

Centers for Disease Control and Prevention

NATIONAL CENTER FOR INJURY PREVENTION AND CONTROL

Rigorously Evaluating Programs and Policies to Prevent Child Sexual Abuse and Problematic Sexual Behavior among Youth

RFA-CE-25-026

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 Programs and Policies to Prevent Child Sexual Abuse and Problematic Sexual Behavior among Youth

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

Reissue of RFA-CE-21-006

Agency Notice of Funding Opportunity Number

RFA-CE-25-026

Assistance Listings Number(s)

93.136

Category of Funding Activity

HL - Health

NOFO Purpose

The Centers for Disease Control and Prevention's National Center for Injury Prevention and Control (NCIPC) is soliciting investigator-initiated research proposals to rigorously evaluate programs and policies for their impact on primary prevention of perpetrating child sexual abuse

(CSA) or engaging in problematic sexual behavior (PSB) among youth. CSA is defined as the involvement of youth (under 18 years of age) in sexual activity that violates the laws or social taboos of society and that youth do not fully comprehend; do not consent to or are unable to give informed consent to; or are not developmentally prepared for. For the purposes of this NOFO, CSA is defined as being perpetrated by adults (18 years of age and older).

- PSB is defined as sexual behaviors among youth (under 18 years of age) that are not developmentally appropriate and have the potential to cause harm to the child or children involved (including behaviors that are unintentionally harmful or inappropriate as well as behaviors intended to cause harm).
- Primary prevention is defined as preventing violence, or other harmful behaviors, before it occurs
- Perpetration prevention is defined as prevention efforts that focus on reducing the likelihood of individuals from committing acts of violence, or other harmful behaviors.

Research funded under this announcement will strengthen the evidence base for primary prevention of CSA and PSB. While proposed approaches must focus on preventing adults from perpetrating CSA or preventing youth from engaging in PSB, the outcomes measured may relate to CSA perpetration or victimization and engaging in or experiencing PSB.

Amendment 1 serves to 1) Update the Collaboration/Partnerships section to define parameters on what is considered a “pass-through” and 2) Clarify what is needed to document PI and or Co-I expertise to meet responsiveness review criteria

Key Dates

Publication Date:
To receive notification of any changes to RFA-CE-25-026, 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
Letter of Intent Due Date: 11/01/2024

While a letter of intent is not mandatory, nor is it binding or a factor in the review of an application, the details it provides help NCIPC staff to plan for the scientific and technical merit peer review process.

Application Due Date:
12/02/2024
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:
04/29/2025
This date is an estimate

Secondary Review:
06/02/2025
This date is an estimate

Estimated Start Date:
09/30/2025

Expiration Date:
03/10/2025

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
The Centers for Disease Control and Prevention's National Center for Injury Prevention and Control (NCIPC) is soliciting investigator-initiated research proposals to rigorously evaluate

programs and policies for their impact on primary prevention of perpetrating child sexual abuse (CSA) or engaging in problematic sexual behavior (PSB) among youth. For the purposes of this NOFO:

- CSA is defined as the involvement of youth (under 18 years of age) in sexual activity that violates the laws or social taboos of society and that youth do not fully comprehend; do not consent to or are unable to give informed consent to; or are not developmentally prepared for. For the purposes of this NOFO, CSA is defined as being perpetrated by adults (18 years of age and older).
- PSB is defined as sexual behaviors among youth (under 18 years of age) that are not developmentally appropriate and have the potential to cause harm to the child or children involved (including behaviors that are unintentionally harmful or inappropriate as well as behaviors intended to cause harm).

Research funded under this announcement will strengthen the evidence base for primary prevention of CSA and PSB. While proposed approaches must focus on preventing adults from perpetrating CSA or preventing youth from engaging in PSB, the outcomes measured may relate to CSA perpetration **or victimization** and engaging in **or experiencing** PSB.

Applicants must propose to rigorously evaluate a program or policy for primary prevention of CSA or PSB that addresses **one** of the following three research priorities:

1. Programs or policies with potential for the primary prevention of perpetrating CSA or engaging in PSB, with an emphasis on approaches addressing community, societal, or structural conditions.
2. Programs or policies focused on primary prevention of perpetrating CSA or engaging in PSB in digital spaces (e.g., downloading or possession of illegal images of children, nonconsensual image sharing, use of digital spaces for commercial sexual exploitation or trafficking of children).
3. Organizational policy approaches focused on primary prevention of perpetrating CSA or engaging in PSB in youth-serving organizations (e.g., community centers, youth development organizations, juvenile residential care facilities, faith-based organizations, group foster care).

Mechanism of Support
The funding mechanism for this Notice of Funding Opportunity (NOFO) will be a U01 research cooperative agreement.

Funds Available and Anticipated Number of Awards
CDC/NCIPC intends to commit up to $1,200,000 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 estimated total funding (direct and indirect) for the first budget period, 9/30/2025 – 9/29/2026 is $400,000. The estimated total funding (direct and indirect) for the entire period of performance, 9/30/2025 – 9/29/2029, is $1,600,000.

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

Eligible Institutions/Organizations
Institutions/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. People from racial and ethnic groups, as well as people 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 10/10/2024 to address questions from prospective applicants regarding NOFO RFA-CE-25-026. The call will begin at 1:00pm Eastern Standard Time (EST) and end at 1:50 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 10, 2024
- Call Start Time: 1:00pm Eastern Standard Time (EST)
- Call End Time: 1:50pm Eastern Standard Time (EST)
- Call Leader: Joyce Dieterly, Scientific Program Official
- Webinar Link: https://cdc.zoomgov.com/j/1606615597?pwd=WEVPbTR4Ykh1RW5kYTY2UVVyT0tOUT09
- Webinar ID: 160 661 5597
- Passcode: a47kJc+3
- 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: 44072093

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

Child sexual abuse (CSA) and problematic sexual behavior (PSB) are preventable public health problems affecting millions of children annually (Finkelhor et al., 2024; Finkelhor et al., 2014a; Gewirtz-Meydan & Finkelhor, 2020). Expanding the evidence base for prevention approaches at multiple levels of the social ecology will help meet the unique needs of communities and move the field towards implementation of effective approaches that hold promise for preventing CSA and PSB at the population level (DeGue et al., 2012). This Notice of Funding Opportunity seeks to evaluate approaches focused on preventing adults from perpetrating CSA and youth from engaging in PSB.

Rigorous evaluation of programs and policies for the primary prevention of CSA and PSB aligns with NCIPC's research priorities related to preventing sexual violence, child abuse and neglect, and adverse childhood experiences (ACEs). For more information, see CDC Injury Research Priorities.

Child Sexual Abuse (CSA)

Based on victimization surveys, 6-32% of girls and 2-11% of boys in the United States experience CSA (Finkelhor et al., 2024; Finkelhor et al., 2014a; Gewirtz-Meydan & Finkelhor, 2020). Due to measurement and methodological issues, known rates likely underestimate the true incidence and prevalence scope of this public health problem (Topping & Barron, 2009; Wiseman, 2015; Zeuthen & Hagelskjær, 2013). CSA occurs throughout childhood and across socioeconomic classes (Singh, et al., 2014), though there are systems of inequities that cause a disproportionate burden of CSA victimization among various youth populations (see *Health Equity* for more detail). CSA is committed by someone known and trusted by the child or their family members 91% of the time (CDC, 2022a).

CSA is associated with numerous short-term and long-term physical and mental health and behavioral consequences (Blakemore et al., 2017) and is among 24 global risk factors identified by the World Health Organization that substantively affect the global burden of disease (Letourneau et al., 2014; Mathers et al., 2009). Thus, increasing the evidence base for CSA prevention is critical.

Most existing CSA prevention programs and policies focus on increasing reporting (e.g., mandatory reporting), preventing repeated perpetration (e.g., sex offender registries and laws), and providing abuse prevention education to children (Assini-Meytin et al., 2020; Finkelhor, 2009). While these strategies are an important part of a community's approach to addressing CSA, additional research is need on strategies that prevent CSA from occurring in the first place.

Problematic Sexual Behavior (PSB) Among Youth

Self-report surveys indicate that PSB accounts for up to 77% of harmful sexual behavior experienced by children (Gewirtz-Meydan & Finkelhor, 2020). PSB among youth refers to sexual behaviors that are not developmentally appropriate and have the potential to cause harm to the child or children involved (National Center for Sexual Behavior of Youth, n.d.). PSB can involve significant differences in age, developmental level, or power or status; lack of freely given consent; signs of discomfort or emotional distress; unusual level of interest in sexual behaviors; or repeated sexual behaviors after adult intervention (Silovsky, 2009; Wurtele & Kenny, 2011). Youth engage in PSB for different reasons, including, but not limited to, having

insufficient information about appropriate or inappropriate sexual behavior, media exposure to sexual content, or previously witnessing or experiencing violence (Letourneau et al., 2017; Ruzicka et al., 2021; Silovsky, 2009; Wurtele & Kenny, 2011).

Programs and policies associated with reductions in PSB among youth are emerging and need further evaluation (Finkelhor et al., 2014b; Letourneau et al., 2017). These programs may be delivered in a variety of settings, including school classrooms and community organizations. Program elements include teaching skills related to healthy relationships, healthy sexuality and sexual development, boundaries and consent, social-emotional health, or differences between developmentally appropriate and problematic sexual behavior (Espelage et al., 2015; Foshee et al., 2004; Letourneau et al., 2017; Ruzicka et al., 2021; Taylor et al., 2012; Wurtele & Kenny, 2011). In addition, strategies that seek to create protective environments by improving the safety of schools (i.e., monitoring the physical and social environment) have shown positive effects in reducing PSB among youth (Taylor et al., 2012).

Note: The use of the term problematic sexual behavior (PSB), as opposed to commonly used terms such as peer-to-peer abuse or youth-perpetrated child sexual abuse (CSA), is not meant to detract from the seriousness or potential harm of youth behaviors, particularly more rare and harmful behaviors such as sexual assault. Rather, it is imperative to acknowledge that childhood is a distinct developmental period to adulthood. Because of this, the response to children engaging in problematic and/or harmful behavior should also be distinct from the response to an adult engaging in similar behavior, particularly with an increased focus on rehabilitative responses over punitive responses.

Health Equity

This funding announcement supports CDC CORE Health Equity Goals to embed health equity principles in the design, implementation, and evaluation of its research, data, surveillance, and intervention strategies. More information about CDC CORE Health Equity Goals can be found at CDC's CORE Commitment to Health Equity | Health Equity | CDC.

Health equity is the state in which everyone has a fair and just opportunity to attain their highest level of health (CDC, 2022b). Achieving this requires recognizing and addressing the social and structural factors that affect health and health care and may increase the risk of youth in certain communities to experience CSA. People at disproportionate risk of experiencing CSA or PSB may include, but are not limited to: girls; youth from racial and ethnic minority groups; youth with disabilities; youth experiencing homelessness; immigrant and refugee youth; youth from sexual and gender minority groups; and youth from disproportionately impacted, underrepresented, or marginalized communities (Bryce et al., 2019; Collin-Vézina et al., 2013; Colin et al., 2020; Heerde et al., 2015; Kenny et al., 2023; Liu et al., 2021; MacMillan et al., 2013; McCabe et al., 2022; Australian Royal Commission, 2017; Walker et al., 2012).

Research is needed to evaluate policies and programs that seek to prevent CSA or PSB by addressing and improving social determinants of health (SDOH) associated with perpetrating CSA or engaging in PSB. SDOH are the non-medical factors that influence health outcomes (CDC, 2022c). Examples include economic policies and systems, social policies, concentrated poverty, structural racism, high rates of unemployment, limited access to high-quality education, and affordable, high-quality childcare. Public health approaches that address upstream factors, such as SDOH, have the potential to reduce CSA and PSB. Research into SDOH for CSA

prevention is limited, but financial stress and housing instability, for example, are associated with higher rates of CSA (Hunter & Flores, 2021). Programs and policies that focus on addressing SDOH for perpetrating CSA or engaging in PSB may result in a reduction of CSA or PSB. However, it is important to consider that all programs and policies have the potential to exacerbate health inequities or otherwise cause harm. This is particularly relevant when addressing the outer levels of the social ecology, as the increased reach magnifies the potential for both benefits and harms. As such, we encourage applicants to clearly describe how the equity implications of the prevention effort will be empirically studied in population(s) at disproportionate risk of experiencing CSA or PSB to ensure that the effort does not widen inequities.

Purpose

The Centers for Disease Control and Prevention's National Center for Injury Prevention and Control (NCIPC) is soliciting investigator-initiated research proposals to rigorously evaluate programs and policies for their impact on primary prevention of perpetrating child sexual abuse (CSA) or engaging in problematic sexual behavior (PSB) among youth. For the purposes of this NOFO:

- CSA is defined as as the involvement of youth (under 18 years of age) in sexual activity that violates the laws or social taboos of society and that youth do not fully comprehend; do not consent to or are unable to give informed consent to; or are not developmentally prepared for. For the purposes of this NOFO, CSA is defined as being perpetrated by adults (18 years of age and older).PSB is defined as sexual behaviors among youth (under 18 years of age) that are not developmentally appropriate and have the potential to cause harm to the child or children involved (including behaviors that are unintentionally harmful or inappropriate as well as behaviors intended to cause harm).

Research funded under this announcement will strengthen the evidence base for primary prevention of CSA and PSB. While proposed approaches must focus on preventing adults from perpetrating CSA or preventing youth from engaging in PSB, the outcomes measured may relate to CSA perpetration **or victimization** and engaging in **or experiencing** PSB.

Applicants must propose to rigorously evaluate a program or policy for primary prevention of CSA or PSB that addresses **one** of the following three research priorities:

1. Programs or policies with potential for the primary prevention of perpetrating CSA or engaging in PSB, with an emphasis on approaches addressing community, societal, or structural conditions. Examples of these conditions include, but not limited to, characteristics of communities that are empirically or theoretically associated with violence such as concentrated poverty, structural racism, high rates of unemployment and community violence, limited access to high-quality education and/or affordable, high-quality childcare that contribute to health inequities across population groups.
2. Programs or policies focused on primary prevention of perpetrating CSA or engaging in PSB in digital spaces (e.g., downloading or possession of illegal images of children, nonconsensual image sharing, use of digital spaces for commercial sexual exploitation or trafficking of children).

3. Organizational policy approaches focused on primary prevention of perpetrating CSA or engaging in PSB in youth-serving organizations (e.g., community centers, youth development organizations, juvenile residential care facilities, faith-based organizations, group foster care).

Healthy People 2030 and other National Strategic Priorities

NCIPC is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2030". This NOFO will support the following Healthy People 2030 Injury and Violence Prevention (IVP) core objectives: IVP-15 (Reduce child abuse and neglect deaths), IVP--16 (Reduce nonfatal child abuse and neglect), and IVP-17 (Reduce adolescent sexual violence by anyone).

This NOFO will also build upon the growing evidence bases in sexual violence and child abuse and neglect prevention as reflected in CDC's Resources for Action: *Sexual Violence Prevention Resource for Action: A Compilation of the Best Available Evidence*, *Child Abuse and Neglect Prevention Resource for Action* and *Adverse Childhood Experiences (ACEs) Prevention Resource for Action.*

Public Health Impact

NCIPC is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2030". This NOFO will support the following Healthy People 2030 Injury and Violence Prevention (IVP) core objectives: IVP-15 (Reduce child abuse and neglect deaths), IVP--16 (Reduce nonfatal child abuse and neglect), and IVP-17 (Reduce adolescent sexual violence by anyone).

This NOFO will also build upon the growing evidence bases in sexual violence and child abuse and neglect prevention as reflected in CDC's Resources for Action.

Relevant Work

For more than 20 years, CDC's National Center for Injury Prevention and Control (NCIPC) has been the nation's leading public health authority on violence and injury prevention. CDC's approach involves three elements: 1) a focus on prevention, 2) a science-driven approach to identify risk and patterns, and 3) multidisciplinary collaboration to address the problem and keep people safe, healthy, and productive.

NCIPC's Division of Violence Prevention (DVP) developed Prevention Resources for Action to help states and communities take advantage of the best available evidence to prevent child abuse and neglect, adverse childhood experiences, and sexual violence: including *Sexual Violence Prevention Resource for Action* (Basile et al., 2016), *Adverse Childhood Experiences Prevention Resource for Action (CDC, 2019a), and Child Abuse and Neglect Prevention Resource for Action* (Fortson et al., 2016). The strategies and approaches in the Prevention Resources for Action represent different levels of the social ecology with efforts intended to impact individual behaviors as well as the relationship, family, school, community, and social structure that influence risk and protective factors for violence.

NCIPC's research priorities and the Division of Violence Prevention's Strategic Vision support the need for evaluating the effectiveness of programs and policies that lack rigorous evaluation,

address all levels of the social ecology, and expand evidence for populations that experience a disproportionate burden of CSA.

NCIPC previously supported three prior funding opportunity announcements to rigorously evaluate approaches to prevent child sexual abuse:

- RFA-CE-20-005 (Rigorously Evaluating Approaches to Prevent Adult-Perpetrated Child Sex Abuse (CSA))
- RFA-CE-21-006 (Rigorously Evaluating Programs and Policies to Prevent Child Sexual Abuse (CSA))
- RFA-CE-22-003 (Rigorously Evaluating Programs and Policies to Prevent Child Sexual Abuse (CSA))

CDC also has an online resource of the best available evidence to support diverse youth-serving organizations in preventing CSA and PSB. Additional examples of previously funded research and descriptions of violence prevention initiatives are available on NCIPC's website.

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2. Approach

The intent of this NOFO is to support rigorous evaluations to strengthen the evidence base on the effectiveness of programs and policies with potential for the primary prevention of perpetrating CSA and engaging in PSB in the United States. The Specific Aims section of the application **must** clearly describe the primary prevention program or policy that will be evaluated. The Specific Aims section of the application **must** also clearly name and describe which of the three Research Priorities aligns with the proposed research study.

Research Priority 1. **Rigorous evaluation of programs or policies with potential for the primary prevention of perpetrating CSA or engaging in PSB, with an emphasis on approaches addressing community, societal, or structural conditions.**

There are existing programs and policies focused on preventing CSA and PSB that have not been rigorously evaluated for their effectiveness. Additionally, some existing programs and policies have been evaluated in certain populations but have not been adapted and evaluated for others (e.g., youth or adults with developmental disabilities; people who live in rural areas; people from different racial and ethnic groups). Some examples, but not an exhaustive list, of programs and policies that could be evaluated under this priority include:

- Social norms and education campaigns in communities (including online communities) that might seek to improve help-seeking among people concerned about their own or others' sexual thoughts or behaviors
- Programs that teach youth about appropriate boundaries and healthy relationships to prevent them from engaging in PSB (distinct from programs that teach youth how to keep themselves safe from experiencing CSA)
- Policies that provide economic supports for families to prevent commercial sexual exploitation of children

The evidence base for prevention approaches for CSA and PSB that address community, societal, or structural conditions remains a critical research gap to be addressed by proposals for this research priority.

Further, there is a need to adapt and evaluate approaches focused on the primary prevention of perpetrating CSA or engaging in PSB for populations with different demographic or social characteristics, since an approach that is effective for one population may not be effective (or may require adaptation to be effective) for another. For example, a program or policy evaluated in an urban community may not have the same impacts in a rural community; a program or policy designed for youth without disabilities may not be effective or accessible for youth with disabilities; and a program or policy evaluated with people from one racial or ethnic group may be inappropriate, ineffective, or even harmful for people from a different racial or ethnic group. NOTE: If an applicant proposes to adapt a program or policy for a new population, the applicant

should provide a strong and detailed plan for how the program or policy will be adapted **and** rigorously evaluated during the four-year study period.

Research Priority 2. **Rigorous evaluation of programs or policies focused on the primary prevention of perpetrating CSA or engaging in PSB in digital spaces (e.g., downloading or possession of illegal images of children, nonconsensual image sharing, use of digital spaces for commercial sexual exploitation or trafficking of children).**

Technology and digital platforms are vehicles for CSA perpetration. Perpetration occurs via digital devices (e.g., tablets, Smartphones) and other platforms (e.g., social media, online forums, chatrooms). For example, technology can be used to facilitate the viewing, downloading, and possession of illegal images of children (Hamilton-Giachritsis et al., 2020; Mountjoy et al., 2016; Shelton et al., 2016). Additionally, adults who perpetrate CSA or commercial sexual exploitation of children may use technology to connect with and build relationships with children (de Sanisteban et al., 2018; Hamilton-Giachritsis et al., 2020) and facilitate in-person contact. Youth can also engage in problematic or harmful sexual behaviors in digital spaces, such as sharing or threatening to share nude images of their peers without their knowledge or permission (Patchin & Hinduja, 2020; Seto et al., 2023).

Applications submitted under Research Priority 2 should focus specifically on preventing CSA or PSB occurring through technology and digital platforms. Evaluated programs or policies can be at the state, federal, tribal, platform, or organization level. Programs and policies that could be evaluated under this priority include, but are not limited to, strategies that prevent:

- The initial contact between adults and children in digital spaces
- Boundary-crossing in digital interactions between adults and children
- Sexually abusive or harmful behaviors by adults or youth in digital spaces (e.g., an online campaign focused on providing resources and support to people who appear to be searching for illegal images of children, a program or policy focused on preventing commercial sexual exploitation of children in digital spaces).

Research Priority 3. **Rigorous evaluation of organizational policy approaches focused on the primary prevention of perpetrating CSA or engaging in PSB in youth-serving organizations (e.g., community centers, youth development organizations, juvenile residential care facilities, faith-based organizations, group foster care)**.

Youth-serving organizations (YSOs) can provide a range of services, including religious-based activities, sports training, and mentorship opportunities or other extracurricular activities. YSOs develop youths' strengths, skills, and connections with other youth and staff, making them critical partners for preventing CSA and PSB.

While YSOs can build protective factors for CSA and PSB, the settings and congregate care may also increase the risk for CSA and PSB (Mathews, 2017; Euser et al., 2013; Webster et al., 2017; (Biehal, 2013; Webster et al., 2017). YSOs often implement an extensive array of policies that influence organizational practices geared towards preventing CSA, including hiring policies, required training on CSA, codes of conduct focused on preventing opportunities for CSA to occur, supervision guidelines, and specific considerations for physical settings (Assini-Meytin, 2021). The effectiveness of these policies have not yet been rigorously evaluated (Kaufman et al., 2010). Applications submitted under Research Priority 3 should focus specifically on evaluating the effectiveness of policies designed to prevent perpetrating CSA or engaging in PSB

within YSOs. Applicants are encouraged to incorporate policy implementation considerations, such as implementation fidelity or barriers and facilitators of implementation.

Considerations Regarding NOFO Scope:

Applicants must identify which of the three research priorities with which their proposed research study aligns. It is possible for a program or policy to align with more than one of the research priorities. For the purposes of this application, the applicant must choose the one that best fits their research proposal. Applicants can incorporate elements of the other research priorities into their proposal.

Applicants are required to evaluate a program or policy that has not yet been rigorously evaluated for its primary prevention impact on CSA or PSB. **Applicants may not propose to evaluate a program or policy that has already been rigorously evaluated or is currently undergoing a rigorous evaluation.** However, approaches that are substantially adapted and include appropriate modifications for a new population (i.e., a population with different demographic or social characteristics) or setting (i.e., youth sports) are permitted, as evidence of effectiveness in one population does not automatically translate to effectiveness in another. If an applicant proposes to adapt a program or policy for a new population, the applicant should provide a strong and detailed plan for how the program or policy will be adapted **and** evaluated during the four-year study period.

Applicants must propose to evaluate a primary prevention program or policy. Public health strategies are often characterized in terms of the timing of prevention: *primary* prevention approaches, which focus on preventing violence before it occurs; *secondary* prevention approaches, which focus on the more immediate responses to recent violence, such as treatment for victims or arrest strategies; and *tertiary* prevention approaches, which 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 on evaluation of primary prevention approaches**.

Applicants must propose rigorous evaluation designs, which for the purposes of this funding opportunity can include those that utilize experimental designs (i.e., randomized controlled trials) or quasi-experimental designs (e.g., comparative interrupted time series design with multiple time points, difference-in-difference with multiple time periods, instrumental variables, regression discontinuity, regression point displacement, stepped wedge, propensity score matching, comparison groups). Applicants are encouraged to also include a qualitative component to support the rigorous quantitative evaluation. If proposing to augment the rigorous quantitative evaluation with qualitative or mixed methods, applications should describe appropriate qualitative analysis methods.

Evaluation of programs or policies that address the needs of communities at disproportionate risk of experiencing CSA (including but not limited to people with disabilities, American Indian or Alaska Native persons, people from racial and ethnic minority groups, people from sexual and gender minority groups) is strongly encouraged.

Applicants **must demonstrate plans to incorporate health equity considerations at multiple stages of the research process**. Examples of considering and advancing health equity at multiple stages of the research process include, but are not limited to:

- Recruiting diverse participants (e.g., different racial/ethnic or gender identities, geographic locations)
- Creating accessible program materials
- Engaging with people with lived experience
- Actively seeking feedback from members of the community on data collection tools and interpretation of results
- Presenting results separately (descriptively or via stratification) for groups with different demographic characteristics
- Collecting additional data with community partners (e.g., in-depth interviews) to supplement the quantitative evaluation findings with a qualitative exploration on how the selected policy or program may work to close or widen existing inequities in CSA or PSB burden across populations
- Considering future translation and adaptation of effective program elements to different populations
- Examining if and how the policy or program inadvertently widens inequities

Applicants should consider that programs and policies have the potential to exacerbate health inequities. This is particularly relevant when addressing the outer levels of the social ecology. Applicants are encouraged to clearly describe and measure indicators of SDOH related to the program or policy to be evaluated. Applicants should also describe how the equity implication of the prevention strategy will be empirically studied in population(s) at disproportionate risk of experiencing CSA or PSB to ensure that the effort does not widen inequities. When addressing specific populations who experience health inequity, it is important to recognize the social determinants of health that affect risk, and not imply that the fault or responsibility of the inequity lies with the affected population. Applicants will have the opportunity to work with CDC Health Equity subject matter expert(s) to implement and strengthen their proposed health equity plans.

Applicants must measure the impact of the program or policy on the primary outcome of CSA victimization/perpetration or engaging in/experiencing PSB. Applicants are also encouraged to measure proximal outcomes, such as decreases in risk factors or increases in protective factors for perpetrating CSA or engaging in PSB. Applicants must describe the research intent and expected research outcomes. The application should:

- Clearly address how the research findings or outcomes will expand the evidence base for the primary prevention of CSA and/or PSB
- Provide relevant and actionable information to practitioners
- Inform the implementation of violence prevention programs or policies in real-world settings

Applicants must clearly describe how the proposed policy or program addresses inequities in CSA and PSB. Applicants should also explain how the policy or program is designed for or accepted by the community and has practical application to prevention practice. Additionally, applicants should include plans to inform communities affected by the research about the proposed study and describe how research outcomes will support or enhance the prevention practice efforts of communities and/or practitioners.

Community, societal, and structural risk and protective factors for perpetrating CSA and engaging in PSB can be affected by federal, state, local, tribal, or organizational policies. Approaches that are hypothesized to impact CSA or PSB prevention at the outer levels of the social-ecological model (i.e., community and societal levels) are strongly encouraged since the evidence base for strategies addressing community, societal, or structural conditions is especially limited. Given that approaches at the outer levels have the potential to reach a large number of people, they also have the potential to demonstrate population-level impacts on preventing and reducing CSA or PSB. ***Communities*** are defined as formal or informal organizations or geographical settings in which social relationships occur (e.g., neighborhoods, schools, cities, states; Dahlberg & Krug, 2002). Communities may include any defined population with shared characteristics, risk/protective factors, and potential for exposure to the program or policy. For the purposes of this NOFO, communities can also refer to online communities.

Applicants are strongly encouraged to seek and include the meaningful involvement of the community or communities where the approach is being implemented in all phases of the development and conduct of the proposed research, and in the translation and dissemination of research results. This can include forming strong partnerships with community members with lived experience, community-based organizations and YSOs who work with communities affected by the research, to meaningfully participate in various phases of the research (e.g., developing study methods, collecting data, interpreting results, and disseminating findings). Applicants are required to provide a letter of support (LOS) or memorandum of understanding (MOU) that describes the nature and extent of the proposed partnership(s) for all partner organizations involved in the proposed research (see Section 2. Approach, *Collaboration/Partnerships)*.

Applicants are strongly encouraged to evaluate the implementation of the program or policy thoroughly, including cost measures, when applicable. This will inform future economic evaluations, offering a clearer view of the effectiveness and value of the chosen approach.

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. Measuring unintended consequences and differential impacts on different groups is particularly important for approaches addressing community, societal, or structural conditions, where the potential to reach a large number of people magnifies the potential to exacerbate health inequities or otherwise cause harm.

Objectives/Outcomes

The primary outcome to be achieved through this research opportunity is to strengthen the evidence base for the effectiveness of programs and policies for the primary prevention of perpetrating CSA and engaging in PSB. Funded projects are expected to **identify a primary prevention program or policy and evaluate its effectiveness in preventing CSA or PSB**. While proposed approaches must focus on preventing adults from perpetrating CSA or preventing youth from engaging in PSB, the outcomes measured may relate to CSA perpetration

or victimization and engaging in **or experiencing** PSB. Examples of CSA or PSB data and sources include, but are not limited to:

- Emergency department
- Law enforcement
- Child abuse reports (e.g., CPS)
- Administrative data from relevant YSOs
- Survey data
- Self-report

Because information about CSA and PSB prevalence/incidence often come from official reports or law enforcement data, which only represent a subset of abuse and other harmful behavior experienced by youth, applicants planning to use these sources of information to demonstrate reductions in CSA or PSB are encouraged to consider additional, supplemental sources, such as self-report surveys.

As an additional measure of effectiveness, applicants are encouraged to measure proximal outcomes (e.g., decreases in risk factors or increases in protective factors for engaging in CSA or PSB, changes in social norms or attitudes around CSA or PSB).

Proposals must provide a clear, well-supported theory of change (ToC) narrative that describes the hypothesized causal relationships between the program or policy, any proposed proximal outcomes (e.g., risk and protective factors), and the primary, behavioral outcome of CSA perpetration/victimization or engaging in/experiencing PSB. See ToC examples in Leviton et al. (2010), Lipsey (1993), and W. K. Kellogg Foundation (2004). Even programs and policies which were not originally developed to have an impact on CSA or PSB specifically (e.g., programs originally designed to prevent other forms of violence, policies providing economic supports for families) must be explicated via a ToC for the purposes of the proposed project.

Applicants must elaborate on the following aspects of their selected program or policy and the evaluation design, as well as other features of their proposed projects that will assist peer reviewers in understanding the potential impact of their work.

- Describe how the proposed project aligns with one of the three research priorities of this funding opportunity.
- The selected approach should have theoretical and empirical support to suggest that the program or policy may be effective in the primary prevention of CSA or PSB.
- The approach should be described in detail, including the current status and, if relevant, plans for adaptation. Details might include background information on the development of the approach; when and where the approach has been implemented in the past and currently; population(s) of interest; any data to support preliminary evidence; and how the 4-year period of performance will allow for measurement of the primary outcome of reducing or preventing CSA perpetration/victimization or engaging in/experiencing PSB, as well as any proposed proximal outcomes (e.g., decreases in risk factors, increases in protective factors).

- If an applicant proposes to adapt a program or policy for a new population, the applicant should provide a strong and detailed plan for how the program or policy will be adapted **and** evaluated during the four-year study period.
- Describe at which level of the social-ecological model the approach will be implemented (i.e., individual, relational, community, and societal) and intended reach (e.g., population, geographic region). Relatedly, describe the level(s) at which the approach and the CSA or PSB outcomes will be measured (e.g., national, state, organization, tribal and local). For example, a local program or policy should be evaluated at the local level only. A state-level approach could be evaluated at the state or local level. A federal-level approach could be evaluated at national, state, or local levels.
- Clearly define how the primary outcome (reducing or preventing CSA perpetration/victimization or engaging in/experiencing PSB) and any proposed proximal outcomes (e.g., risk and protective factors) will be measured. Document at what frequency outcomes will be measured and how CSA or PSB outcomes will be presented separately (either descriptively or via stratification) for different sociodemographic variables, such as gender identity, age, or race/ethnicity.
- Describe any potential unintended or adverse consequences of the approach you propose to evaluate, including potential differential impacts for groups with certain demographic or social characteristics.

Process Evaluation

Applicants are encouraged to evaluate the implementation of the program or policy thoroughly, including cost measures, when applicable. This will improve future economic evaluations, offering a clearer view of the effectiveness and value of the chosen approach. Applicants are strongly encouraged to measure any unintended consequences and examine the differential impacts on different groups, if applicable, to ensure a comprehensive understanding of the approach's purpose and effects.

Rigorous Evaluation Designs

For the purposes of this research opportunity, required rigorous evaluation designs include those that utilize experimental designs (i.e., randomized controlled trials) or quasi-experimental designs (e.g., comparative interrupted time series design with multiple time points, difference-in-difference with multiple time periods, instrumental variable methods, regression discontinuity, regression point displacement, stepped wedge, propensity-score matching, matched comparison groups). Applicants may 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.

Data Collection, Acquisition, and Analysis

Applicants must identify and describe appropriate data sources and provide evidence of their ability to acquire or collect data of sufficient quantity and quality to conduct a rigorous evaluation. Applications should clearly describe and justify the proposed sampling methods, sample size, power estimates, and data collection methods for the primary outcome of reductions in CSA or PSB perpetration or victimization and any proposed proximal outcomes and secondary measures. The timeline for data acquisition (requests for extant data or primary data collection) must be specified. Appropriate data sources will vary by the approach selected, the

exact specification of the CSA or PSB outcome measure and the evaluation design. The CSA or PSB outcome(s) can be measured at or below the level at which the program was implemented (e.g., national, state, organization, local). For example, a local program or policy should be evaluated at the local level only. A state-level approach could be evaluated at the state or local level. A federal-level approach could be evaluated at national, state, or local levels. Applicants must also identify the population of interest (e.g., teachers or students in a certain school, coaches or young athletes in a YSO, caregivers or children in a community), and the data sources available or collected for the purposes of this project (e.g., administrative, survey, surveillance, hospital or emergency departments, detention facilities).

Population of Focus

CSA and PSB affect children under age 18 years, their family and friends, and society at large. CSA and PSB are adverse childhood experiences (ACEs) with numerous serious consequences. The main intended outcome of the rigorous evaluation supported by this funding opportunity is reducing and preventing CSA and PSB. Children under the age of 18 years may be directly (through programs implemented during the funding period) or indirectly (through policies that focus on CSA and PSB beyond the individual- or family-level) affected by this research.

Identification of groups at disproportionate risk of experiencing CSA or PSB is encouraged for this evaluation and may illuminate effective approaches to reduce risk caused by socioeconomic, geographic, or other conditions. Populations at disproportionate risk of experiencing CSA or PSB include, but are not limited to, girls; youth from racial ethnic minority groups; youth with disabilities; youth experiencing homelessness; immigrant and refugee youth; youth from sexual and gender minority groups; and youth who are from multiple disproportionately impacted communities.

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

For all applications, it is anticipated that the applicant organization and the principal investigator (PI) will provide the necessary scientific and technical leadership to carry out the proposed research for the duration of the project. The Research Strategy section of the application, along with the SF-424 Research and Related Budget, should reflect the organization's leadership and engagement for the full period of performance. It is expected that for all applications, the majority (60% or greater) of the proposed research work plan, as evidenced by the proposed budget, will be directly carried out by the applicant organization throughout the entirety of the period of performance. The applicant organization must not act merely as a "pass through" to fund another entity to conduct most of the research or to provide the essential scientific or technical leadership needed to complete the project.

Applicants are highly encouraged to meaningfully involve communities, including state and/or local health departments, local government agencies, businesses, tribal nations, and/or community and youth organizations and community members with lived experience. The application must distinctly outline the roles and responsibilities of each partner. This includes proof of the applicant's access to the intended data sources and study populations as well as all necessary partnerships to carry out the proposed project. The applicant must delineate the nature and scope of the partnership, including the duties of the Principal Investigator(s) and partner

entities, the current working relationship, research plans, the level of involvement from both the applicant institution and the partner, the partner's work scope, and how the partnership will facilitate the execution and continuity of the proposed evaluation. Additionally, the Research Strategy must comprehensively outline all data sources and the established partnerships that will ensure data availability for all intended analyses within the period of performance.

Each partnering entity's roles and responsibilities must be validated with a signed Data Sharing Agreement, Letter of Support (LOS), or Memorandum of Understanding (MOU). These documents must detail the partner's commitment to resources, time, and personnel for the proposed research. Applications lacking a signed Data Sharing Agreement, Letter of Support, or Memorandum of Understanding from each partner may not be recommended for funding (refer to *Section V. Application Review Information, 4. Review and Selection Process*).

This NOFO aims for diversity among applicant institutions, research investigators, and partnering organizations to ensure research experiences and outcomes benefit all segments of the population and social ecology. Applicant organizations from or conducting research in collaboration or partnership with institutions that have a demonstrated record of or historical commitment to serving underrepresented students, including students from racial and ethnic minority groups, 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 supports the involvement of early-stage investigators on the SF-424 Senior/Key Personnel research team to foster experience and expertise in violence prevention research.

Demonstration of Necessary Skills and Experience

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 or mentorship roles into their research activities should describe the plans for the recruitment, training, and supervision of trainees/mentees and the ongoing quality assurance of their scientific products.

Evaluation/Performance Measurement

Applicants are expected to rigorously evaluate a program or policy for its effectiveness on the primary prevention of CSA or PSB; therefore, most of the application should be dedicated to describing the approach proposed for rigorous evaluation, the evaluation plan, and measurement issues. A detailed project workplan and timeline should describe the project’s recruitment, implementation, data acquisition, and management goals and processes. The applicant should include a discussion of how unanticipated delays or adverse events of any kind will be handled. Applicants must measure the primary outcome of reductions in CSA perpetration/victimization or engaging in/experiencing PSB and are also encouraged to measure proximal outcomes. Applicants are also encouraged to examine aspects of the primary prevention approach, such as implementation and cost, as well as the effectiveness of the approach by groups at disproportionate risk of experiencing CSA or PSB or engaging in these behaviors.

Translation Plan

The application is expected to clearly describe the potential for widespread dissemination, implementation, and sustainability of the proposed program or policy. Research findings should be disseminated through publications, including articles in peer reviewed scientific journals, and "Research Briefs" for diverse audiences, as well as presentations at professional conferences and in institutional and community-based venues. The translation plan should include a description of how findings may be used to promote, enhance, or advance translation of the research into practice or to inform public health policy and practice. This description 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 describe how these findings can guide future research or related activities, and recommendations for translation. The description should include how results of this project could be generalized to populations and communities outside of the study or how findings could be used to inform adaptations of the program or policy for other populations. The application should include plans to inform communities affected by the research about the proposed study and describe how research outcomes will support or enhance the prevention practice efforts of communities and/or practitioners.

Applicants should also include plans to appropriately document the program or policy implementation methods as well as lessons learned to facilitate future replication in another research or non-research setting if the prevention strategy is found to be effective. These plans may include but are not limited to identifying the core components of the program or policy and documenting lessons learned from the study that might inform decisions about future adaptation or modification of the strategy for other settings or populations.

Grant recipients may be required to attend one reverse site visit per year in Atlanta 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:
$4,800,000
The maximum award amount will be $400,000 per award for the first 12 month budget period. This includes both direct and indirect costs. An applicant may request a period performance of up to four years. The maximum total project funding amount is $1,600,000 (including both direct and indirect costs) over the expected period of performance, with a maximum of $400,000 per award per budget period. The period of performance for this award is expected to run from 9/30/2025 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:
$400,000
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*

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

1. Applicants must include a SF-424 Biographical Sketch for the contact Principal Investigator (PI) or Co-Investigator (Co-I) that documents expertise in conducting empirical research with direct relevance to child sexual abuse (CSA), problematic sexual behavior (PSB), or other violence prevention-related research. The knowledge, experience, and expertise necessary must be documented with at least one first-authored, peer-reviewed journal publication as defined by the NIH National Library of Medicine, in the relevant area of violence prevention OR by serving as a principal investigator on a research grant in this area of violence prevention. Experience requirements may be demonstrated through the combined experiences of the PI or Co-I(s) (if applicable). The citation of the relevant publication(s) and/or research experience must be clearly identified (by bold text or highlight) in the appropriate SF-424 Biographical Sketch. **Applications that do not meet this requirement will be considered nonresponsive and will not be forwarded for peer review.**
2. The proposed budget for each fiscal year must be less than or equal to the budget ceiling of $400,000 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.**

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 organizations may submit multiple applications to this NOFO, provided each is scientifically distinct. To prevent duplication, project titles must be unique. However, institutions may only submit one application per contact PD/PI. Only one application for each contact PD/PI will be considered for 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 in Grants.gov, will be reviewed. Applicants must withdraw any duplicate applications before the review date.

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

Due Date for Letter Of Intent 11/01/2024

11/01/2024
While a letter of intent is not mandatory, nor is it binding or part of the subsequent application review, it does help NCIPC staff in preparing for the peer review of scientific and technical merit. By the date specified in *Part 1. Overview Information*, interested applicants are encouraged to submit a letter of intent containing the following details:

- Descriptive title of the proposed research
- The objective(s) the application will address

- A brief description (one to two paragraphs) of the proposed research, including its objectives
- Contact information of the Principal Investigator/Project Director (name, address, and telephone number)
- Names of all other Senior/Key Personnel
- Names of all participating institutions
- The number and title of this funding opportunity

The letter of intent should be sent electronically to:

Aisha Wilkes
Scientific Review Official
National Center for Injury Prevention and Control (NCIPC)
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.

Applicants should develop and include, as part of the application's Resource Sharing Plan section of the PHS 398 Research Plan Component, a data management plan that meets the requirements of AR-25 using their own template. Award recipients funded under this NOFO will be required to use NCIPC's Data Management Plan Template, OMB NO: 0920-1301 and to make revisions to the DMP as required during the award's period of performance.

6. Appendix

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

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

7. Page Limitations

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

- If successfully completed, to what extent will the proposed activities advance current knowledge and build the evidence base of the effectiveness of programs and policies to prevent CSA or PSB?
- To what extent does the applicant describe the need to evaluate the policy or program (e.g., it has not been previously evaluated; shows promise of reducing CSA or PSB)?
- To what extent, does the application include a plan to consider and advance health equity at multiple stages of the research process? Examples include but are not limited to: actively seeking feedback from members of the community on data collection tools and

interpretation of results; presenting results separately (descriptively or via stratification) for groups with different demographic characteristics; collecting necessary data; and considering future translation and adaptation of effective program elements to different populations.

- To what extent will the proposed project address the needs of communities at disproportionate risk of experiencing CSA or PSB (including but not limited to girls; youth from racial and ethnic minority groups; youth with disabilities; youth experiencing homelessness; immigrant and refugee youth; youth from sexual and gender minority groups; and youth from disproportionately impacted, underrepresented, or marginalized communities)?

Investigator(s)

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

- To what extent do the PI/Co-I Team have sufficient prior experience and knowledge in conducting rigorous outcome evaluations consistent with that which is proposed in the application?
- To what extent does the PI or Co-I have sufficient prior experience and knowledge in conducting CSA or PSB prevention or other violence-prevention-related research consistent with that which is proposed in the application?
- To what extent does the applicant or its collaborators/partner organizations (if any) have the experience to implement CSA or PSB prevention programs or implement or evaluate policies that are relevant to the proposed population and setting that will be the focus of the research?
- To what extent is there evidence of past collaboration with the proposed research team to support the success of the proposed research?

Innovation

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

- Does the research approach focus on **preventing adults from perpetrating CSA or preventing youth from engaging in PSB**? Applicants that propose to evaluate approaches to increase the capacity of children to reduce or prevent their own victimization (e.g., via educational programs teaching children to recognize, resist, and report abuse) does not fit the scope of this project.
- To what extent does the research approach go beyond individual-level factors and address community, social and structural factors that can increase or reduce risk for CSA perpetration/victimization or engaging in/experiencing PSB?

- To what extent is the proposed research innovative (e.g., propose use of novel data sources and/or methodology to address research questions).

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 primary prevention program or policy align with one of the three research priorities outlined in the NOFO? Applications must propose to evaluate **primary prevention approaches**, meaning approaches designed to prevent CSA or PSB before they occur. For purposes of this NOFO, **primary prevention does not include** programs or policies that: 1) focus on increasing or improving reporting CSA or PSB behavior policies; 2) use criminal justice approaches (e.g., policing, arrest, trial, sentencing, incarceration, mandated interventions and treatment strategies); 3) prevent CSA re-offending; 4) provide therapy for adults who perpetrate CSA, youth who engage in PSB, youth who have experienced CSA or PSB, or their families; and/or 5) focus on preventing PSB solely or primarily in the specific context of dating/romantic relationships (i.e., teen dating violence [TDV] or intimate partner violence [IPV]).To what extent does the proposed program or policy have a strong theoretical and empirical basis?
- To what extent does the proposed research describe an appropriate and rigorous evaluation strategy for assessing effectiveness of the selected approach on CSA or PSB outcomes? Applications must propose to measure and evaluate outcomes of CSA perpetration/victimization or engaging in/experiencing PSB.
- To what extent does the program model clearly describe the hypothesized relationships between the approach, any proposed proximal outcomes (e.g., decreases in risk factors, increases protective factors), and the primary outcome of reducing or preventing CSA perpetration/victimization or engaging in/experiencing PSB?
- To what extent does the applicant appropriately anticipate, conceptualize, and measure the intended and potential unintended outcomes relevant to the study proposed?
- To what extent does the applicant demonstrate the ability to access the necessary data for the evaluation (e.g., health data or community/societal level data)? Are these data appropriate for documenting the research and likely to show the expected changes in outcomes in the time available?
- To what extent is the proposed study feasible?

- To what extent is the timeline sufficiently detailed, complete, and realistic for a four-year period of performance?
- If a policy or program is still in development or will be adapted for a new population, to what extent does the applicant provide a strong and detailed plan for how they will accomplish the rigorous evaluation in addition to completing these developmental activities in the four-year period of performance?
- To what extent does the application describe working collaboratively and in equitable partnership with communities and community members at disproportionate risk of experiencing violence to create a plan for disseminating findings with communities affected by the research?

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 the partnerships that are necessary to complete the proposed project supported by letters of support (LOS) or memoranda of understanding (MOU)?
- To what extent is the described nature of and extent of each entity's involvement sufficient for the successful completion of the rigorous evaluation of the proposed program or policy?

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/VASchecklist.pdf).

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

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

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

3. Additional Review Considerations

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

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:

- Consideration for meritorious applications that contribute to a diverse mix of approaches in proposed research to address CSA/PBS as evidenced by the Research Strategy section of the application's research plan.
- Consideration for meritorious applications that contribute to a geographic balance of proposed projects, as evidenced by the congressional district of the applicant organization, to broaden the distribution of awards.
- Consideration for applicant organizations from or conducting research in collaboration or partnership with institutions that have a demonstrated record of or historical commitment to serving underrepresented students, including racial and ethnic minorities, individuals from disadvantaged backgrounds and individuals with disabilities. Applicants may indicate this in the Research Strategy section of their application.
- Consideration for applications in which the contact Eligible PD/PI meets NIH Early Stage Investigator (ESI) status, as verified by the NIH Determination of Investigator Status process.

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.

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/additionalrequirements/index.html

Additional CDC Award Requirements

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

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

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

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

3. Additional Policy Requirements

The following are additional policy requirements relevant to this NOFO:

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

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

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

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

Copyright Interests Provision: This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. 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:

- Complying with the responsibilities for the Extramural Investigators as described in the Policy on Public Health Research and Non-research Data Management and Access https://www.cdc.gov/grants/additionalrequirements/ar-25.html
- Designing and conducting research to address the described research objectives of this cooperative agreement.
- Undertaking any data collection solely to meet the applicant’s research needs. Retaining custody of and exercising primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and CDC policies.
- Partnering effectively with any outside entities expected to participate in the proposed research. Such partnerships should be well-defined and documented by letters of support or Memoranda of Understanding detailing the nature and extent of involvement.
- Establishing goals and objectives that are realistic, measurable, and time-oriented for all phases of the project.
- Developing a research protocol involving human subjects for Institutional Review Board (IRB) review and approval by all cooperating institutions participating in the research project, including CDC if applicable.
- Assuring that IRB approvals are current for research involving human subjects for all participating sites.
- Considering suggestions from CDC on the design and implementation of research and the analysis, interpretation, and dissemination of study findings.
- Developing, designing, and piloting research protocols and instruments; recruiting participants; and conducting appropriate data management procedures.
- Analyzing data and disseminating findings in peer-reviewed journals and presentations at scientific conferences and other meetings.

- Requesting consultation and technical assistance from CDC, as needed. Considering suggestions from CDC on the design and implementation of research and the analysis, interpretation, and dissemination of study findings.
- Collaborating with CDC in translating and disseminating research findings.
- Participating in an initial kick-off meeting with CDC by phone or in Atlanta.
- Participating in one reverse site visit with CDC in Atlanta on an annual basis to review the project's progress with CDC scientists and staff.
- Developing and implementing a plan for sharing research resources and data with other collaborating partners, the agency, the public, and scientific community. The PI is responsible for developing and updating a data management plan that identifies the level of data access and plans for data sharing.

CDC staff 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:

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

Areas of Joint Responsibility include:

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

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

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.

Annual Reporting Requirements

The Annual Report should include:

- A description of the completion status of each Specific Aim and/or research objective or milestone for the budget period.
- A complete list of the publications planned or completed to date - including status (e.g., published [include reference], in review, under development).
- A description of any changes made in the use of human subjects or IRB approval status.
- A description of any changes made in the Data Management Plan. Award recipients funded under this NOFO will be required to use NCIPC's Data Management Plan Template, OMB NO: 0920-1301 and 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
Joyce Dieterly
National Center for Injury Prevention and Control (NCIPC)
Email: NCIPC_ERPO@cdc.gov

Peer Review Contact
Aisha Wilkes
National Center for Injury Prevention and Control (NCIPC)
Email: awilkes@cdc.gov

Financial/Grant Management Contact(s)
Angie Willard

Grants Management Specialist
CDC Office of Grants Services
Email: awillard@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.