monitoring data before and after implementing the approach that demonstrates positive changes in intimate partner violence, sexual violence, or established risk and protective factors for intimate partner violence and/or sexual violence

- Have evidence that evaluating the proposed program, policy, or practice will expand on, and not replicate, modify, or adapt, the existing evidence base. More specifically:
    - The selected approach does not have existing evidence of effectiveness from a rigorous evaluation for reducing intimate partner violence or sexual violence
    - The selected approach is not currently undergoing a rigorous evaluation of effects on intimate partner violence or sexual violence.
- Focus on primary prevention programs, policies, and practices being implemented **outside of school-based settings**. For example, approaches implemented in neighborhoods, community-based organizations, businesses or workplaces, faith-based organizations, or youth-serving organizations.
- Not represent a criminal justice approach (e.g., community policing, arrest strategies)
- Not represent solely surveillance or etiological research examining the prevalence or correlates of behavior with the intent to uncover the causes or correlates of violence

Research Plan

The research plan should describe the overall concept for the proposed rigorous evaluation. This includes, but is not limited to:

- research questions
- study design
- hypotheses
- theory of change
- primary and secondary outcomes to be measured
- data collection methods
- proposed data analysis plan
- estimated sample size and power for each proposed hypothesis
- timeline and milestones for all research activities

The proposed research design is expected to be well described and appropriate to meet the objectives of this NOFO and the applicant's proposed study. The proposed research design must allow for a rigorous quantitative evaluation of the effectiveness of the program, policy, or practice for its impact on intimate partner violence and/or sexual violence outcomes. The intimate partner violence and/or sexual violence outcomes to be assessed in the evaluation must be clearly described and appropriate for the evaluation method and research objectives. Analytic plans should anticipate and evaluate the effects of potential threats to the internal and external validity. Applicants are encouraged to additionally propose a qualitative component to support the rigorous quantitative evaluation.

The applicant should include Timelines and Milestones for all research activities. The Timelines and Milestones should be sufficiently detailed, complete, and clearly describe research activities consistent with the goals of this funding opportunity. The Timeline and Milestones should also illustrate the path to completion for the research as a whole. The Timelines should be realistic for completing a rigorous evaluation within a 4-year period of performance.

Primary Prevention Approach: Significance and Innovation.

The Research Strategy section should clearly address the significance and innovation of the promising practice-based prevention approach proposed for rigorous evaluation, including the following topics:

- How the proposed program, policy, or practice focuses on the primary prevention of intimate partner, including teen dating violence, and/or sexual violence.
- A description of current uptake and implementation of the proposed program, policy, or practice by the state, tribal, and/or local organization that will be responsible for implementation. This should include evidence of implementation for a minimum of two years. Description should also clearly designate the proposed implementation setting (e.g., community-based organizations, alcohol-serving establishments, businesses or workplaces).
- How the applicant intends to collaborate or partner with practitioners and other community members or community organizations in the planning and implementation of the proposed research.
- How the evaluation of the program, policy, or practice will expand on, and not replicate or adapt, the evidence base for intimate partner violence and/or sexual violence prevention and provide relevant information on the effectiveness of the program, policy, or practice.
- A description of preliminary data demonstrating prior positive implementation-related outcomes (e.g., data demonstrating reach, fidelity, availability, and/or acceptability of the approach) and/or outcome monitoring data collected before and after implementing the approach that demonstrates positive changes in intimate partner violence, sexual violence, or established risk and protective factors for intimate partner violence and/or sexual violence.

Examples of such preliminary evidence include, but are not limited to, quantitative or qualitative data on the reach, feasibility, or acceptability of the approach. Additional examples include data indicating positive changes in relevant violence-related behavioral mediators or risk behaviors. Positive changes would be determined by an assessment of data collected before and after implementation of the program, policy, or practice (pre/post data). “Positive changes” are changes that are expected or desired, based on the aims of the program, policy or practice.

Theory of Change

The theory of change (TOC) describes the causal processes through which the proposed program, policy, or practice is expected to result in change in intimate partner violence and/or sexual violence outcomes (e.g., Leviton et al., 2010; Lipsey, 1993; W. K. Kellogg Foundation, 2004). Applicants should describe in their TOC how their proposed evaluation meets the following criteria. Specifically, the TOC must demonstrate:

- Sufficient theoretical and/or empirical support to suggest that the proposed prevention approach may be effective in reducing intimate partner and/or sexual violence outcomes.
- Consistency with the best available evidence for prevention practice, behavioral interventions, and intimate partner violence and/or sexual violence etiology, as outlined in CDC’s Prevention Resources for Action for intimate partner violence and sexual violence prevention.

- Identification of targeted mediators or moderators (i.e., risk and protective factors), and the primary behavioral outcomes (i.e., intimate partner violence and/or sexual violence perpetration and/or victimization) (see Nation et al., 2013).
- Plans for enhancing and assessing program fidelity and program exposure during the evaluation.
- Description of any potential unintended or adverse consequences of the program, policy, or practice.

Research Design

Rigorous evaluation designs measure the impact and effectiveness of the program, policy, or practice by examining intimate partner violence and/or sexual violence outcomes among persons exposed to the program, policy, or practice compared to those who were not exposed.

Rigorous quantitative outcome evaluation designs include:

- Experimental designs with random assignment to an intervention and control/comparison condition (e.g., randomized controlled trial [RCT], cluster RCT).
- Rigorous quasi-experimental designs, such as:
    - comparative interrupted time series
    - regression discontinuity
    - difference in difference
    - matched comparison groups, for prevention approaches where random assignment is not possible due to implementation restrictions (e.g., evaluation of policy)

- In some cases, a program, policy, or practice is already in place or is implemented outside the control of the investigators (e.g., natural experiment). In this case, applicants may propose to utilize an appropriately matched comparison group or other design that would maximize the ability to make causal inferences from the findings. Such designs may include:
    - regression discontinuity designs
    - regression point displacement
    - propensity score matching
    - comparative interrupted time series designs
    - instrumental variable approaches that allow for natural experiments and control for secular trends (Eccles, Grimshaw, Campbell, & Ramsay, 2003)
    - In these cases, the applicants should also describe plans to test the validity of their results through techniques like falsification tests, sensitivity analyses, and placebo tests (Athey & Imbens, 2017).

Successful applications are expected to demonstrate the potential to complete an adequately powered rigorous evaluation. The proposed experimental or quasi-experimental research design must allow for a rigorous, scientific evaluation of the effectiveness of the program, policy, or practice for its impact on intimate partner and/or sexual violence.

Applicants are encouraged to additionally propose a qualitative component to support the rigorous quantitative evaluation. If proposing to augment the rigorous quantitative with qualitative or mixed methods, applications should propose rigorous qualitative research methods.

These rigorous qualitative or mixed methods should be stringent and disciplined to ensure credibility, dependability, confirmability, and transferability of research findings.

Applicants should clearly describe the research design and plan for the rigorous evaluation. Information to be included in the evaluation plan includes, but is not limited to:

- Valid and reliable measures of intimate partner violence and or sexual violence outcomes. Outcome data may include rates of perpetration, victimization, or both.
- A description of how potential mediator and/or moderator variables, process or implementation factors, and strategies to address potential threats to the internal and external validity of the evaluation design will be assessed.
- Plans to include at least one baseline and a minimum of a 6-month post-intervention follow-up assessment of the intervention and control/comparison groups. Research designs that allow for multiple follow-ups over a longer period of time are preferred.
- Plans for measuring and monitoring implementation fidelity and participant exposure to the program, policy or practice.
- Estimate of the cost of implementation to inform economic evaluation of the program, policy, or practice.
- Plan for sharing results with the public, funding agency, impacted communities, and collaborating partners.

Data Collection, Acquisition, and Analysis

Applicants must demonstrate the ability to obtain and/or access the proposed data. Administrative data from relevant agencies and surveys are potential sources, but appropriate data sources will vary by strategy and study design. Applicants are encouraged to explore innovative and cost-effective data collection methods for measuring intimate partner violence and/or sexual violence outcomes (e.g., online survey panels such as Amazon Mechanical Turk, YouGov, Gallup, etc.).

Applicants must identify and provide evidence of access to appropriate data sources for assessing changes in rates of intimate partner violence and/or sexual violence. Administrative data from relevant agencies and surveys are potential sources, but appropriate data sources will vary by violence outcome, approach, and study design. The indicator of intimate partner violence and/or sexual violence used for outcome measurement purposes should be appropriate to the level at which the approach was implemented, the population of interest (e.g., age, context), and data sources available (e.g., administrative, survey, surveillance).

The use of multiple sources of data for intimate partner violence and/or sexual violence outcomes is encouraged to improve validity and reliability of each of the measured violence outcomes. Primary outcomes should focus on follow-up assessments of intimate partner violence and/or sexual violence outcomes measured in baseline data collection.

Objectives/Outcomes

All proposals are expected to include valid and reliable measures of intimate partner violence and/or sexual violence as the primary outcomes of interest. Measures should examine rates or prevalence of perpetration, victimization, or both. Applicants are strongly encouraged, but not required, to include measurement of both intimate partner violence and sexual violence outcomes to examine the impact of the program, policy, or practice on these two related outcomes.

Primary Outcomes.

The focus of research conducted with these funds should be on reducing intimate partner violence and/or sexual violence outcomes. Outcome data may include rates or prevalence of perpetration, victimization or both.

Examples of primary outcome data include, but are not limited to:

- violence-related mortality data
- police records of community arrests for violent crimes including domestic violence, sexual assault and rape
- violent injury-related hospital or emergency department data (e.g., aggregated by community and disaggregated by age)
- workplace sexual-violence-related insurance claims
- state-level surveillance data (e.g., Youth Risk Behavior Surveillance System)

Additional considerations for measurement of intimate partner violence and/or sexual violence outcomes are noted below:

- *Intimate Partner Violence*: Applicants are encouraged to include measures that assess all forms of intimate partner violence, including teen dating violence, that are feasible based on the proposed data sources and relevant to the proposed evaluation design. These forms include psychological, physical, and sexual violence, and stalking behaviors.
- *Sexual Violence:* An assessment of sexual violence perpetration and/or victimization is to include actual behavior, including subtypes of sexual violence whenever possible. Examples of these subtypes include, but are not limited to, rape, sexual coercion, unwanted sexual contact, non-contact unwanted sexual experiences, and sex trafficking. Measurement of sexual violence is expected to include *any* perpetration and/or victimization during the assessed period. This should include sexual violence perpetrated by/against strangers, intimate/dating partners, peers, acquaintances, family members, or others. Measurement of sexual violence is strongly encouraged to include multiple types of victim-perpetrator relationships (e.g., sexual violence against an intimate partner) as relevant to the project.
- *Technology-Facilitated Intimate Partner Violence and/or Sexual Violence*: Applicants are strongly encouraged to include measurement of technology-facilitated intimate partner violence and/or sexual violence. Measures may include, for example, use of online or digital technologies to coerce or control an intimate partner, sexual harassment via social media, gaming, or text-communications, and use of sexual images to cause harm, etc.

Secondary Outcomes.

Applicants may also examine other secondary outcomes, such as adverse childhood experiences, self-directed violence, firearm violence, youth violence/bullying, or gang membership.

Measurement of key mediators and moderators addressed by the program, policy or practice is strongly encouraged (e.g., risk or protective factors). Applicants are also strongly encouraged to measure any unintended consequences and examine the differential impacts of the selected program or policy on subpopulations, if applicable, to ensure a comprehensive understanding of the approach's purpose and effects. This includes understanding the extent to which the evidence

reflects experiences of the intended populations or settings and whether it addresses social and structural factors that may lead to inequities.

Implementation Outcomes.

Research conducted with these funds should also provide an estimate of the cost of implementation to inform future economic evaluation of the approach. Subsequent economic evaluations may include cost-effectiveness analyses or cost-benefit analyses but are not required under this solicitation. Applicants may consider measuring other implementation outcomes (e.g., adoption, acceptability, feasibility, core components/essential features) as relevant to their proposed approach (Damschroder, Aron, Keith, Kirsh, Alexander, & Lowery, 2009; Massetti, Holland, & Gorman-Smith, 2016).

Population of Focus

Intimate partner violence and sexual violence affect millions of women and men every year, yet some populations are disproportionately affected by these forms of violence. To make a significant impact on rates and burden of intimate partner violence and sexual violence, it is important to implement and rigorously evaluate prevention approaches that meet the needs of populations experiencing inequitable risk for intimate partner violence and/or sexual violence.

A consideration of subpopulations and communities that experience a disproportionate amount of violence is strongly encouraged. Applicants proposing to evaluate approaches for specific target populations should provide a detailed description in their application of the following:

- how they intend to identify target populations and communities
- relevant data sources that will be used for this process.

Applicants should describe how they will address populations and communities that experience inequitable risk for intimate partner violence and/or sexual violence including, but not limited to:

- racial/ethnic minority persons
- people with disabilities
- undocumented immigrants
- asylum seeking and refugee populations
- tribal populations
- rural communities and other geographically underserved areas
- sexual and gender minority persons,
- people experiencing poverty and/or housing instability, and
- people who exchange sex

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 populations, including racial and ethnic minority persons, 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 in 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 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.

This NOFO, including funding and eligibility, is not limited based on, and does not discriminate on the basis of race, color, national origin, disability, age, sex (including gender identity, sexual orientation, and pregnancy) or other constitutionally protected statuses.

Collaboration/Partnerships

This funding announcement seeks proposals that leverage the combined knowledge, expertise, and experiences of researchers, practitioners, and communities to generate evidence for prevention of intimate partner violence and sexual violence. Applications must demonstrate significant and meaningful partnerships and connections to the community to ensure successful implementation and evaluation of the prevention approach. This should include partnerships and connections in the jurisdiction where implementation of the practice-based program, policy, or practice will occur. In particular, applications must demonstrate partnerships with the following:

- State, tribal, and/or local organizations and entities involved in implementing the proposed prevention approach.
- All entities participating in the development, implementation, and/or evaluation of the approach.
- All organizations and entities providing access to outcome data or study participants.
- All organizations and entities supporting and facilitating community engagement. Activities during the development, implementation, and/or evaluation of the approach.

Letters of Support

The Letters of Support section of the application must include an appropriate Letter of Support from the state, tribal, and/or local organization(s) that are responsible for implementing the selected approach. This Letter of Support must attest that the organization supports the evaluation in the jurisdiction where the organization is implementing the practice-based program, policy, or practice. In cases where the applicant is the organization directly responsible for implementing the proposed approach, a letter of support from the director is still required.

All Letters of Support must document the roles and responsibilities of the applicant and the partner organization. They should include:

- The partner organization’s anticipated involvement and scope of work.
- Any necessary permission from the state/tribal/local organization for the applicant to conduct a rigorous evaluation and an agreement of collaboration in the evaluation.

- Agreement from the state/tribal/local organization to join the Research Advisory Board and research team.
- Specific roles of PI(s), Co-PI(s), and partners, detailing site and participant recruitment, data collection and analysis, results interpretation, presentation of findings and development of recommendations and dissemination products.
- Duties, time commitments, and responsibilities of project personnel, including authority and supervision over behavioral, administrative, data management, and statistical aspects.
- Plans for facilities, equipment, assessment programming, data processing, analysis capacity, and procedures for managing data security and participant confidentiality.

Research Advisory Board.

The application must include plans to develop and engage a Research Advisory Board (RAB). The purpose of a RAB is to engage partners in reviewing and providing feedback on study materials. This includes, but is not limited to, study assessments, protocols for recruitment, retention, implementation and other study activities. The collaborating state, tribal, and/or local organization responsible for implementation of the proposed program, policy, or practice will serve in the role of implementing agency and contribute as a part of the Research Advisory Board and the research team.

Community Engagement

Applicants are strongly encouraged to seek and include the meaningful involvement of communities and build partnerships with relevant collaborators. This may include, but not be limited to state, tribal, and/or local health departments, coalitions, local governmental agencies and/or businesses, and community-based organizations. Applicants are encouraged to seek community engagement in all phases of the development and conduct of the proposed research, including translation and dissemination of findings. This can include strong partnerships with community members with lived experience.

Applicants are expected to discuss whether and how the community was engaged in choosing or designing the program, policy, or practice. In addition, applicants should discuss whether or how the research coincides with community input into the approach to ensure the acceptability relevance, appropriateness, and feasibility of the proposed research. The application should also include plans to inform impacted communities about the proposed study and to share with participants and communities how research outcomes will support or enhance prevention efforts.

Evaluation/Performance Measurement
The application is expected to include a plan to evaluate and document progress towards completion of the proposed specific aims during each stage of the research process, including:

- partnership development
- study development
- recruitment and retention
- process and outcome measurement
- data collection
- data analysis

The application is expected to include a clear description of relevant progress and performance measures documented in the Timeline and Milestones. Comparison of actual progress to the progress and performance measures are expected to document whether research is progressing appropriately and in a timely manner. Evaluation of progress and performance should also document whether the research activities are of high scientific quality.

Translation Plan
The application is expected to clearly describe the potential for widespread dissemination, implementation, and sustainability of the proposed program, policy, or practice. Applicants must describe how their research may be applied to prevention practice, including how their research findings will be used to expand the evidence base for populations at risk for intimate partner violence and/or sexual violence. The application should include plans to inform impacted communities about the proposed study and describe how research outcomes will inform and support or enhance the prevention practice efforts of communities and/or practitioners. Where feasible, applicants are expected to either have formalized program materials or procedures ***or*** plans to develop these materials based on the program, policy, or practice being implemented. Examples of materials or procedures include program curricula, facilitator guides or manuals, sample policy language, state landscape assessments, and/or policy briefs. These materials are intended to support implementation, fidelity training and monitoring. Materials are also intended to aid in widespread dissemination of the proposed program, policy, or practice, if found to be effective. Dissemination of these materials can help ensure that effective prevention approaches will be sustained by communities (i.e., without prohibitive costs or resources).

Additionally, the research findings should be disseminated through publications, including articles in peer reviewed journals and “Research Briefs” for diverse audiences. Research findings should also be disseminated through presentations at professional conferences and other venues. A translation plan should include products and presentations that are specifically intended to reach practitioner audiences (e.g., webinars, fact sheets, professional meetings/conferences, electronic communications via listservs, social media, news coverage, etc.). Practitioner audiences should include, but not be limited to, currently funded recipients of CDC’s Rape Prevention and Education Program and CDC’s DELTA AHEAD program.

Grant recipients may be required to attend one reverse site visit per year in Atlanta, GA with CDC/NCIPC staff during the period of performance to review their progress and findings and to discuss opportunities for widespread dissemination of their research achievements and lessons learned. Travel costs for attending this meeting must be included in the application's travel budget 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:
$6,000,000
NCIPC intends to commit approximately $1,500,000 in FY 2025 to fund up to three applications. The maximum award amount will be $500,000 per award for the first 12-months budget period. This includes both direct and indirect costs. An applicant may request a period of performance of up to four years. The maximum total project funding amount per project is $2,000,000, with a maximum of $500,000 per award year. NCIPC intends to commit approximately $6,000,0000 to fund up to three applications over the 4-year period of performance. The period of performance for these awards is expected to run from 9/25/2025 to 9/29/2029.

Anticipated Number of Awards:
3
Awards issued under this NOFO are contingent on the availability of funds and submission of a sufficient number of meritorious applications.

Award Ceiling:
$500,000
Per Budget Period

Award Floor:
$0
Per Budget Period

Total Period of Performance Length:
4 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

Applicant organizations may not include collaborators or consultants from foreign institutions. All applicable federal laws and policies apply. All of the proposed research work plan must be carried out domestically by the applicant organization throughout the period of performance.

The applicant organization cannot serve as a “pass through" to fund another entity to conduct the majority of the research. An applicant organization proposing a “pass through” scenario will be found ineligible for this NOFO.

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

Applications which do not meet ***all*** of the following Responsiveness criteria will be considered non-responsive and will not be forwarded for peer review.

1. The SF 424 Biographical Sketch must clearly document that the Principal Investigator (PI) or Co-Principal Investigator (Co-PI) has previous, relevant experience conducting rigorous outcome evaluations by having conducted at least one rigorous outcome evaluation. Evidence of the previous experience must be documented by at least one relevant first-authored, peer-reviewed journal article. The citation of the relevant

publication(s) must be clearly identified (by bold text or highlight) in the appropriate SF 424 Biographical Sketch. Prior PI experience with violence-related outcome evaluation research, particularly intimate partner violence and/or sexual violence research, is preferred, but not required. **Applications that do not clearly document that the PI or Co-PI have the necessary relevant experience will be considered non-responsive and will not be forwarded for peer review.**

2. The Letters of Support section of the application must include a Letter of Support from the state, tribal, and/or local organization that is responsible for implementing the program, policy, or practice to be evaluated. **Applications that do not include a Letter of Support from the state, tribal, and/or local organization that is responsible for implementing the proposed program, policy, or practice will be considered non-responsive and will not be forwarded for peer review and will not be funded.**
3. The Specific Aims section of the application must demonstrate evidence that the proposed program, policy, or practice has been implemented in the field for a minimum of two years. **Applicants proposing to evaluate approaches that have been implemented in the field for less than two years will be considered non-responsive and will not be forwarded for peer review and will not be funded.**
4. The Specific Aims section of the application must demonstrate that a *primary* prevention approach is proposed for evaluation. Primary prevention approaches aim to prevent violence before it occurs. In contrast, secondary prevention approaches focus on more immediate responses to recent violence, such as victim treatment or arrest strategies, while tertiary prevention approaches focus on long-term care after violence has occurred, such as rehabilitation/reintegration, attempts to lessen trauma or reduce the long-term disability associated with violence. **Applicants proposing secondary or tertiary prevention approaches will be considered nonresponsive and will not be forwarded to peer review and will not be funded.**
5. The application must propose to evaluate approaches that are NOT solely under the influence or control of the criminal justice system. **Applications proposing to evaluate approaches that are solely under the influence or control of the criminal justice system (i.e., policing, arrest, trial, sentencing, incarceration, mandated intervention and treatment approaches), as evidenced in the Research Strategy section of the application's research plan, will be considered nonresponsive, and these applications will not be peer-reviewed and will not be funded.**
6. The Specific Aims section of the application must demonstrate that the proposed program, policy, or practice to be evaluated is not a school-based prevention approach. Examples of school-based prevention approaches that are considered nonresponsive include program, policy, or practice implemented in a K-12 school, college, and a university-based setting. **Applicants proposing to rigorously evaluate school-based prevention approaches will be considered nonresponsive, will not be peer reviewed, and will not be funded.**
7. This research is intended to support rigorous effectiveness research to evaluate strategies focused on preventing intimate partner violence and/or sexual violence. The application must propose a study within the stated objective of the NOFO and propose an evaluation of a primary prevention program, policy, or practice, as evidenced in the Research Strategy section of the Research Plan. **Applications that propose studies outside of the stated objectives of this NOFO will be considered nonresponsive and will not be**

forwarded for peer review. Examples of studies that are considered nonresponsive include etiologic research to examine the prevalence or correlates of behavior, research to strengthen surveillance, and proposals to conduct development and feasibility testing. In addition, applications that do not propose an evaluation of a primary prevention program, policy, or practice, 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.

8. The proposed budget for each fiscal year must be less than or equal to the budget ceiling of $500,000 as outlined in Section II: Award Information. **Applications that exceed the budget in any year will be considered nonresponsive and will not be forwarded for peer review and will not be funded.**

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

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. CDC does not make awards to individuals directly. Individuals from organizations that are uniquely prepared to examine research relevant to undeserved groups, including sexual orientation and gender identity minorities as well as individuals with disabilities are always encouraged to apply.

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.

Eligible applicant organizations may submit more than one application, provided that each application is scientifically distinct. However, applicant institutions can submit only one grant application with the same principal investigator in response to this NOFO. Only one application per principal investigator will be reviewed or funded under this announcement. If two or more applications from the same PI are received, 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).

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

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 NOFOs will not be funded under more than one NOFO.

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

Application guides for 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.

3. Letter of Intent

11/01/2024
Carlisha Gentles, PharmD
Scientific Review Official
National Center for Injury Prevention and Control (NCIPC)
Telephone: 404-639-6473
Email: ncipc-peer-review@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 timeline.

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. **Other Plan(s)**
12. **Authentication of Key Biological and/or Chemical Resources**
13. **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 Other Plan(s) 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 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);
- A statement (required) of any limitations you may encounter with sharing data collected or generated under this award with CDC (such as legal, regulatory, policy, or technical concerns);
- 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).

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

CDC OMB approved templates may be used (e.g. NCCDPHP template https://www.cdc.gov/nccdphp/dch/media/files/Data-Management-Plan-template.docx

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

tools/data-management/data-management-plans

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

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 appendices are limited to a total of 10 PDF files to include the 3 publications, not publicly available as described above and up to 5 PDF files of supporting materials for the Research Plan described below (7. Page Limitations). The appendix has a total maximum page limit of 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 5 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.

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

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/support
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 12/02/2024

12/02/2024
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 Other Plan(s) section of the PHS 398 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, but not limited to, any statutory limitations prohibiting data sharing, privacy and confidentiality considerations, embargo issues).

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.

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.

Protection of Human Subjects and Personally Identifiable Information
The Research Strategy section should clearly outline the data type, source, accessibility, and safeguards for the data and human subjects involved in the study. It must detail access to non-public, previously collected data, supported by a signed Data Sharing Agreement or Letter of Support within the Research Strategy. Similarly, access to public, pre-existing data should be explicitly stated in the Research Strategy.

Safeguarding previously collected data encompasses the protection of personal identifiable information against loss and/or misuse.

Each performance site engaged in human subjects research must be identified in the application, including the FWA number for the applicant institution and each performance site. For research involving multiple institutions, a single Institutional Review Board (sIRB) is expected to carry out the ethical review mandated by HHS regulations.

11. Intergovernmental Review

This NOFO is not subject to executive order 12372, Intergovernmental Review of Federal Programs. No action is needed.

12. Other Submission Requirements and Information

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/divisions-offices/index.html), 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 public health be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

- Describe the extent to which the application aligns with the stated purpose and Research Objectives described in the notice of funding opportunity
- To what extent will the successful completion of the proposed activities significantly advance current knowledge and build the evidence base on the effectiveness of programs, policies, or practices to prevent intimate partner violence and/or sexual violence?
- To what extent will the proposed project address one or more of the outer layers of the social ecological model (https://www.cdc.gov/violence-prevention/about/index.html); e.g., community-, or societal-level)?

- To what extent will the proposed project address the needs of communities experiencing inequitable risk for intimate partner violence and/or sexual violence (including but not limited to, racial/ethnic minority persons, people with disabilities, undocumented immigrants, asylum seeking and refugee populations, tribal populations, rural communities and other geographically underserved areas, sexual and gender minority persons, people experiencing poverty and/or housing instability, and people who exchange sex)?
- To what extent will the proposed project rigorously evaluate programs, policies, or practices with demonstrated theoretical or empirical support for impact on intimate partner violence and/or sexual violence outcomes, as evidenced by data demonstrating preliminary evidence of the proposed approach's potential to reduce these outcomes?

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 does the application clearly demonstrate the research team has the experience to conduct the proposed research (e.g., experience and capability to collect, manage, and analyze data in an appropriate manner)?
- Describe the strength of the investigator(s) experience and knowledge in conducting rigorous outcome evaluations as evidenced in the biosketch of either the PI or Co-PI and documented by at least one relevant first-authored, peer-reviewed journal article on rigorous evaluation.
- Describe the strength of the investigator(s) experience and knowledge in conducting intimate partner violence, sexual violence, or other violence-related research as evidenced in the biosketch of either the PI or Co-PI and documented by at least one first-authored, peer-reviewed journal article on intimate partner violence, sexual violence, or other violence-related research.
- To what extent do the applicant and/or its partner organization(s) have the experience and capability to implement intimate partner violence and/or sexual violence prevention programs, policies, or practices that are relevant to the proposed target population?
- To what extent is there evidence of past collaboration with the proposed research team and collaborators to support the success of the proposed research?
- Do members of the proposed research team include prevention practitioners working in the field of intimate partner violence and/or sexual violence? To what extent does the applicant demonstrate the capacity to build or strengthen relationships with prevention practitioners and other community members?
- To what extent is the community and population of focus factored into the various sections of the application (e.g., need, partnerships and collaborations, dissemination plans, etc.)?

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 is the proposal innovative and promising for advancing the field of violence prevention and adding to the current evidence base?
- To what extent does the applicant propose to evaluate a program, policy or practice that has never been and is currently not being rigorously evaluated for impact on intimate partner violence and/or sexual violence outcomes? If the proposed program, policy, or practice has been evaluated for other violence outcomes previously, to what extent does the proposed research extend evidence to intimate partner violence and/or sexual violence outcomes such that it will not be duplicative of previous or current research?
- To what extent is the proposed program, policy, or practice for the prevention of intimate partner violence and/or sexual violence well-supported by the Theory of Change with a strong theoretical basis and program model consistent with the best available evidence for prevention practice, behavioral interventions, and intimate partner violence and sexual violence etiology?
- To what extent does the Theory of Change delineate the hypothesized causal relationships between the program, targeted mediators or moderators (i.e., risk and protective factors) and the primary behavioral outcomes (i.e., intimate partner violence and/or sexual violence outcomes)?
- To what extent does the proposed research describe an appropriate experimental or quasi-experimental evaluation strategy that will lead to a firm conclusion (i.e., causal inference) about the effectiveness of the proposed program, policy, or practice on intimate partner violence and/or sexual violence outcomes?

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 research project is in the early stages of development, will the strategy establish feasibility, and will particularly risky aspects be managed?

If the project involves human subjects and/or 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?

If applicable, how will populations with health disparities be considered and addressed in the design and implementation of the proposed research activities?

- To what extent does the proposed practice-based program, policy, or practice focus on the primary prevention of intimate partner violence and/or sexual violence?
- To what extent does the proposed program, policy, or practice represent an existing practice-based approach that has been implemented for a minimum of two years and demonstrated to be feasible for practitioners to implement and acceptable to communities?

- To what extent does the applicant clearly describe the current implementation plan of the state, tribal, and/or local organization responsible for implementation?
- Describe the extent to which the proposed evaluation is based on a rigorous research design (i.e., an experimental or quasi-experimental design) and well described and appropriate to meet the objectives of the NOFO and the applicant's proposed study, including quantitative and qualitative methods. Research design considerations include, for example, inclusion of baseline and appropriate follow-up assessments for the approach being evaluated, a description of sampling methods, sample size, power estimates, and data collection methods, and a data analytic plan appropriate to the study design and level of intervention.
- To what extent does the applicant describe preliminary evidence of the proposed prevention approach's potential to reduce intimate partner violence and/or sexual violence (e.g., data demonstrating positive implementation-related outcomes or outcome monitoring data before and after implementing the approach that demonstrate positive changes in intimate partner violence, sexual violence, or established risk and protective factors for intimate partner violence and/or sexual violence)?
- To what extent does the study assess the health equity implications of selected approach on population(s) disproportionately impacted by intimate partner violence and/or sexual violence (e.g., racial/ethnic minority persons, people with disabilities, undocumented immigrants, asylum seeking and refugee populations, tribal populations, rural communities and other geographically underserved areas, sexual and gender minority persons, people experiencing poverty and/or housing instability, and people who exchange sex).
- To what extent does the applicant demonstrate ability to recruit and retain an adequate study population to demonstrate significant intervention effects, as well as ability to access relevant data over an adequate amount of time (consistent with the proposed evaluation design) to rigorously evaluate the proposed program, policy, or practice?
- Applications must conduct a rigorous evaluation that includes collecting or securing baseline and follow up data on intimate partner violence and/or sexual violence as the primary outcomes. To what extent does the evaluation plan include valid and reliable measures of intimate partner violence and/or sexual violence outcomes and plans to measure actual behavior?
- To what extent is the proposed study feasible and the timeline sufficiently detailed, complete and realistic for completing research activities within a 4-year period of performance?
- To what extent does the application describe working collaboratively and in equitable partnership with communities and community members disproportionately impacted by intimate partner violence and/or sexual violence to create a plan for disseminating findings with impacted communities?

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?

To what extent will findings be disseminated to communities and populations of focus in an

appropriate and accessible manner?

- To what extent are all of the partnerships necessary to complete the proposed work formalized by letters of support that include detailed information about the nature of the relationships, and the extent of involvement and scope of work each partner is willing to commit?
- To what extent does the partnership and engagement with prevention practitioners and other community members support a rigorous and collaborative research effort? Do the letters of support outline the roles and responsibilities of PI(s) and the state, tribal, or local partners responsible for implementing the proposed program, practice, or policy? Do the agreements state that the partner organization will serve as implementing agency and be a part of the Research Advisory Board and research team? Do the agreements describe the level of collaboration planned for the implementation of the practice-based program, policy, or practice, and the collection, analysis, write-up, and dissemination of findings during the entire project?
- To what extent do the description of the duties, percentage-of-time commitments, and responsibilities of all project personnel include clear lines of authority and supervisory capacity over the behavioral, administrative, data management, and statistical aspects of the research?
- To what extent do the plans for facilities, equipment, assessment programming, data processing, analysis capacity, and procedures for management of data security and participant confidentiality support the research objectives?
- To what extent does the applicant describe whether or how the community was engaged in choosing or designing the program, policy, or practice and whether or how the research coincides with community input into the program, policy, or practice to ensure the relevance, appropriateness, and feasibility of the proposed research?

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).

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/grants/additional-requirements/ar-28.html).

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)
Reviewers will comment on whether the Resource Sharing Plan(s) (e.g. Sharing Model Organisms) or the rationale for not sharing the resources, is reasonable.

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.

Applications that meet scientific and technical merit as determined by scientific peer review may also undergo consideration at the second level of review for:

- Potential for the approach to impact population-wide changes by addressing the outer layers of the social ecological model.
- Potential for the evaluation to demonstrate empirical support for impact on intimate partner violence and/or sexual violence outcomes, including through appropriate measurement of outcomes focused specifically on intimate partner violence and/or sexual violence.
- Potential for the approach to address needs of a vulnerable population; populations and communities that experience inequitable risk for intimate partner violence and/or sexual violence. These include, but are not limited to, racial/ethnic minority persons, people with disabilities, undocumented immigrants, asylum seeking and refugee populations, tribal populations, rural communities and other geographically underserved areas, sexual and gender minority persons, people experiencing poverty and/or housing instability, and people who exchange sex.
- The Specific Aims section of the application must demonstrate that the proposed program, policy, or practice to be evaluated has not previously been evaluated with demonstrated effectiveness in a rigorous outcome evaluation for intimate partner violence and/or sexual violence, or is not currently being rigorously evaluated with CDC funding.
- The Specific Aims section of the application must demonstrate that the proposed prevention approach does not constitute an advocacy effort designed to enact laws, regulations, or administrative actions, in compliance with anti-lobbying restrictions for CDC recipients.
- Potential for 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. This includes 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 minority persons, individuals from disadvantaged backgrounds and individuals with disabilities.
- Potential for the evaluation to help build experience and expertise in violence prevention research through the inclusion of early-stage investigators as members of the SF-424 Senior/Key Personnel research team.

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 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 review of risk may impact award eligibility.

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. Additionally, we may ask for additional information prior to the award based on the results of this risk review.

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 recipient'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.

Specific requirements that apply to this NOFO are the following:

AR-1: Human Subjects Requirements
AR-2: Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR-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-14: Accounting System Requirements
AR-16: Security Clearance Requirement
AR-21: Small, Minority, And Women-owned Business
AR-22: Research Integrity
AR-24: Health Insurance Portability and Accountability Act Requirements
AR-25: Data Management and Access
AR-26: National Historic Preservation Act of 1966
AR-28: Inclusion of Persons Under the Age of 21 in Research
AR-29: Compliance with EO13513, "Federal Leadership on Reducing Text Messaging while Driving", October 1, 2009
AR-30: Information Letter 10-006, - Compliance with Section 508 of the Rehabilitation Act of 1973
AR-31: 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-34: Accessibility Provisions and Non-Discrimination Requirements
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/additional-requirements/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. Applicants may include reasonable publication costs and costs associated with submission, curation, management of data, and special handling instructions as allowable expenses in all research budgets. 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 without any embargo or delay after publication. Also at the time of submission, Recipient and/or Recipient's submitting author must also post the manuscript through PMC without any embargo or delay after publication. 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. Recipients (foreign and domestic) receiving CDC funding on or after September 24, 2015, are subject to this policy. Research funded by CDC, involving the agents or toxins named in the policy, must be reviewed to determine if it involves one or more of the listed experimental effects and if so, whether it meets the definition of DURC. This review must be completed by an Institutional Review Entity (IRE) identified by the funded institution.

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

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

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

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

This 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 the 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's 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 reside 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:

- 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.
- 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/index.html

CDC staff has substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below. CDC staff will work collaboratively with the PIs/PDs, as described below:

- Providing suggestions refining research protocols (e.g., for sampling, recruitment, assessment, and data management).
- Participating in analysis, interpretation, and dissemination of study findings, and may include co-authorship of peer-reviewed manuscripts and scientific presentations as needed. 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.
- Collaborating with the recipient to ensure human subjects assurances are in place as needed. As necessary, collaborating 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. Obtaining 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.

- 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.
- Assisting the PI, as needed, in complying with the Investigator responsibilities described in the Policy on Public Health Research and Nonresearch Data Management and Access https://www.cdc.gov/grants/additional-requirements/index.html
- 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 recipient and CDC will establish a schedule for regular phone calls to discuss ongoing progress. This schedule will be agreed on by both the recipient and CDC.

5. Reporting

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

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

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

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

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

A. Submission of Reports

The Recipient Organization must submit:

Annual Performance Report (APR)/RPPR is due 120 days before the end of the current budget period, or the date identified in the guidance that CDC distributes. 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.

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.**

Closeout Reports: a final progress report, invention statement, equipment/inventory report, and the **Final FFR (SF-425)** are required **120 days after the end of the period of performance.**

B. Content of Reports

1. Annual Performance Report (APR)/RPPR: The recipient's continuation application/progress report 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:

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. 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 period of performance.

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 (SF-425) 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 (SF-425), final progress report, and Final Invention Statement and Certification within 120 days after the end 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 recipient's final report should include:

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

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

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

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

Final Data Management Plan: Applicants must include an updated final Data Management Plan that describes the data collected, the location of where the data is stored (example: a repository), accessibility restrictions (if applicable), and the plans for long term preservation of the data.

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
https://www.grants.gov/support
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

https://www.era.nih.gov/need-help
Email: commons@od.nih.gov
Hours: Monday - Friday, 7am - 8pm U.S. Eastern Time; closed on Federal holidays

Scientific/Research Contact
Tamara Crawford, DBH
National Center for Injury Prevention and Control (NCIPC)
Email: NCIPC_ERPO@cdc.gov

Peer Review Contact
Carlisha Gentles, PharmD
National Center for Injury Prevention and Control (NCIPC)
Email: ncipc-peer-review@cdc.gov

Financial/Grant Management Contact(s)
Angie Willard, Grants Management Specialist
CDC Office of Grants Services
Email: aen4@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.

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

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.