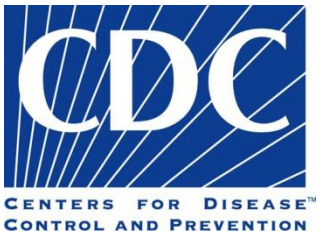

Centers for Disease Control and Prevention

NATIONAL CENTER FOR INJURY PREVENTION AND CONTROL

Evaluating Practice-based Programs, Policies, and Practices from CDCs Rape Prevention and Education (RPE) Program: Expanding the Evidence to Prevent Sexual Violence

RFA-CE-20-001

12/16/2022

Table of Contents

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

Evaluating Practice-based Programs, Policies, and Practices from CDCs Rape Prevention and Education (RPE) Program: Expanding the Evidence to Prevent Sexual Violence

Activity Code

Applications in response to this NOFO will be funded using the U01 activity code for a cooperative agreement.

Cooperative agreements are an assistance 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.

Notice of Funding Opportunity Type

Reissue of RFA-CE-20-001

Agency Notice of Funding Opportunity Number

RFA-CE-20-001

Assistance Listings Number(s)

93.136

Category of Funding Activity

HL - Health

NOFO Purpose

The CDC's *STOP SV: A Technical Package to Prevent Sexual Violence* outlines the best available evidence for sexual violence prevention and is used by state and local health departments participating in CDC's Rape Prevention and Education (RPE) Program to develop and implement programs, policies and practices to prevent sexual violence.

This NOFO seeks proposals to support research to rigorously evaluate the effectiveness of primary prevention programs, policies, or practices implemented by RPE programs to prevent sexual violence. Research funded under this announcement is intended to expand the evidence base for sexual violence prevention in one or more of the following strategy areas identified in the *STOP SV* technical package: *Promote Social Norms that Protect Against Violence, Provide Opportunities to Empower and Support Girls and Women,* and *Create Protective Environments.* Research conducted with these funds will rigorously evaluate practice-based prevention approaches (i.e., programs, policies, or practices being implemented in the field or that are planned to be implemented by an RPE-funded organization or partner) to increase the evidence for sexual violence prevention programs, policies, or practices that have traction within the sexual violence field and are, therefore, feasible to implement by practitioners and acceptable to communities. Research aimed at building evidence at the community- or societal-levels and/or for populations and communities that disproportionately bear the burden of sexual violence is of particular interest under this announcement.

This Notice of Funding Opportunity (NOFO) covers a five (5) year program plan consisting of Component A and Component B. Component A has a 3-year project period. During Component A up to six recipients will work with one or more state or local RPE programs to develop a partnership and build capacity for the proposed research study. Activities to be conducted in Component A include, but are not limited to, finalize the research evaluation plan, collect or secure baseline data, and conduct formative research. If applicable, recipients can conduct a pilot study on the feasibility of the proposed research approach to generate practice-based evidence from the program, policy, or practice to be evaluated (funded under RFA-CE19-1902, *Rape Prevention and Education: Using the Best Available Evidence for Sexual Violence Prevention*). **During the third (final) year of Component A, all of the initial recipients (from this announcement, RFA-CE20-001) will be invited to submit an application and compete for additional funding under Component B.** During Component B, up to four (4) recipients will be funded for a 2-year project period to complete a full-scale rigorous evaluation, leveraging successful completion of milestones met during Component A.

The purpose of this second amended NOFO is to clarify the application submission process and the process to be used to review all Component B applications to this NOFO. The application to the amended NOFO for Component B should clearly describe the current research plan to conduct the rigorous evaluation expected of Component B informed by the results of the activities conducted to date for Component A.

Modifications made in this amended version of the NOFO are shown in highlighted text. Applicants are strongly encouraged to review the entire NOFO prior to developing or submitting an application.

Applications for RFA-CE-20-001 Component B funding must be submitted as Type 3 Competing Revision applications. Applicants should ensure to include their existing grant number in Column 4a

Key Dates

Publication Date:

To receive notification of any changes to RFA-CE-20-001, 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:

10/28/2022

A letter of intent is requested by **October 28, 2022**. Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows CIO staff to estimate the potential review workload and plan the review.

Application Due Date:

12/16/2022

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

02/15/2023

This is an estimated date.

Secondary Review:

04/12/2023

This is an estimated date.

Estimated Start Date:
09/30/2023
This is an estimated start date.

Expiration Date:
01/02/2023

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 20 pages.

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

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

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

Executive Summary

The CDC's *STOP SV: A Technical Package to Prevent Sexual Violence* outlines the best available evidence for sexual violence prevention and is used by state and local health departments participating in CDC's Rape Prevention and Education (RPE) Program to develop and implement programs, policies and practices to prevent sexual violence.

This NOFO seeks proposals to support research to rigorously evaluate the effectiveness of primary prevention programs, policies, or practices implemented by RPE programs to prevent sexual violence. Research funded under this announcement is intended to expand the evidence base for sexual violence prevention in one or more of the following strategy areas identified in the *STOP SV* technical package: *Promote Social Norms that Protect Against Violence, Provide Opportunities to Empower and Support Girls and Women,* and *Create Protective Environments.* Research conducted with these funds will rigorously evaluate practice-based prevention approaches (i.e., programs, policies, or practices being implemented in the field or that are planned to be implemented by an RPE-funded organization or partner) to increase the evidence for sexual violence prevention programs, policies, or practices that have traction within the sexual violence field and are, therefore, feasible to implement by practitioners and acceptable to communities. Research aimed at building evidence at the community- or societal-levels and/or for populations and communities that disproportionately bear the burden of sexual violence is of particular interest under this announcement.

This Notice of Funding Opportunity (NOFO) covers a five (5) year program plan consisting of Component A and Component B. Component A has a 3-year project period. During Component A up to six recipients will work with one or more state or local RPE programs to develop a

partnership and build capacity for the proposed research study. Activities to be conducted in Component A include, but are not limited to, finalize the research evaluation plan, collect or secure baseline data, and conduct formative research. If applicable, recipients can conduct a pilot study on the feasibility of the proposed research approach to generate practice-based evidence from the program, policy, or practice to be evaluated (funded under RFA-CE19-1902, *Rape Prevention and Education: Using the Best Available Evidence for Sexual Violence Prevention*). During the third (final) year of Component A, all of the initial recipients (from this announcement, RFA-CE20-001) will be invited to submit an application and compete for additional funding under Component B. During Component B, up to four (4) recipients will be funded for a 2-year project period to complete a full-scale rigorous evaluation, leveraging successful completion of milestones met during Component A.

Modification Purpose
The purpose of this second amended NOFO is to clarify the application submission process and the process to be used to review all Component B applications to this NOFO. The application to the amended NOFO for Component B should clearly describe the current research plan to conduct the rigorous evaluation expected of Component B informed by the results of the activities conducted to date for Component A.

Modifications made in this amended version of the NOFO are shown in highlighted text. Applicants are strongly encouraged to review the entire NOFO prior to developing or submitting an application.

Applications for RFA-CE-20-001 Component B funding must be submitted as Type 3 Competing Revision applications. Applicants should ensure to include their existing grant number in Column 4a.

Mechanism of Support: U01; Research Cooperative Agreement

Funds Available and Anticipated Number of Awards: NCIPC intends to commit approximately $2,250,000 (direct and indirect costs) in FY2020 to support up to six (6) applications for this NOFO for a three-year project period (Component A). During the third (final) year of the Component A project period, all of the initial recipients (from this announcement, RFA-CE20-001) will be invited to submit a Component A Progress Report / Component B Application for a competitive review. Up to four of the most meritorious Component A Progress Report / Component B Applications will be selected for additional funding for a two-year project period to complete the proposed research (Component B). During Component B, NCIPC intends to commit approximately $2,250,000 (direct and indirect) per year for the 2-year project period.

The total funding and the number of awards is contingent upon availability of funds and a sufficient number of meritorious applications.

NCIPC intends to commit approximately $2,250,000 (direct and indirect costs) in FY2023 to support up to four (4) applications for this NOFO for a two-year project period (Component B).

The total funding and number of awards for Component B is contingent upon availability of

funds and a sufficient number of meritorious applications.

Budget and Project Period: Component A; the maximum total funding for a single 12-month budget period (three-year project period) is $375,000 (direct and indirect) per award.

Component B; the maximum total funding for a single 12-month budget period (two-year project period) is $562,500 (direct and indirect) per award.

The submitted application may request a project period of up to 3 years for Component A. The maximum total project funding is $1,125,000 (direct and indirect) per award, over the three-year project period (Component A). For applicants selected for Component B the maximum total project funding for the two-year project period is $1,125,000 per award. The initial application should include the budgets for both Component A and Component B.

Throughout the project period, CDC's commitment to continuation of awards will be conditional on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), scientific and technical merits of the competitive application to complete the research for the final two years, and the determination that continued funding is in the best interest of the Federal government.

This amended NOFO is focused on Component B. For Component B, the maximum total funding for a single 12-month budget period (two-year project period) is $562,500 (direct and indirect) per award. The submitted application may request a project period of up to 2 years. The maximum total funding for Component B is $1,125,000 (direct and indirect) per award, over the two-year project period. The application to this amended NOFO must include budgets for both years of the two-year project period.

Application Research Strategy Length: Page limits for the Research Strategy are clearly specified in Section IV, Application and Submission Information in this Notice of Funding Opportunity (NOFO).

Eligible Institutions/Organizations: Institutions/organization listed in Section III.1 are eligible to apply.

Eligible Project Directors/Principal Investigators (PDs/PIs): Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. NOTE: CDC does not make awards to individuals directly.

Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply.

The application must clearly document that the Project Director/Principal Investigator or Co-Investigator has expertise in conducting rigorous outcome evaluations, as evidenced by at least one relevant first-authored, peer-reviewed journal article. The relevant publication(s)

demonstrating evidence of expertise must be clearly identified in SF 424 Biographical Sketch of the appropriate personnel by highlight or bold text.

Number of PDs/PIs: Co-principal investigators are allowed for the announcement; their names must appear on the face page of the application. However;

- One (1) principal investigator must be designated as the contact PI for all correspondence related to the application.
- All PD/PIs must include their eRA Commons Identification in the Credential Field of the Senior/Key Person Profile Component of the SF 424 (R&R) Application Package.
- Institutions/organizations proposing multiple PDs/PIs must visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF 424 (R&R) Application Guide.

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

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

Application Type: Type 3 Competing Revision. The applications for Component B funding must be submitted as Type 3 Competing Revision applications.

Special Dates

A pre-application call will not be conducted for this amended NOFO. Potential applicants are encouraged to submit their questions via email to **NCIPC_ERPO@cdc.gov.** A redacted version of all questions received by **October 14, 2022** and the response will be published on the Grants.gov link for this NOFO by **October 21, 2022**.

Application Materials: See Section IV.1 for application materials.

Section I. Funding Opportunity Description

Statutory Authority

Sections 301(a) of the Public Health Service Act, 42 U.S.C. 241(a) and 391(a) of the Public Health Service Act, 42 U.S.C. 280b(a).

1. Background and Purpose

An estimated 1.5 million women are raped each year in the U.S. with approximately 25.5 million women and 2.8 million men reporting a lifetime experience of completed or attempted rape

(Smith et al., 2018). In addition, 43.6% of women (nearly 52.2 million) and nearly a quarter of men (24.8% or 27.6 million) have experienced some form of contact sexual violence in their lifetime (Smith et al., 2018). The CDC defines sexual violence as a sexual act that is committed or attempted by another person without freely given consent of the victim or against someone who is unable to consent or refuse, including forced or alcohol/drug facilitated penetration, making a victim penetrate a perpetrator or someone else, non-physically pressured unwanted penetration; unwanted sexual touching; or unwanted non-contact acts of a sexual nature (Basile, Smith, Breiding, Black, & Mahendra, 2014).

Rape and other forms of sexual violence are preventable. Recognizing this, Congress passed the Violence Against Women Act in 1994. This landmark legislation established the Rape Prevention and Education (RPE) Program at CDC. The goal of the RPE Program is to strengthen sexual violence prevention efforts at the local, state, and national level. CDC funds health departments in all 50 states, the District of Columbia, Puerto Rico, and four U.S. territories (http://www.cdc.gov/violenceprevention/rpe/states.html) to work with rape crisis centers, state sexual assault coalitions, and others to advance sexual violence prevention. RPE recipients are currently engaged in implementing prevention strategies that are culturally relevant and based on the best available evidence for sexual violence prevention. The RPE Program encourages the development of comprehensive prevention strategies through a continuum of activities that address all levels of the social ecological model (http://www.cdc.gov/violenceprevention/overview/social-ecologicalmodel.html). The model considers the complex interplay between individual, relationship, community, and societal factors, and addresses risk and protective factors from multiple domains.

This announcement seeks proposals to support research to rigorously evaluate the effectiveness of primary prevention programs, policies, or practices implemented by CDC-funded RPE programs (funded under RFA-CE19-1902) to prevent sexual violence. Research funded under this announcement (RFA-CE20-001) is intended to expand the evidence base for sexual violence prevention in the following strategy areas identified in the *STOP SV* technical package: *Promote Social Norms that Protect Against Violence, Provide Opportunities to Empower and Support Girls and Women,* and *Create Protective Environments.* Currently, CDC is funding health departments in all 50 states, the District of Columbia, Puerto Rico, and four U.S. territories under RFA-CE19-1902; *Rape Prevention and Education: Using the Best Available Evidence for Sexual Violence Prevention.* The health departments receiving this funding are implementing programs, policies, and practices identified within the CDC's *STOP SV: A Technical Package to Prevent Sexual Violence*.

This Notice of Funding Opportunity (NOFO) covers a five (5) year program plan consisting of Component A and Component B. Component A has a 3-year project period. During Component A up to six recipients will work with one or more state or local RPE programs to develop a partnership and build capacity for the proposed research study. Activities to be conducted in Component A include, but are not limited to, finalize the research evaluation plan, collect or secure baseline data, and conduct formative research. If applicable, recipients can conduct a pilot study on the feasibility of the proposed research approach to generate practice-based evidence from the program, policy, or practice to be evaluated (funded under RFA-CE19-1902, *Rape*

Prevention and Education: Using the Best Available Evidence for Sexual Violence Prevention). During the third (final) year of Component A, all of the initial recipients (from this announcement, RFA-CE20-001) will be invited to submit an application and compete for additional funding under Component B. During Component B, up to four (4) recipients will be funded for a 2-year project period to complete a full-scale rigorous evaluation, leveraging successful completion of milestones met during Component A.

Background for the CDC-Funded Rape Prevention and Education (RPE) Program

For the purposes of this announcement, "RPE recipients" are funded under RFA-CE19-1902; *Rape Prevention and Education: Using the Best Available Evidence for Sexual Violence Prevention, and* are implementing programs, policies, and practices identified within the CDC's *STOP SV: A Technical Package to Prevent Sexual Violence*. The *STOP SV* technical package outlines five strategies representing directions or actions to achieve the goal of preventing sexual violence (Basile et al., 2016). Each strategy outlines approaches to advance the strategy through specific programs, policies, and practices. The following three strategies are of particular interest for the purposes of this NOFO: The strategy ***Promoting Social Norms that Protect Against Violence*** focuses on changing social norms (i.e., group-level beliefs and expectations about how members of the group should behave) that accept or allow indifference to violence or represent restrictive gender norms. The strategy ***Provide Opportunities to Empower and Support Girls and Women*** emphasizes approaches that strengthen education, employment, and income outcomes in women and girls that have been established as protective factors against risk for sexual violence victimization. The strategy ***Create Protective Environments*** focuses on modifying characteristics of communities, such as changes to policies, institutional structures, or the social and physical environment, in order to create conditions that promote community protective factors and reduce risk for violence. More information about the approaches and existing evidence for each of these strategies can be found in *STOP SV: A Technical Package to Prevent Sexual Violence*, available on the CDC website (Basile et al., 2016; http://www.cdc.gov/violenceprevention/pdf/sv-prevention-technical-package.pdf).

RPE recipients funded under the RFA-CE19-1902 programmatic cooperative agreement are expected to implement community-level strategies (representing between 50-75% of total strategies being implemented) that have the greatest potential for impact on rates of SV perpetration and victimization. *Community-level strategies* are defined as strategies that target the characteristics of ***settings*** that increase or buffer against the risk for violence, particularly the social, economic, and environmental characteristics of neighborhood, school, workplace, and other organizational settings (Dahlberg, 2018), as indicated by the outer levels of the social ecological model (DeGue, Hipp, & Herbst, 2016). In contrast, *community-based strategies* are implemented in community settings but target change in individual-, peer-, or other proximal relationship and family-level factors (e.g., conflict resolution skills, parenting skills, personal attitudes, knowledge about violence, bystander behaviors). *Communities* are defined as formal or informal organizations or geographical settings in which social relationships occur (e.g., neighborhoods, cities, states, etc.; Dahlberg & Krug, 2002). Communities may include any defined population with shared characteristics, risk/protective factors, and potential for exposure to the program, policy, or practice. Research aimed at building evidence at the community-level is of particular interest under this announcement.

RPE recipients funded under RFA-CE19-1902 are also implementing approaches aimed at addressing health disparities including, but not limited to, race, ethnicity, gender identity, biological sex, sexual orientation, geography, socioeconomic status, disability status, primary language, and health literacy. The CDC's Division of Violence Prevention has outlined a strategic vision for preventing multiple forms of violence (CDC, 2016), which includes focusing on populations and communities that disproportionately bear the burden of violence. Identifying the needs, barriers, and supports that are necessary for preventing violence within populations and communities at heightened risk for violence has the potential to inform prevention efforts and produce greater impacts (CDC, 2016). However, limited evidence exists for program implementation within diverse populations (e.g., racial/ethnic or sexual and gender minorities). Rigorous evaluation of programs, policies, or practices that have been tailored and designed to meet the needs of communities experiencing a disproportionate burden of sexual violence can also fill important gaps in the evidence (Basile et al., 2016).

Background for the Research Gaps to be Addressed with this NOFO (RFA-CE20-001)

Although progress has been made in building the evidence-base for sexual violence prevention, many important gaps remain. The *STOP SV* technical package outlines the best available evidence, including examples of programs, policies, and practices with impact on risk and protective factors for sexual violence. However, there is still a need to evaluate the programs, policies, and practices that have impact on factors related to sexual violence to be sure they also have impact on sexual violence outcomes. In addition, there is a need to build the evidence at the community- and societal-levels and for populations and communities that disproportionately bear the burden of sexual violence. Communities require a broader and more comprehensive set of effective programs, policies, and practices that allow them to select approaches to meet their unique needs. The availability of a broad range of evidence-based strategies will also help move the field towards implementation of effective, multilevel approaches that address risk and protective factors across all levels of the social ecology and hold promise for reducing sexual violence at the population level (DeGue et al., 2012).

The CDC's National Center for Injury Prevention and Control's (NCIPC) research priorities for sexual violence prevention (http://www.cdc.gov/injury/pdfs/researchpriorities/cdc-injury-research-priorities.pdf) include evaluating the effectiveness of sexual violence prevention approaches that have substantial uptake in practice but lack evaluation research evidence. Research funded under this announcement is expected to add to the limited existing evidence base and address immediate and divergent needs in the field by rigorously evaluating practice-based approaches (i.e., programs, policies, or practices) for their impact on sexual violence outcomes. By practice-based approaches we mean programs, policies, or practices being implemented in the field or that are planned to be implemented by an RPE-funded organization or partner. Research to evaluate practice-based prevention approaches (i.e., programs, policies, or practices being implemented in the field) will increase the evidence for sexual violence prevention approaches that have traction within the sexual violence field and are, therefore, feasible to implement by practitioners and acceptable to communities.

Programs, policies, or practices that are designed to address one or more of the outer layers of the social ecological model (http://www.cdc.gov/social-ecologicalmodel.html) and/or address the needs of communities experiencing disproportionate burden of sexual violence (including, but not limited to, people with disabilities, non-English speaking populations, tribal populations, rural communities and other geographically underserved areas, sexual and gender minorities, and people with limited health literacy) are strongly encouraged.

Background for the Research Goals for this NOFO (RFA-CE20-001)

RPE recipients (funded under RFA-CE19-1902) are currently working with rape crisis centers, state sexual assault coalitions, various community organizations, and others to implement primary prevention programs, policies, or practices to reduce sexual violence. Programs, policies, and practices that are eligible for evaluation under this announcement include: 1) those that were developed by an RPE-funded organization or partner (i.e., sometimes called "homegrown" approaches) and are currently being implemented by an RPE-funded organization or partner; OR 2) those developed elsewhere in the field that are currently being implemented or planned to be implemented by an RPE-funded organization or partner. In addition, to expand the existing evidence base, eligible programs, policies, and practices include those that have not been or are not currently being rigorously evaluated for the primary prevention of sexual violence. Programs, policies, or practices that are planned to be implemented should be part of a CDC- or state-approved RPE work plan with a clearly selected strategy and an established timeline for initiating implementation. If the approach is planned for implementation by an RPE sub-recipient and not part of the CDC-approved RPE work plan, include the sub-recipient's approved work plan to provide more detailed documentation.

Of note, public health strategies are often characterized in terms of the timing of prevention: *primary* prevention approaches, which aim to prevent violence before it occurs; *secondary* prevention approaches, which focus on the more immediate responses to recent violence, such as victim treatment 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 rigorous evaluation of *primary* prevention approaches.

For the purpose of this announcement, rigorous evaluation designs are those that utilize experimental designs with random assignment to an intervention and control/comparison condition (e.g., randomized controlled trial [RCT], cluster RCT) or, when appropriate, quasi-experimental designs, such as interrupted time series or regression discontinuity, for strategies where random assignment is not possible due to implementation restrictions (e.g., evaluation of policy). In cases when a program, policy, or practice is already in place or is implemented outside the control of the investigators (e.g., natural experiment), applicants may propose to utilize an appropriately matched comparison group or other design that would maximize the ability to make causal inferences from the findings. Such designs may include regression discontinuity designs, interrupted time series designs, and instrumental variable approaches that allow for natural experiments and control for secular trends (Eccles, Grimshaw, Campbell, &

Ramsay, 2003). In these cases, the applicants should also describe plans to test the validity of their results through techniques like falsification tests, sensitivity analyses, and placebo tests (Athey & Imbens, 2017).

References:

Ackard, D. M., Eisenberg, M. E., & Neumark-Sztainer, D. (2007). Long-term impact of adolescent dating violence on the behavioral and psychological health of male and female youth. *Journal of Pediatrics, 151,* 476–481.

Athey, S., & Imbens, G.W. (2017). The state of applied econometrics: Causality and policy evaluation. *Journal of Economic Perspectives, 31(2)*, 3-32.

Basile KC, DeGue S, Jones K, Freire K, Dills J, Smith SG, Raiford JL. (2016). *STOP SV: A Technical Package to Prevent Sexual Violence*. Atlanta, GA: National Center for Injury Prevention and Control, Centers for Disease Control and Prevention.

Basile, K. C., Smith, S. G., Breiding, M. J., Black, M. C., & Mahendra, R. R. (2014). *Sexual violence surveillance: Uniform definitions and recommended data elements, Version 2.0*. Atlanta (GA): National Center for Injury Prevention and Control, Centers for Disease Control and Prevention.

Black, M.C. (2011). Intimate partner violence and adverse health consequences: Implications for clinicians. *American Journal of Lifestyle Medicine, 5*, 428-4

Campbell, J.C. (2002). Health consequences of intimate partner violence. *Lancet, 359*, 1331–1336.

Coker, A.L., Bush, H.M., Cook-Craig, P.G., DeGue, S.A., Clear, E.R., Brancato, C.J., et al. (2017). RCT testing bystander effectiveness to reduce violence. *American Journal of Preventive Medicine*, *52(5)*, 566-578.

Coker, A.L., Davis, K.E., Arias, I., Desai, S., Sanderson, M., Brandt, H.M., et al. (2002). Physical and mental health effects of intimate partner violence for men and women. *American Journal of Preventive Medicine, 23*, 260–268.

Centers for Disease Control and Prevention (2016). *Preventing Multiple Forms of Violence: A Strategic Vision for Connecting the Dots.* Atlanta, GA: Division of Violence Prevention, National Center for Injury Prevention and Control.

Dahlberg, L.L. (2018). *The Distinction between Community-based vs. Community-level Prevention: Implications for the Prevention of Sexual Violence.* Centers for Disease Control and Prevention and the National Sexual Violence Resource Center Regional Training Workshops for the Rape Prevention and Education Program Directors – April 24, 2018 (Atlanta, GA) and May 1, 2018 (Portland, OR).

Dahlberg, L. L., & Krug, E. G. (2002). Violence-a global public health problem. In E. G. Krug, L. L. Dahlberg, J. A. Mercy, A. B. Zwi, & R. Lozano (Eds.), *World report on violence and health* (pp. 1–56). Geneva, Switzerland: World Health Organization.

Damschroder, L.J., Aron, D.C., Keith, R.E., Kirsh, S.R., Alexander, J.A., & Lowery, J.C. (2009). Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implementation Science*, 4, 50.

DeGue S., Hipp T.N., Herbst J.H. (2016) Community-Level Approaches to Prevent Sexual Violence. In: Jeglic E., Calkins C. (eds) *Sexual Violence*. Springer, Cham

DeGue, S., Holt, M. K., Massetti, G. M., Matjasko, J. L., Tharp, A. T., & Valle, L. A. (2012). Looking ahead toward community-level strategies to prevent sexual violence. *Journal of Women's Health, 21*, 1-3.

Eccles, M., Grimshaw, J., Campbell, M., & Ramsay, C. (2003). Research designs for studies evaluating the effectiveness of change and improvement strategies. *Quality and Safety in Health Care, 12*(1), 47-52.

Edwards, K. M., Banyard, V. L., Sessarego, S. N., Waterman, E. A., Mitchell, K. J., & Chang, H. (2019). Evaluation of a bystander-focused interpersonal violence prevention program with high school students. *Prevention Science, 20(4)*, 488-498.

Espelage, D. L., Low, S., Polanin, J. R., & Brown, E. C. (2015). Clinical trial of Second Step© middle-school program: Impact on aggression & victimization. *Journal of Applied Developmental Psychology, 37*, 52–63.

Foshee, V. A., Bauman, K. E., Ennett, S. T., Linder, G. F., Benefield, T., & Suchindran, C. (2004). Assessing the long-term effects of the Safe Dates program and a booster in preventing and reducing adolescent dating violence victimization and perpetration. *American Journal of Public Health, 94*(4), 619–624.

Foshee, V. A., Bauman, K. E., Ennett, S. T., Suchindran, C., Benefield, T., & Linder, G. F. (2005). Assessing the effects of the dating violence prevention program "Safe Dates" using random coefficient regression modeling. *Prevention Science, 6*(3), 245-258.

Heise, L., & Garcia-Moreno, C. (2002). Violence by intimate partners (pp. 87-121). In E. Krug, L.L. Dahlberg, J.A. Mercy, A.B. Zwi, & R. Lozano (Eds), *World report on violence and health*. Geneva, Switzerland: World Health Organization.

Jewkes, R., Sen, P., & Garcia-Moreno, C. (2002). Sexual violence (pp. 213-239). In E. Krug, L.L. Dahlberg, J.A. Mercy, A.B. Zwi, & R. Lozano (Eds), *World report on violence and health*. Geneva, Switzerland: World Health Organization.

Leserman, J., & Drossman, D.A. (2007). Relationship of abuse history to functional gastrointestinal disorders and symptoms. *Trauma Violence and Abuse, 8*, 331–343.

Massetti, G.M., Holland, K.M., & Gorman-Smith, D. (2016). Implementation measurement for evidence-based violence prevention programs in communities. *Journal of Community Health, 41(4)*, 881-894.

Miller E., Tancredi, D.J., McCauley, H.L., Decker, M.R., Virata, M.C.D., Anderson, H.A., O'Connor, B., Silverman, J.G. (2013). One-year follow-up of a coach-delivered dating violence prevention program: a cluster randomized controlled trial. *American Journal of Preventive Medicine, 45(1)*, 108–112.

Moynihan, M. M., Banyard, V. L., Cares, A. C., Potter, S. J., Williams, L. M., & Stapleton, J. G. (2015). Encouraging responses in sexual and relationship violence prevention: What program effects remain 1 year later? *Journal of Interpersonal Violence*, *30*(1), 110-132.

Nation, M., Crusto, C., Wandersman, A., Kumpter, K. L., Seybolt, D., Morrissey-Kane, E., & Davino, K. (2013). What works in prevention: Principles of effective prevention programs. *American Psychologist, 58*, 449-456. (http://209.198.129.131/images/AmPsy_WhatWorksInPrevention_6-7-2003.pdf)

Reidy, D. E., Holland, K. M., Cortina, K., Ball, B., & Rosenbluth, B. (2017). Evaluation of the expect respect support group program: A violence prevention strategy for youth exposed to violence. *Preventive medicine*, *100*, 235-242.

Salazar, L. F., Vivolo-Kantor, A., Hardin, J., & Berkowitz, A. (2014). A web-based sexual violence bystander intervention for male college students: randomized controlled trial. *Journal of Medical Internet Research, 16* (9), e203.

Shadish, W. R., Cook, T. D., & Campbell, D. T. (2002). *Experimental and quasi-experimental designs for generalized causal inference.* Boston: Houghton Mifflin Company.

Smith SG, Chen J, Basile KC, Gilbert LK, Merrick MT, Patel N, Walling M, Jain A. (2017). *The National Intimate Partner and Sexual Violence Survey (NISVS): 2010-2012 State Report*. Atlanta, GA: National Center for Injury Prevention and Control, Centers for Disease Control and Prevention.

Taylor, B. G., Stein, N. D., Mumford, E. A., Woods, D. (2013). Shifting Boundaries: An experimental evaluation of a dating violence prevention program in middle schools. *Prevention Science, 14*, 64–76.

Warshaw, C., Brashler, B., & Gil, J. (2009). Mental health consequences of intimate partner violence. In C. Mitchell & D. Anglin (Eds*.), Intimate partner violence: A health based perspective* (pp. 147-171). New York: Oxford University Press.

Yuan, N.P., Koss, M.P., & Stone, M. (2006). The psychological consequences of sexual trauma. National On-line Resource Center on Violence Against Women. Available from: http://new.vawnet.org/AssocFiles_VAWnet/AR_PsychConsequences.pdf

Healthy People 2030 and other National Strategic Priorities

The National Center for Injury Prevention and Control (NCIPC) at CDC within HHS is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2030" and to measuring program performance as stipulated by the Government Performance and Review Act (GRPA). This funding announcement addresses the Healthy People 2030 priority areas of injury and violence prevention and is in alignment with NCIPC goals to conduct a targeted program of research to reduce injury-related death and disability. For more information, see https://www.healthypeople.gov/. For additional information about the CDC Injury Research Agenda, see https://www.cdc.gov/injury/index.html.

Public Health Impact

Sexual violence is a significant public health problem; an estimated 1.5 million women are raped each year in the U.S. with approximately 25.5 million women and 2.8 million men reporting a lifetime experience of completed or attempted rape (Smith et al., 2018). In addition, 43.6% of women (nearly 52.2 million) and nearly a quarter of men (24.8% or 27.6 million) experience some form of contact sexual violence in their lifetime (Smith et al., 2018). Experiencing sexual violence has been linked to serious and chronic physical and mental health conditions, including but not limited to, cardiovascular, gastrointestinal, endocrine, and immune system disorders (Ackard et al., 2007; Black, 2011; Campbell, 2002; Jewkes et al., 2002; Leserman & Drossman, 2007) and depression, anxiety, and PTSD symptomatology (e.g., Black, 2011; Coker et al., 2002, Heise & Garcia-Moreno, 2002: Warshaw et al., 2009; Yuan et al., 2006). The proposed research will add to the limited existing literature on effective strategies for prevention of sexual violence by evaluating a diverse set of approaches currently implemented by a RPE-funded organization that address immediate and divergent needs in the field. These strategies have the potential to reach a large number of people and could significantly reduce morbidity and mortality associated with sexual violence.

Relevant Work

For more than 20 years, NCIPC has been the nation's leading public health authority on violence and injury prevention. NCIPC's approach involves three elements: a focus on prevention, a science-driven approach to identify risk and protective factors, and multidisciplinary collaboration to address the problem and keep people safe, healthy and productive. NCIPC's Division of Violence Prevention recently developed technical packages to help states and communities take advantage of the best available evidence to prevent violence (https://www.cdc.gov/violenceprevention/pub/technical-packages.html). The strategies and approaches in the technical packages represent different levels of the social ecology with efforts intended to impact individual behaviors as well as the relationship, family, school, community, and societal factors that influence risk and protective factors for violence. NCIPC's research priorities (https://www.cdc.gov/injury/researchpriorities/index.html) and the Division of Violence Prevention's Strategic Vision (https://www.cdc.gov/violenceprevention/pdf/Strategic_Vision.pdf) support the need for evaluating the effectiveness of programs, policies, and practices that have substantial uptake in practice but lack evaluation research evidence. In addition, the Center's research priorities and DVP's Strategic Vision highlight the need to evaluate the efficacy and effectiveness of programs, policies or practices across all levels of the social ecology and to expand evidence for populations that experience a disproportionate burden of sexual violence. Examples of previously-funded research and descriptions of violence prevention initiatives are available on NCIPC's website: http://www.cdc.gov/injury/.

Under the Rape Prevention and Education (RPE) Program, CDC funds health departments in all 50 states, the District of Columbia, Puerto Rico, and four U.S. territories to work with rape crisis centers, state sexual assault coalitions, and others to advance sexual violence prevention. RPE recipients funded under CE19-1902 *Rape Prevention and Education: Using the Best Available Evidence for Sexual Violence Prevention* are implementing programs, policies, and practices that align with strategies outlined in CDC's *STOP SV: A Technical Package to Prevent Sexual Violence*. A list of current RPE recipients and state sexual assault coalitions are available at: http://www.cdc.gov/violenceprevention/rpe/states.html. The goal of CDC's RPE Program is to

strengthen sexual violence prevention efforts at the local, state, and national level. RPE recipients are currently engaged in implementing prevention strategies that are culturally relevant and based on the best available evidence for sexual violence prevention. The RPE Program encourages the development of comprehensive prevention strategies through a continuum of activities that address all levels of the social ecological model (http://www.cdc.gov/violenceprevention/overview/social-ecologicalmodel.html).

2. Approach

While the original information below in this section is still relevant, applications to this amended NOFO for Component B are expected to focus on the research plan to conduct the rigorous evaluation expected of Component B, informed by the results of the activities conducted to date for Component A and consistent with the guidance presented in this section.

Research funded under this announcement is expected to add to the limited existing evidence base and address immediate and divergent needs in the Rape Prevention and Education (RPE) field by rigorously evaluating practice-based approaches (i.e., programs, policies, or practices) for their impact on sexual violence outcomes. For this announcement, practice-based approaches are defined as programs, policies, or practices being implemented or are planned to be implemented by an RPE-funded organization or partner funded under RFA-CE19-1902; both Category A and Category B RPE-funded partners are eligible to participate. This announcement (RFA-CE-20-001) seeks research to evaluate practice-based prevention approaches which will increase the evidence for sexual violence prevention approaches that have traction within the sexual violence field and are, therefore, feasible to implement by practitioners and acceptable to communities.

This Notice of Funding Opportunity (NOFO) covers a five (5) year program plan consisting of Component A and Component B. Component A has a 3-year project period. During Component A up to six recipients will work with one or more state or local RPE programs to develop a partnership and build capacity for the proposed research study. Activities to be conducted in Component A include, but are not limited to, finalize the research evaluation plan, collect or secure baseline data, and conduct formative research. If applicable, recipients can conduct a pilot study on the feasibility of the proposed research approach to generate practice-based evidence from the program, policy, or practice to be evaluated (funded under RFA-CE19-1902, *Rape Prevention and Education: Using the Best Available Evidence for Sexual Violence Prevention*). During the third (final) year of Component A, all of the initial recipients (from this announcement, RFA-CE20-001) will be invited to submit an application and compete for additional funding under Component B. During Component B, up to four (4) recipients will be funded for a 2-year project period to complete a full-scale rigorous evaluation, leveraging successful completion of milestones met during Component A.

Applicants to this NOFO (RFA-CE20-001) will need to clearly describe the research plans and budgets for both Component A and Component B. Note that an award for Component A does not guarantee continued support in Component B. Only Component A recipients will be eligible to submit an application for Component B. It is anticipated that up to four (4) of the intended six (6) original Component A recipients will receive support for Component B. The review criteria in this NOFO (***Section V. Application Review Information***) will be used to evaluate the scientific

and technical merit of the initial application to this NOFO and serve as the basis of the criteria to evaluate the scientific and technical merit of the Component A Progress Report / Component B Application to complete the full- scale, rigorous evaluation.

This NOFO (RFA-CE20-001) describes the requirements of the application in general, and the specific requirements for Component A and Component B. The application to this NOFO (CE20-001) is expected to clearly describe the research plans and budgets for Component A and Component B activities. The application is expected to demonstrate that successful completion of proposed Component A activities will allow for successful completion of proposed Component B activities and culminate in a meaningful research evaluation of the selected approach. Applicants are expected to demonstrate that completion of Component A activities will provide actionable information and recommendations for both the RPE-funded programs (recipients funded under RFA-CE19-1902) and the community of RPE evaluation researchers.

This funding announcement seeks proposals that will help expand and advance the understanding of what works to prevent sexual violence. The intent of this research is to rigorously evaluate the effectiveness of *primary* prevention programs, policies, and practices implemented by RPE recipients to prevent sexual violence (currently funded under CE19-1902 *Rape Prevention and Education: Using the Best Available Evidence for Sexual Violence Prevention*). Researchers are expected to focus on approaches that are currently implemented or planned to be implemented by RPE-funded organizations that address immediate and divergent needs in the field. This research is expected to address critical gaps in the evidence base for sexual violence prevention aligned with the following strategy areas from the *STOP SV* package: ***Promote Social Norms that Protect Against Violence***, ***Provide Opportunities to Empower and Support Girls and Women***, and ***Create Protective Environments*** (https://www.cdc.gov/violenceprevention/pdf/sv-prevention-technical-package.pdf). Research aimed at building evidence at the community- or societal-levels and/or for populations and communities that disproportionately bear the burden of sexual violence is of particular interest under this announcement. The research results are expected to add to the limited existing literature on effective strategies for prevention of sexual violence.

Applicants to this NOFO (RFA-CE20-001) who are not a state or local organization funded through the CDC's RPE Program (RPE recipients funded under RFA-CE19-1902) must partner and collaborate with one or more RPE Program recipients or their locally-funded partners in the planning and implementation of the proposed research (see the Collaboration/Partnership section for the requirements to document the partnership in the application).

At least one of the partner RPE-funded organization(s) (funded under RFA-CE19-1902) should have an established history of providing rape prevention and education services to their community. The evaluation should occur in the jurisdiction where the RPE-funded organization implements or plans to implement the practice-based program, policy or practice. For a complete list of RPE recipients visit (http://www.cdc.gov/violenceprevention/rpe/states.html). Additionally, applicants are encouraged to have significant connections to the community to ensure successful evaluation in the jurisdiction where the RPE-funded organization implements

the practice-based program, policy, or practice (see the Collaboration/Partnership section for details).

Applicants must closely review the criteria and guidance provided in the Collaborations/Partnerships section of this NOFO to ensure they are providing the required information to be responsive to this NOFO.

*Requirements for **Primary** Prevention of Sexual Violence Strategies Eligible for Evaluation*

This funding announcement seeks proposals to evaluate the effectiveness of strategies for the ***primary*** prevention of sexual violence. Primary prevention approaches are those that aim to prevent violence before it occurs. In contrast, *secondary* prevention approaches focus on the more immediate responses to recent violence, such as victim treatment or arrest strategies; and *tertiary* prevention approaches focus on long-term care after violence has occurred, such as rehabilitation/reintegration, attempts to lessen trauma or reduce the long-term disability associated with violence. Secondary or tertiary approach include interventions designed to stop violence from continuing (e.g., arrest strategies, justice responses, victim treatment, community policing, advocacy efforts). The Specific Aims section of the application must demonstrate that a primary prevention strategy is proposed for evaluation. **Applicants proposing secondary or tertiary strategies will be considered nonresponsive. Applications deemed nonresponsive will not be peer reviewed and will not be funded.**

The Specific Aims section of the application must demonstrate that the proposed prevention strategy is not a criminal justice approach. **Applicants proposing to evaluate criminal justice approaches (e.g., community policing, arrest strategies) or perform criminal justice research will be considered nonresponsive; they will not be peer reviewed and they will not be funded.**

The Specific Aims section of the application must demonstrate that the proposed prevention strategy is not solely etiological research. **Applicants proposing to only conduct etiological research to examine the prevalence or correlates of behavior (i.e., surveillance and/or research that is intended to uncover the causes of violence) without also proposing a rigorous evaluation of a RPE-funded program, policy, or practice will be considered nonresponsive; they will not be peer reviewed and they will not be funded.**

RPE recipients (funded under CE19-1902 *Rape Prevention and Education: Using the Best Available Evidence for Sexual Violence Prevention*) are currently working with rape crisis centers, state sexual assault coalitions, various community organizations, and others to implement primary prevention programs, policies, or practices to reduce sexual violence. These include programs, policies, or practices that are evidence-based and those that are locally-developed in the field but have not been rigorously evaluated for sexual violence outcomes. The objective of this funding opportunity is to add to the evidence base of effective sexual violence prevention programs, policies, and practices in the following strategy areas identified in the *STOP SV* technical package: ***Promote Social Norms that Protect Against Violence, Provide***

Opportunities to Empower and Support Girls and Women*,* and ***Create Protective Environments****.* The Specific Aims section of the application must demonstrate that the proposed programs, policies, or practices to be evaluated align with one or more of these STOP SV strategy areas. **Applicants proposing to evaluate programs, policies, or practices that do not align with these strategies in the STOP SV technical package will be considered nonresponsive; they will not be peer reviewed and they will not be funded.**

*Strategies that Align with STOP SV for the **Primary** Prevention of Sexual Violence and are Eligible for Evaluation*

Examples of potential programs, policies, and practices within these three strategy areas from the STOP SV technical package that could be evaluated for effects on sexual violence outcomes, include:

- ***Promote Social Norms that Protect Against Violence***
    - Social marketing campaigns, popular opinion leader or peer-to-peer interventions, and personalized normative feedback (e.g., via traditional mail, text messages, e-mail communications);
    - Policies and other community- or societal-level approaches as they relate to influencing and impacting social norms in society, communities/neighborhoods, school systems, organizational settings, and other areas;
    - Social norms approaches implemented in novel or innovative settings (e.g., bars, workplaces)
- ***Provide Opportunities to Empower and Support Girls and Women***
    - Policies to strengthen economic supports for women and families (e.g., comparable worth policies, access to affordable quality child care, paid family and medical leave, etc.);
    - Programs aimed at strengthening household financial security (e.g., microfinance, financial literacy, job skills training programs);
    - Programs aimed at strengthening leadership and opportunities for adolescent girls, such as community based organizations that build adolescent girls' confidence, job readiness, and marketability;
- ***Create Protective Environments***
    - Efforts that improve safety and monitoring in schools and other neighborhood or community settings by enhancing and maintaining the physical characteristics of settings (e.g., increased lighting, abandoned building and vacant lot remediation, creating green space, sponsoring community events that bring residents together);
    - Policies to improve organizational settings to address protective and risk factors for multiple forms of violence and create a healthy organizational climate to reduce violence (e.g., sexual harassment policies);
    - Efforts focused on addressing community-level risks through environmental approaches that change, enact, or enforce laws, regulations, or organizational policies or other characteristics of the community (e.g., alcohol-related policies);

The examples listed above is not an exhaustive list. However, applicants must propose evaluations of RPE-funded prevention programs, policies, or practices that have not yet been rigorously evaluated for their impact on sexual violence outcomes.

For the purposes of this NOFO, research to evaluate approaches that address community-level risks through environmental approaches involving, laws, regulations, organizational policies, or community characteristics (described above as an approach to Create Protective Environments) may not engage in advocacy efforts to enact laws, regulations, administrative actions, or incentives in compliance with anti-lobbying restrictions for CDC grantees (See the document "Anti-Lobbying Restrictions for CDC Grantees" (https://www.cdc.gov/grants/documents/anti-lobbying_restrictions_for_cdc_grantees_july_2012.pdf) for more information.) Proposed research may focus on evaluating the effectiveness of existing or modified organizational policies or other characteristics of the community, or the effectiveness of existing laws or regulations.

The Specific Aims section of the application must demonstrate that the proposed prevention strategy does not constitute an advocacy effort designed to enact laws, regulations, or administrative actions, in compliance with anti-lobbying restrictions for CDC grantees. **Applicants who propose to engage in advocacy efforts designed to enact laws, regulations, administrative actions, or incentives will be considered nonresponsive; they will not be peer reviewed and they will not be funded.** (Additional information about lobbying restrictions is available in the following document "Anti-Lobbying Restrictions for CDC Grantees" (https://www.cdc.gov/grants/documents/anti-lobbying_restrictions_for_cdc_grantees_july_2012.pdf).

RPE-funded programs, policies, or practices that address evidence-based risk and protective factors at the outer levels of the social ecological model (i.e., community-, societal-level) are encouraged. In addition, programs, policies, or practices that address populations or communities that disproportionately bear the burden of sexual violence are encouraged.

The research results (both Component A and Component B) are expected to expand on, and not replicate or adapt, the existing evidence base in sexual violence prevention. The CDC's *STOP SV: A Technical Package to Prevent Sexual Violence* outlines the best available evidence for preventing sexual violence. Despite a growing evidence base on the etiology and prevention of sexual violence, few primary prevention approaches have yet been rigorously evaluated for their demonstrated effectiveness in reducing rates of sexually violent behavior. Existing evidence-based programs for preventing sexual violence largely focus on the individual or relationship-level of the social-ecological model (http://www.cdc.gov/violenceprevention/overview/social-ecologicalmodel.html).

Strategies that are NOT Eligible for Evaluation

For the purposes of this NOFO, the following programs, policies, or practices have been identified as having existing evidence of effectiveness for preventing sexually violent behavior in

a rigorous evaluation: *Safe Dates* (Foshee et al., 2004; Foshee et al., 2005), *Shifting Boundaries - Building Level Intervention* (Taylor, Stein, Mumford, Woods, 2013), *GreenDot* (Coker et al., 2017), *RealConsent* (Salazar, Vivolo-Kantor, Hardin, & Berkowitz, 2014), *Coaching Boys into Men* (Miller et al., 2013), *Bringing in the Bystander* (Moynihan et al., 2014; Edwards et al., 2019), *Second Step* (Espelage et al., 2015), and *Expect Respect Support Groups* (Reidy et al., 2017). **Applicants proposing to rigorously evaluate these existing evidence-based programs, or adaptations of these programs will be considered nonresponsive; they will not be peer reviewed and they will not be funded.**

Additionally, several programs, policies, or practices aimed at preventing sexual violence are currently being evaluated for sexual violence outcomes under existing CDC-funded initiatives. These include the programs, policies, and practices listed in Table 1 below. **Applicants proposing to rigorously evaluate these programs, or adaptations of these programs that are currently being evaluated with existing CDC-funding will be considered nonresponsive; they will not be peer reviewed and they will not be funded.**

The Specific Aims section of the application must demonstrate that the proposed program, policy, or practice to be evaluated has not previously been evaluated with demonstrated effectiveness in a rigorous outcome evaluation for sexual violence, and is not currently being rigorously-evaluated with CDC funding. **Applicants proposing to rigorously evaluate a program, policy or practice that has results from a previous (or ongoing) rigorous outcome evaluation, or adaptations of an evidence-based program, will be considered nonresponsive; nonresponsive applications will not be peer reviewed or funded.**

The majority of existing evidence-based programs are curriculum-based and designed for group-based delivery in school-, college-, or university-based settings. For the purposes of this announcement *school-based curricula* refer to programs delivered in schools, colleges, or university-based settings that provide students with opportunities to acquire the attitudes, knowledge, and skills necessary for making health-promoting decisions, achieving health literacy, adopting health-enhancing behaviors, and promoting the health of others. While they tend to focus on individual-level strategies, they may also address aspects of interpersonal relationships. The intent of this NOFO is to broaden the evidence beyond school-based curricula. The Specific Aims section of the application must demonstrate that the proposed program, policy, or practice to be evaluated is not a school-based curriculum. **Applicants proposing to rigorously evaluate school-based curricula will be considered nonresponsive; they will not be peer reviewed and they will not be funded.**

Table 1. Existing CDC-funded initiatives aimed at rigorous evaluation of programs, policies, or practices for impact on sexual violence outcomes; except as noted, these strategies are not eligible for evaluation under this NOFO (RFA-CE20-001)

Funding Opportunity:

	Recipient:	***Program, policy, or practice:***
RFA-CE-14-005: *Evaluating Promising Strategies to Build the Evidence Base for Sexual Violence Prevention*	**Engendering Healthy Masculinities to Prevent Sexual Violence**	*Manhood 2.0*
	Preventing Sexual Aggression among High School Boys	*Your Voice Your View*
RFA-CE-15-003: *Evaluating Structural, Economic, Environmental, or Policy Primary Prevention Strategies for Intimate Partner Violence and Sexual Violence*	**Prevention at the Outer Layers of the Ecology: GreenDot to Build Collective Efficacy and Change Injunctive Norms**	*GreenDot Community*
	Bystander Program Adoption and Efficacy to Reduce Sexual Violence and Intimate Partner Violence in College Community	*Bystander intervention components**
	Community Level Primary Prevention of Dating and Sexual Violence in Middle Schools	*Your Voice Your Data*
	Testing the Efficacy of a Strengths-Based Curriculum to Reduce Risk for Future Sexual Violence Perpetration among Middle School Boys	*Brothers as Allies (adapted from the Council for Boys and Young Men)*
	Preventing Sexual Violence Through a Comprehensive, Peer-Led Initiative: A Process and Outcome Evaluation	*Youth Voices in Prevention*
RFA-CE-16-005: *Evaluating Practice-based Sexual Violence Primary Prevention Approaches from CDC's Rape Prevention and Education (RPE) Program*	**The Impact of Sources of Strength, a Primary Prevention Youth Suicide Program, on Sexual Violence Perpetration among Colorado High School Students**	*Sources of Strength*
	A Randomized Trial of Wise Guys: The Next Level	*Wise Guys: The Next Level*
	Youth Empowerment Solutions for Healthy Relationships: Engaging Youth to Prevent Sexual Violence	*Youth Empowerment Solutions for Healthy Relationships*

**This funded initiative is not evaluating a specific bystander program. Specific bystander approaches are eligible if they meet the other responsiveness criteria (see Section III, Eligibility Information, 5 Responsiveness).*

Additionally, the Specific Aims section of the application must describe where the plan to develop and engage a Research Advisory Board (RAB) is located within the application. The plan should clearly be labeled as the "Research Advisory Board Plan". **Applications that do not include a plan for the development and use of a Research Advisory Board will be deemed nonresponsive; nonresponsive applications will not be peer reviewed or funded.**

Research Strategy

The Research Strategy section should clearly address the following topics:

- How the proposed RPE-funded program, policy, or practice focuses on the primary prevention of sexual violence;
- How the proposed program, policy, or practice addresses at least one of the following strategy areas from the STOP SV technical package: ***Promote Social Norms that Protect Against Violence, Provide Opportunities to Empower and Support Girls and Women****, or* ***Create Protective Environments.***
- The current implementation plan of the RPE-funded organization, or their locally-funded partner, in the jurisdiction where the RPE-funded organization routinely implements or plans to implement the program, policy, or practice (with an established timeline for initiating implementation).
- How the applicant intends to collaborate or partner with the RPE-funded state health department or locally-funded partner organization in the planning and implementation of the proposed research (if the applicant organization is not the RPE-funded state health department).
- How the proposed evaluation of the program, policy, or practice will expand on, and not replicate or adapt, the existing evidence base.
- How the evaluation of the program, policy, or practice as a whole, and the evaluation of essential components when feasible, will expand the evidence base for sexual violence prevention in general and provide relevant information on the effectiveness of the program, policy, or practice.

The Research Strategy should include a narrative Theory of Change (TOC). The TOC describes the causal processes through which a RPE-funded program, policy, or practice is expected to result in change in sexual violence outcomes (e.g., Leviton et al., 2010; Lipsey, 1993; W. K. Kellogg Foundation, 2004). In their description of the TOC, applicants should describe how it meets the following criteria:

- The proposed evaluation must be based on sufficient theoretical and/or empirical support to suggest that the RPE-funded program, policy, or practice may be effective in reducing sexual violence outcomes.

- The theoretical basis must be consistent with the best available evidence for prevention practice, behavioral interventions, and sexual violence etiology, as outlined in the STOP SV technical package (Basile et al., 2016).
- The TOC must delineate targeted mediators or moderators (i.e., risk and protective factors), and the primary behavioral outcomes (i.e., sexual violence perpetration and/or victimization) (see Nation et al., 2013).
- The TOC must clearly describe the plans for enhancing and assessing program fidelity and program exposure during the evaluation.
- The TOC must describe any potential unintended or adverse consequences of the program, policy, or practice.

Research Plans

The research plan should describe the overall concept for the proposed research and the research plans for both Component A and Component B as appropriate to understand the activities proposed for each component. This includes, but is not limited to, the research questions, study design, hypotheses, theory of change, primary and secondary outcomes to be measured, and data collection methods, proposed data analysis plan, and the estimated sample size and power for each proposed hypothesis. Outcomes to be evaluated must be clearly specified. Analytic plans should anticipate and evaluate the effects of potential threats to the internal and external validity. Successful applications are expected to demonstrate how the proposed Component A activities will lead to successful completion of a rigorous evaluation within a 2-year time frame. Successful applicants are expected to demonstrate that completion of Component A activities will provide actionable information and recommendations for both the RPE-funded programs (recipients funded under RFA-CE19-1902) and the community of RPE evaluation researchers.

The proposed research design is expected to be well described and appropriate to meet the objectives of this NOFO and the applicant's proposed study. The sexual violence outcomes to be targeted in the evaluation must be clearly described and appropriate for the evaluation method and research objectives. The proposed research design must allow for a rigorous, scientific evaluation of the effectiveness of the program, policy, or practice for its impact on sexual violence perpetration, victimization, or both.

The application should propose and clearly describe the rigorous outcome evaluation for primary prevention of sexual violence outcomes to be completed in Component B. Rigorous evaluation designs measure the impact and effectiveness of the program, policy, or practice by examining sexual violence outcomes among persons exposed to the program, policy, or practice compared to those who were not exposed.

For the purposes of this NOFO, rigorous outcome evaluation designs include:

- Experimental designs with random assignment to an intervention and control/comparison condition (e.g., randomized controlled trial [RCT], cluster RCT).
- Rigorous quasi-experimental designs, such as comparative interrupted time series, regression discontinuity, difference in difference, or matched comparison groups, for

strategies where random assignment is not possible due to implementation restrictions (e.g., evaluation of policy).

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

For the purposes of this NOFO a rigorous evaluation should also include collection and analysis of data related to the costs of implementation in order to inform a future economic evaluation of the strategy.

The application should clearly describe each partnership or collaboration necessary to conduct the research (Component A and Component B). The roles and responsibilities of each partner must be documented in a signed letter of support. These include, but are not limited to, partnerships with the RPE Program implementing the prevention strategy, entities participating in the research evaluation, and entities providing research data or access to study populations.

The first page of the Research Strategy should clearly address the following questions in a table or bullet format:

- What is the name of the program, policy or practice to be evaluated?
- Which CDC-funded RPE Program is currently or is planning to, implement the program, policy or practice?
- Is a Letter of Support from the RPE-funded partner entity and RPE Director included with the application?
- Is this program, policy or practice focused on primary prevention of sexual violence?
- Which sexual violence outcomes are included for measurement in the evaluation plan?
- Which of the following three strategy areas is aligned with the program, policy or practice?
    - Promote Social Norms that Protect Against Violence.
    - Provide Opportunities to Empower and Support Girls and Women.
    - Create Protective Environments.
- Does the program, policy or practice to be evaluated currently lack rigorous evidence of effectiveness for sexual violence outcomes?

Include Timelines and Milestones for both the Component A and Component B activities. The Timelines and Milestones should be sufficiently detailed, complete, and clearly describe research

activities consistent with each component of this program plan, describe the goals for both Component A and Component B, and illustrate the path to completion for the research as a whole. The Timelines should be realistic for completing Component A activities within a 3-year project period and completing Component B activities within a 2-year project period.

Research Plans for Component A

The purpose of Component A is to build capacity for the proposed research study, conduct formative research, obtain baseline data, conduct a pilot study (if applicable) on the feasibility of the approach to generate practice-based evidence, and complete the necessary preparations in order to complete the rigorous evaluation within the 2-year time period. During Component A, the proposed activities should focus at a minimum on refining a rigorous evaluation plan for Component B, securing partnerships necessary for Component B, securing approval from ***all*** applicable Institutional Review Boards (IRBs) for the proposed research activities, collecting or securing baseline data, and, if applicable, pilot data collection. Examples of Component A activities include, but are not limited to:

- Refining a rigorous evaluation plan for Component B
- Securing partnerships necessary for Component B
- Securing approval from all applicable Institutional Review Boards (IRBs) for all proposed research activities
- Finalizing measures for assessing sexual violence outcomes, and collecting or securing baseline data (as relevant to the proposed research design). Baseline data collection must have adequate power and, if applicable, include comparison group data that will be used during Component B for the proposed rigorous design. Applicants are encouraged, but not required, to consider other ways baseline data collection could be useful in addition to the goals of the Component B outcome evaluation (e.g., providing prevalence of sexual violence in the target population, identifying sub-populations at disparate risk for victimization or perpetration, increasing understanding of risk and protective factors for sexual violence).
- Refining or adapting existing prevention approaches that have not been evaluated (as applicable)
- Identifying and recruiting intervention and comparison sites (as applicable) for evaluation and securing agreements
- Conducting formative research (quantitative and qualitative) to inform the selected RPE-funded program, policy, or practice (e.g., collecting data on perceived sexual violence and related descriptive and injunctive norms and outlining a robust message selection process to inform a social norms approach, collecting data on the legislative language and the timing of implementation of a policy, etc.)
- Conducting a pilot study on the feasibility of rigorously evaluating an approach in order to inform rigorous evaluation under Component B (as applicable). Applicants proposing a pilot study may utilize a variety of designs (e.g., pre/post, multiple baseline). Rigorous pilot study designs will be prioritized over less rigorous ones.
- Developing and refining all implementation materials and guidance needed to implement the strategy with fidelity and ensure it can be disseminated for widespread adoption, if effective.

- Other tasks as needed to ensure success in rigorous evaluation during Component B.

Research Plans for Component B

The purpose of Component B is to provide up to two additional years of competitive funding to complete a full-scale rigorous evaluation. Successful Component B applications are expected to demonstrate the potential to complete an adequately powered rigorous evaluation that leverages successful completion of the planned Component A activities. **Funding of Component A does not guarantee support of Component B, and not all funded projects funded for Component A will transition to Component B. Only current Component A recipients will meet responsiveness criteria for consideration for funding under Component B.** The proposed experimental or quasi-experimental research design must allow for a rigorous, scientific evaluation of the effectiveness of the program, policy, or practice for its impact on sexual violence. **Priority for Component B funding will be given to applicants evaluating programs, policies, or practices with evaluation plans that are likely to demonstrate empirical support for impact on sexual violence outcomes.**

Clearly describe the plan for the rigorous evaluation. Information to be included in the evaluation plan includes, but is not limited to:

- Valid and reliable measures of sexual violence perpetration, victimization, or both. The evaluation plan is also expected to include plans to measure actual behavior for all perpetrator types and not limited to a particular victim-perpetrator relationship (e.g., sexual violence against an intimate partner only).
- Describe how potential mediator and/or moderator variables, process or implementation factors, and strategies to address potential threats to the internal and external validity of the evaluation design will be assessed.
- Demonstrate IRB approval for all of the proposed research activities.
- Describe how the research plan builds from the Component A baseline data collection (or demonstration of data availability, if applicable) and includes appropriate follow-up assessments. A minimum of a 6-month post-intervention follow-up assessment is strongly encouraged. Research designs that allow for multiple follow-ups over a longer period of time are preferred.
- When feasible, the proposed study design should include plans for measuring and monitoring implementation fidelity and participant exposure to the program, policy or practice.
- Estimate of the cost of implementation to inform economic evaluation of the program, policy, or practice.
- Describe a plan for sharing results with the public, funding agency, the RPE program, and collaborating partners.

If the evaluation of a community- or policy-level change strategy is proposed, the application must describe plans to assess indicators or proxies for sexual violence at the community- or population-level. Measurement data should be consistent with the level at which the approach is implemented (e.g., county, state, etc.). The application must describe the feasibility of the

implementation of the program, policy, or practice as proposed and whether the setting for implementation is appropriate.

Applicants must demonstrate an ability to recruit and retain an adequate study population to demonstrate significant intervention effects. Applicants must also demonstrate an ability to access the relevant data over an adequate amount of time in order to rigorously evaluate the proposed program, policy, or practice. The application should clearly describe and justify the proposed sampling methods, sample size, power estimates and data collection methods. Applicants are encouraged to include valid and reliable measures of other forms of violence, as appropriate (e.g., intimate partner violence, youth violence, bullying, self-directed violence). Applicants must demonstrate the ability to obtain and/or access the proposed data. Administrative data from relevant agencies and surveys are potential sources, but appropriate data sources will vary by strategy and study design. Applicants are encouraged to explore innovative and cost-effective data collection methods for measuring sexual violence outcomes (e.g., online survey panels such as Amazon Mechanical Turk, YouGov, Gallup, etc.). A data analytic plan must appropriately consider the level of intervention, and data and study design.

The application is expected to clearly describe the potential for widespread dissemination, implementation, and sustainability of the proposed program, policy, or practice. This is intended to enable implementation, fidelity training and monitoring, and aid in widespread dissemination of the proposed program, policy, or practice, if found to be effective, and ensure it will be sustained by communities (i.e., without prohibitive costs or resources). These include, but are not limited to, formalized program materials or procedures (for example, program curricula and/or facilitator guides or manuals) ***or*** plans to develop these materials during the Component A activities.

Applicants are encouraged to provide preliminary evidence of the proposed program, policy, or practice's potential to reduce sexual violence in their application. Examples of such preliminary evidence include data indicating statistically significant positive changes in relevant sexual violence-related behavioral mediators or risk behaviors, as determined by an assessment of data collected before and after delivery of the program, policy, or practice (pre/post data). "Positive changes" are changes that are expected or desired, based on the aims of the program, policy or practice. Demonstration of preliminary evidence of effectiveness, while encouraged, is not a requirement of this NOFO.

Applicants should include plans to provide staffing, training and support to conduct all facets of research and for monitoring implementation rigor to ensure fidelity to the program, policy, or practice and research design. Applicants should include plans to estimate the implementation costs associated with the proposed program, policy, or practice during the course of the study in order to inform future economic evaluations of the approach (e.g., cost-effectiveness); a completed cost effectiveness estimate is not required for the application.

Objectives/Outcomes

The overarching goal for this research is to determine the effectiveness of primary prevention programs, policies, and practices implemented by RPE recipients to prevent sexual violence

(currently funded under CE19-1902). Thus, all proposals are expected to include valid and reliable measures of sexual violence perpetration and/or victimization as the primary outcomes of interest.

Applicants must identify and provide evidence of access to appropriate data sources for assessing changes in rates of sexual violence at the appropriate level to measure impact. Administrative data from relevant agencies and surveys are potential sources, but appropriate data sources will vary by sexual violence outcome, approach, and study design. The indicator of sexual violence used for outcome measurement purposes should be appropriate to the level at which the approach was implemented, the population of interest (e.g., age, context), and data sources available (e.g., administrative, survey, surveillance). Outcome data may include rates of perpetration, victimization, or both. However, collecting data on perpetration outcomes is strongly encouraged when possible. Examples of primary outcome data include, but are not limited to, violence-related mortality data; police records of community arrests for violent crimes including sexual assault and rape; violent injury-related hospital or emergency department data (e.g., aggregated by community and disaggregated by age); and workplace sexual-violence-related insurance claims. The use of multiple sources of data for the sexual violence outcomes is encouraged to improve validity and reliability of each of the measured violence outcomes.

Outcomes of interest will also vary by component. Outcomes of interest for both components of the program plan are described below and must be described in the application.

Research Objectives for Component A

Primary outcomes for Component A should focus on collecting or securing baseline data on sexual violence outcomes (as relevant to the proposed research design). The indicator of sexual violence used for outcome measurement purposes may vary depending on the population of interest (e.g., age, context) and data sources available (e.g., survey, administrative). An assessment of sexual violence perpetration and/or victimization is to include actual behavior, including subtypes of sexual violence (e.g., rape, sexual coercion, unwanted sexual contact, non-contact unwanted sexual experiences, and sex trafficking) whenever possible, among the population of interest. Measurement of sexual violence is expected to include *any* perpetration and/or victimization during the assessed period, including sexual violence perpetrated by/against strangers, intimate/dating partners, peers, acquaintances, family members, or others and not be restricted to specific types of victim-perpetrator relationship (e.g., sexual violence against an intimate partner).

Because the focus of Component A also involves conducting formative research and building capacity for the rigorous evaluation in Component B, applicants are encouraged to measure additional secondary outcomes relevant to reaching Component A milestones (e.g., community readiness, community capacity, partnership engagement) as relevant to their proposed approach. Applicants are encouraged, but not required, to consider other ways baseline data collection could be useful in addition to the goals of the Component B outcome evaluation (e.g., providing prevalence of sexual violence in the target population, identifying sub-populations at disparate risk for victimization or perpetration, increasing understanding of risk and protective factors for sexual violence).

Research Objectives for Component B

Primary outcomes for Component B should focus on follow-up assessments of sexual violence outcomes measured in baseline data collection (as described in Component A section above) and completion of the rigorous evaluation to assess the effectiveness of the program, policy, or practice for reducing sexual violence outcomes and the cost of implementation.

Although the central focus of research conducted with these funds should be on reducing sexual violence outcomes, the inclusion of *measures of dating or intimate partner violence perpetration and/or victimization outcomes* (e.g., physical, sexual, psychological, and stalking) is encouraged to examine the impact of the program, policy, or practice on these related outcomes. Applicants can also examine other secondary outcomes, such as self-directed violence, youth violence/bullying, or gang membership; although the majority of resources should be devoted to achieving and measuring impacts on sexual violence perpetration and/or victimization.

As additional secondary outcomes, applicants are encouraged to examine impacts of the program, policy, or practice on risk or protective factors for violence, and/or other mediators/moderators; although the majority of resources should be devoted to achieving and measuring impacts on the primary sexual violence outcomes. Examples of these secondary outcomes include, but are not limited to, census data or other indicators of inequity, employment and poverty. Measurement of key mediators and moderators addressed by the program, policy or practice is strongly encouraged. Measurement of unintended consequences and differential impact of the program, policy, or strategy on various subpopulations is also strongly encouraged.

Research conducted with these funds should also provide an estimate of the cost of implementation to inform future economic evaluation of the strategy. Subsequent economic evaluations may include cost-effectiveness analyses or cost-benefit analyses but are not required under this solicitation. Applicants may consider measuring other implementation outcomes (e.g., adoption, acceptability, feasibility, core components/essential features) as relevant to their proposed approach (Damschroder, Aron, Keith, Kirsh, Alexander, & Lowery, 2009; Massetti, Holland, & Gorman-Smith, 2016). **While applicants are encouraged to include risk and protective factors for violence outcomes as secondary outcomes, applicants proposing research focused on risk and protective factors only without measures of sexual violence as primary outcomes will be considered nonresponsive; these applications will not be peer reviewed or funded.** The Specific Aims section of the application must clearly identify the measures of sexual violence that will be used as the primary outcomes. **Applications that do not clearly identify the measures of sexual violence that will be used as the primary outcomes of the evaluation will be considered nonresponsive; nonresponsive applications will not be peer reviewed or funded. O**nly applicants currently funded may apply for the competitive supplement for Component B.

Target Population

Injuries and violence affect people of all ages and socioeconomic groups. This announcement is intended to support rigorous evaluations of RPE-funded programs, policies, and practices implemented in diverse settings. Sexual violence affects millions of women and men every year,

yet some populations are disproportionately affected by sexual violence. In order to make a significant impact on sexual violence perpetration and victimization rates, it is important to implement and rigorously evaluate prevention programs that meet the needs of target populations. This announcement is intended to support rigorous evaluations of the effectiveness of primary prevention programs, policies, or practices implemented by RPE programs to prevent sexual violence in the following strategy areas from the *STOP SV* package: ***Promote Social Norms that Protect Against Violence***, ***Provide Opportunities to Empower and Support Girls and Women***, and ***Create Protective Environments***.

CDC does not define specific target populations. A consideration of subpopulations and communities that experience a disproportionate amount of violence is encouraged. Applicants proposing to evaluate approaches for specific target populations should provide a detailed description in their application of how they intend to identify target populations and communities and provide relevant data sources that will be used for this process. These applicants should include a description of how they will address populations and communities that disproportionately bear the burden of sexual violence including, but not limited to, race, ethnicity, gender identity, sex, sexual orientation, geography, socioeconomic status, disability status, primary language, and health literacy.

Collaboration/Partnerships

Applications must demonstrate significant and meaningful connections to the community to ensure successful implementation and evaluation of the strategy in the jurisdiction where the RPE-funded state health department or locally-funded partner organization implements the practice-based program, policy, or practice. This includes the partnership with the state- or territorial health department RPE Director, the RPE-funded entity (i.e., state health department or locally-funded partner organization) from the jurisdiction implementing the strategy, all RPE-funded entities participating in the development, implementation, and/or evaluation of the strategy, all organizations and entities providing access to outcome data or study participants, and all organizations and entities supporting and facilitating community engagement activities during the development, implementation, and/or evaluation of the strategy.

The Letters of Support section of the application must include a Letter of Support from the state- or territorial health department RPE Director where the program, policy, or practice to be evaluated is being implemented. This Letter of Support must attest that the organization supports the evaluation in the jurisdiction where the RPE-funded organization is implementing or planning to implement the practice-based program, policy, or practice. In cases where the RPE Director is not employed by the state- or territorial health department, the application must include a Letter of Support from both the RPE Director and the Director of the state- or territorial health department. **Applications that do not include an appropriate Letter(s) of Support from the jurisdiction where implementation will occur will be considered nonresponsive; nonresponsive applications will not be peer reviewed or funded.**

The Letters of Support section of the application must include an appropriate Letter of Support from the state or local organization funded through CDC's RPE Program (RFA-CE19-1902) that is responsible for implementing the program, policy, or practice to be evaluated. Letters of

Support are not required from sites where the implementation will occur (e.g., schools, community organizations). The Letter of Support must clearly document the roles and responsibilities of the state or local organization and each evaluation partner. **Applications that do not include a Letter of Support from the state or local organization funded through CDC's RPE Program that is responsible for implementing the strategy to be evaluated will be considered nonresponsive; nonresponsive applications will not be peer reviewed or funded.**

The application should specify the roles of all research partners, and describe whether and how each partner has been involved in developing the research proposal and the manner in which the partners will participate in the rigorous evaluation. Partner roles should be specified for site and participant recruitment, collecting and analyzing the proposed data, interpreting results, developing any practice recommendations based on outcomes, presenting findings at public or professional venues, identifying audiences, crafting information products for dissemination, etc. For applications proposing to evaluate an RPE-funded program, policy, or practice that is planned for implementation, the program, policy, or practice should be part of a CDC- or state-approved RPE work plan. The planned implementation should be within a timeframe that would allow for completion of baseline data by the end of Component A and completion of a rigorous evaluation (including follow-up assessments of sexual violence outcomes) at the end of Component B.

All Letters of Support need to clearly document the roles and responsibilities of the applicant and the partner organization and be included in the Letters of Support section of the application. The level of detail expected in a final version of a Letter of Support includes but is not limited to:

- The anticipated extent of involvement and scope of work to which the partner organization is willing to commit;
- That the RPE-funded organization gives the applicant permission to conduct the rigorous evaluation and the applicant agrees to collaborate with the RPE-funded organization in the evaluation of the RPE-funded program, policy, or practice, and the collection, analysis, write-up, and presentation of process and outcome data during the entire project period.
- That the RPE-funded organization will serve as "implementing agency" and be a part of the Research Advisory Board and research team;
- The extent of partnership and engagement with recipients of the RPE Program, state sexual assault coalitions, or their state health department;
- The roles and responsibilities of PI(s), Co-PI(s) and the RPE-funded state or local partners, specifically identifying who will recruit sites and participants, collect and analyze the proposed data, interpret results, and develop practice-based recommendations and presentation of findings, including developing products for dissemination;
- The duties, percentage-of-time commitments, and responsibilities of project personnel including clear lines of authority and supervisory capacity over the behavioral, administrative, data management, and statistical aspects of the research.

- The plans for facilities, equipment, assessment programming, data processing, analysis capacity, and procedures for management of data security and participant confidentiality in order to achieve the research objectives.
- For applications proposing to evaluate an RPE-funded program, policy, or practice that is planned for implementation, include documentation showing that the program, policy, or practice is part of a CDC- or state-approved RPE work plan. If the approach is planned for implementation by an RPE sub-recipient and not part of the CDC-approved RPE work plan, the sub-recipient's approved work plan must be included to provide more detailed documentation.

The application must include plans to develop and engage a Research Advisory Board (RAB). The purpose of a RAB is to engage stakeholders and partners in the review of, and feedback on, study materials including, but not limited to, study assessments, protocols for recruitment, retention, implementation and other study activities. The collaborating RPE-funded organization will serve in the role of implementing agency and contribute as a part of the Research Advisory Board and the research team. The state health department RPE Program must also contribute as part of the Research Advisory Board. A list of current RPE recipients and state sexual assault coalitions are available at: http://www.cdc.gov/violenceprevention/rpe/states.html. **Applications that do not include a plan for the development and use of a Research Advisory Board will be deemed nonresponsive; nonresponsive applications will not be peer reviewed or funded.** The Specific Aims section of the application must describe where the plan to develop and engage a Research Advisory Board (RAB) is located within the application. The plan should be included in the Research Strategy section of the application and clearly labeled as "Research Advisory Board Plan".

Applicants are encouraged to ensure that the total proposed budget adequately reflects shared research costs with the RPE-funded organization. The intent is to assure that there is adequate support for the RPE-funded organization in informing the proposed research project(s), project planning, and research implementation and evaluation. However, **funding from this NOFO cannot be used to support ongoing implementation of the program, policy, or practice which is currently funded by CDC's RPE program cooperative agreement (CE19-1902). Funding from this NOFO (CE20-001) can only be used to support the research evaluation of an implemented program, policy, or practice.** The proposed budget should include all costs incurred by the applicants and/or RPE recipients that are directly related to the conduct of, or preparation for in Component A, a rigorous evaluation research study. Supporting documentation in the Budget Justification section of the application should clearly demonstrate that costs related to implementation of the program, policy, or practice are being funded by CDC's RPE program cooperative agreement (CE19-1902 *Rape Prevention and Education: Using the Best Available Evidence for Sexual Violence Prevention*). The applicant may use additional resources to support the implementation and rigorous evaluation of the selected program, policy or practice. The applicant is expected to clearly demonstrate these additional resources support complementary evaluation activities and are not duplicative with the evaluation supported by this NOFO.

Applicants are expected to discuss whether and how the community was engaged or will be in choosing or designing the program, policy, or practice and whether or how the research coincides

with community input into the program, policy, or practice to ensure the relevance, appropriateness, and feasibility of the proposed research for supporting the prevention of sexual violence. The application should also include plans to inform impacted communities about the proposed study and to share with participants and communities how research outcomes will support or enhance prevention efforts. For the purposes of this NOFO, "community" is defined as the population living and/or working in the geographic catchment area of the state and/or local health department(s) partners for the proposal.

Evaluation/Performance Measurement
The application is expected to include a plan to evaluate and document progress towards completion of the proposed specific aims during each stage of the research process, including partnership development, study development, recruitment and retention, process and outcome measurement, data collection, and data analysis. The application is expected to include a clear description of relevant progress and performance measures documented in the Timeline and Milestones. Comparison of actual progress to the progress and performance measures are expected to document whether research is progressing appropriately and in a timely manner, and whether the research activities are of high scientific quality.

Translation Plan
The application is expected to clearly describe the potential for widespread dissemination, implementation, and sustainability of the proposed program, policy, or practice. To support wide-spread dissemination of programs, policies, or practices that are found to be effective, where feasible, applicants are expected to either have formalized program materials or procedures (for example, program curricula and/or facilitator guides or manuals) **or** plans to develop these materials based on the program, policy, or practice being implemented. These materials are intended to enable implementation, fidelity training and monitoring, and aid in wide-spread dissemination of the proposed program, policy, or practice, if found to be effective, and ensure it will be sustained by communities (i.e., without prohibitive costs or resources).

Additionally, the research findings should be disseminated through publications, including articles in peer reviewed journals and "Research Briefs" for diverse audiences, as well as presentations at professional conferences and other venues. Translation plan should include products and presentations that are specifically intended to reach practitioner audiences, including but not limited to, currently funded RPE recipients (e.g., webinars, fact sheets, professional meetings/conferences, electronic communications via listservs, social media, news coverage, etc.).

3. Funding Strategy

Section II. Award Information

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

Application Types Allowed:

Revision (formerly Competing Supplement) - Request for additional funds for a current award to expand the scope of work. Applicants should contact the awarding agency for advice on submitting any revision/supplement application.

Estimated Total Funding:
$11,250,000
NCIPC intends to commit approximately $11,250,000 to support a five (5) year research program plan consisting of Component A and Component B as described below.

During Component A (estimated as September 30, 2020 through September 29, 2023), NCIPC intends to fund up to six (6) applications. The estimated annual total funding (direct and indirect) during the 3-year project period is $6,750,000 for up to six applications. The estimated total funding (direct and indirect) for the first 12-month budget period (estimated as September 30, 2020 to September 29, 2021) is $2,250,000 for up to six applications; with a maximum of $375,000 per award, per year, for the 3-year project period.

During Component B (estimated as September 30, 2023 through September 29, 2025), NCIPC intends to fund up to four (4) applications. The estimated annual total funding (direct and indirect) during the 2-year project period is $4,500,000 for up to four applications. The estimated total funding (direct and indirect) for the first 12-month budget period (estimated as September 30, 2023 to September 29, 2024) is $2,250,000 for up to four applications; with a maximum of $562,500 per award, per year, for the 2-year project period.

This research will use a five (5) year program plan consisting of Component A and Component B. During Component A recipients will build capacity for the proposed research study and conduct formative research to generate practice-based evidence from programs, policies, or practices that are being implemented or planned to be implemented by RPE-funded organizations. Component A culminates with the submission and competitive review of a Component A Progress Report / Component B Application. All of the initial recipients of Component A will be invited to submit an application and compete for the final 2-year project period. Only Component A recipients will be eligible to submit an application for Component B. NCIPC intends to award up to four cooperative agreements with a 2-year project period to complete the five-year program plan. During Component B the successful recipients will complete the full-scale, rigorous evaluation. Note that an award for Component A does not guarantee continued support in Component B. It is anticipated that up to four of the intended six Component A recipients will receive support for Component B.

Applications for RFA-CE-20-001 Component B funding must be submitted as Type 3 Competing Revision applications.

Anticipated Number of Awards:
6
This research will use a five (5) year program plan consisting of Component A and Component B. During Component A, NCIPC intends to award up to six (6) cooperative for a 3-year project period. Component A culminates with each recipient submitting a Component A Progress Report / Component B Application for competitive review. All of the initial recipients of Component A will be invited to submit an application. Only Component A recipients will be eligible to submit

an application for Component B. Based on the results of the competitive review. NCIPC intends to award up to four (4) cooperative agreements with a 2-year project period to complete Component B. During Component B the successful recipients will complete the full-scale, rigorous evaluation. Note that an award for Component A does not guarantee continued support in Component B. It is anticipated that up to four of the intended six Component A recipients will receive support for Component B.

With this amended NOFO, NCIPC intends to award up to four (4) cooperative agreements for a 2-year project period for Component B activities. All of the initial recipients of Component A recipients will be invited to submit an application. Only Component A recipients will be eligible to submit an application for Component B. During Component B the successful recipients will complete the full-scale, rigorous evaluation. Note that an award for Component A does not guarantee continued support in Component B. It is anticipated that up to four of the intended six Component A recipients will receive support for Component B.

The updated Award Ceiling for **Component B** is shown below:

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

Award Ceiling:
$562,500
Per Budget Period

Award Floor:
$0
Per Budget Period

Total Period of Performance Length:
2 year(s)

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

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

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:
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)

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)

Governments:

U.S. Territory or Possession

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

See Section III. Eligibility Information.

4. Justification for Less than Maximum Competition
5. Responsiveness

For this amended NOFO for Component B, the applicant Contact PI must be the Contact PI named on the current award for CE20-001 for Component A. **Applications that do not clearly document that the Component B Contact PI is the Contact PI named on the current award for CE20-001 for Component A will be deemed non-responsive; non-responsive applications will not be peer reviewed or funded.**

Applications which do not meet ***all*** of the following Responsiveness criteria will be deemed "Non-Responsive" and will not be sent to Peer Review and will not be funded.

1. For this amended NOFO for Component B, the applicant Contact PI must be the Contact PI named on the current award for CE20-001 for Component A. **Applications that do not clearly document that the Component B Contact PI is the Contact PI named on the current award for CE20-001 for Component A will be deemed non-responsive; non-responsive applications will not be peer reviewed or funded.**
2. The SF 424 Biographical Sketch must clearly document that the Principal Investigator (PI) or Co-Principal Investigator (Co-PI) have previous, relevant

experience conducting rigorous outcome evaluations by having conducted at least one rigorous outcome evaluation. Evidence of the previous experience must be documented by at least one relevant first-authored, peer-reviewed journal article. The citation of the relevant publication(s) must be clearly identified (by bold text or highlight) in the appropriate SF 424 Biographical Sketch. Prior PI experience with violence-related outcome evaluation research, particularly sexual violence research, is preferred, but not required. **Applications that do not clearly document that the PI or Co-PI have the necessary relevant experience will be deemed non-responsive; non-responsive applications will not be peer reviewed or funded.**

3. The SF 424 Biographical Sketch must clearly document that the Principal Investigator (PI) or Co-Principal Investigator (Co-PI) have prior experience conducting empirical research with direct relevance to ***sexual violence- or other violence-related research***. Evidence of the experience must be documented by at least one relevant first-authored, peer-reviewed journal article. The citation of the relevant publication(s) must be clearly identified (by bold text or highlight) in the appropriate SF 424 Biographical Sketch. **Applications that do not clearly document that the PI or Co-PI have the necessary relevant experience will be deemed non-responsive; non-responsive applications will not be peer reviewed or funded.**
4. The Letters of Support section of the application must include a Letter of Support from the state- or territorial health department RPE Director. This Letter of Support must attest that the state- or territorial health department supports the evaluation in the jurisdiction where the RPE-funded organization (RPE recipient funded under RFA-CE19-1902) is implementing or planning to implement the practice-based program, policy, or practice to be evaluated. In cases where the RPE Director is not employed by the state- or territorial health department, the application must include a Letter of Support from both the RPE Director and the Director of the state- or territorial health department. **Applications that do not include an appropriate Letter(s) of Support from the jurisdiction where implementation will occur will be considered nonresponsive; nonresponsive applications will not be peer reviewed or funded."** Applications for this amended NOFO for Component B must include a current Letter of Support from both the RPE Director and the Director of the state- or territorial health department attesting that the state- or territorial health department continues to support the evaluation in the jurisdiction where the RPE-funded organization is implementing the practice-based program, policy, or practice to be evaluated. **Applications that do not include an appropriate Letter(s) of Support from the jurisdiction where implementation will occur will be considered nonresponsive; nonresponsive applications will not be peer reviewed or funded.**
5. The Letters of Support section of the application must clearly identify and include an appropriate Letter of Support from the state or local organization funded through CDC's RPE Program (RFA-CE19-1902) that is responsible for implementing the program, policy, or practice to be evaluated. Letters of Support are not required from sites where the implementation will occur (e.g.,

schools, community organizations). The Letter of Support must clearly document the roles and responsibilities of the state or local organization and each evaluation partner. **Applications that do not include a Letter of Support from the state or local organization funded through CDC's RPE Program that is responsible for implementing the strategy to be evaluated will be considered nonresponsive; nonresponsive applications will not be peer reviewed or funded.** Applications for this amended NOFO for Component B must include a current Letter of Support from the state or local organization funded through CDC's RPE Program that is responsible for implementing the strategy to be evaluated will be considered nonresponsive; nonresponsive applications will not be peer reviewed or funded.

6. The Specific Aims section of the application must demonstrate that a *primary* prevention strategy is proposed for evaluation. **Applicants proposing secondary or tertiary prevention strategies will be considered nonresponsive. Applications deemed nonresponsive will not be peer reviewed and will not be funded.**
7. The Specific Aims section of the application must demonstrate that the proposed prevention strategy is not a criminal justice approach. **Applicants proposing to evaluate criminal justice approaches (e.g., community policing, arrest strategies) or perform criminal justice research will be considered nonresponsive; nonresponsive applications will not be peer reviewed or funded.**
8. The Specific Aims section of the application must demonstrate that the proposed prevention strategy is not solely etiological research. **Applicants proposing to only conduct etiological research to examine the prevalence or correlates of behavior (i.e., surveillance and/or research that is intended to uncover the causes of violence) without also proposing a rigorous evaluation of an RPE-funded program, policy, or practice will be considered nonresponsive; nonresponsive applications will not be peer reviewed or funded.**
9. The Specific Aims section of the application must demonstrate that the proposed program, policy, or practice to be evaluated aligns with at least one these STOP SV strategy areas: *Promote Social Norms that Protect Against Violence, Provide Opportunities to Empower and Support Girls and Women,* or *Create Protective Environments.* **Applicants proposing to evaluate programs, policies, or practices that do not align with these strategies in the STOP SV technical package will be considered nonresponsive; nonresponsive applications will not be peer reviewed or funded.**
10. The Specific Aims section of the application must clearly identify the measures of sexual violence that will be used as the primary outcomes. **Applications that do not clearly identify the measures of sexual violence that will be used as the primary outcomes of the evaluation will be considered nonresponsive; nonresponsive applications will not be peer reviewed or funded.**
11. The Specific Aims section of the application must demonstrate that the proposed prevention strategy does not constitute an advocacy effort designed to enact laws, regulations, or administrative actions, in compliance with anti-lobbying restrictions for CDC grantees. **Applicants who propose to engage in advocacy**

efforts designed to enact laws, regulations, administrative actions, or incentives will be considered nonresponsive; nonresponsive applications will not be peer reviewed or funded.

12. The Specific Aims section of the application must demonstrate that the proposed program, policy, or practice to be evaluated has not previously been evaluated with demonstrated effectiveness in a rigorous outcome evaluation for sexual violence, or is not currently being rigorously-evaluated with CDC funding. **Applicants proposing to rigorously evaluate a program, policy or practice that has results from a previous (or ongoing) rigorous outcome evaluation, or adaptations of an evidence-based program, will be considered nonresponsive; nonresponsive applications will not be peer reviewed or funded.**
13. The Specific Aims section of the application must demonstrate that the proposed program, policy, or practice to be evaluated is not a school-based curriculum. **Applicants proposing to rigorously evaluate school-based curricula will be considered nonresponsive; nonresponsive applications will not be peer reviewed or funded.**
14. The Specific Aims section of the application must describe where the plan to develop and engage a Research Advisory Board (RAB) is located within the application. The plan should clearly be labeled as the "Research Advisory Board Plan". **Applications that do not include a plan for the development and use of a Research Advisory Board will be deemed nonresponsive; nonresponsive applications will not be peer reviewed or funded.**

6. Required Registrations

Applicant organizations must complete the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. Applicants must have a valid Unique Entity Identifier (UEI) number in order to begin each of the following registrations.

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

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

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

However, it is best to start the registration process at least two weeks prior to application submission.

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

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

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

Additionally, organizations must maintain the registration with current information at all times during which it has an application under consideration for funding by CDC and, if an award is made, until a final financial report is submitted or the final payment is received, whichever is later.

SAM.gov is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at SAM.gov and the SAM.gov Knowledge Base.

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

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

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

9. Cost Sharing

This NOFO does not require cost sharing as defined in the HHS Grants Policy Statement (http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

10. Number of Applications

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

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

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

The applicant must ensure that duplicate applications are withdrawn prior to the application review date. Additionally, applicant institutions submitting applications with essentially the same proposed research to two or more CDC NOFOs will not be funded under more than one NOFO.

Section IV. Application and Submission Information

1. Address to Request Application Package

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

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

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

- Email: commons@od.nih.gov

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

2. Content and Form of Application Submission

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

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

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

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

Please use the form and instructions for SF424 (R&R) Form G.

Applications for RFA-CE-20-001 Component B funding must be submitted as Type 3 Competing Revision applications. Applicants should ensure to include their existing grant number in Column 4a

3. Letter of Intent

Due Date for Letter Of Intent 10/28/2022

10/28/2022
A letter of intent is requested by **October 28, 2022**.

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

By the date listed in Part 1. Overview Information, eligible applicants are asked to submit a letter of intent that includes the following information:

Descriptive title of proposed research

Description (one-two paragraphs) of the proposed research including a description of the proposed research objectives

Name, address, and telephone number of the PD(s)/PI(s)

Names of other key personnel and participating institutions

Number and title of this funding opportunity

The letter of intent should be sent to:

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

4. Required and Optional Components

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

5. PHS 398 Research Plan Component

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

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

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

Other Research Plan Sections

5. **Vertebrate Animals**

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

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

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

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

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

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

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

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

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

Please use the form and instructions for SF424 (R&R) Form G.

6. Appendix

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

The appendices are limited to a total of 10 PDF files to include the 3 publications, not publicly available as described above and up to 5 PDF files of supporting materials for the Research Plan described below (7. Page Limitations). The appendix has a total maximum page limit of 25 pages.

7. Page Limitations

All page limitations described in this individual NOFO must be followed. For this specific NOFO, the Research Strategy component of the Research Plan narrative is limited to 20 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.

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

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

Please use the form and instructions for SF424 (R&R) Form G.

9. Submission Dates & Times

Part I. Overview Information contains information about Key Dates. Applicants are strongly encouraged to allocate additional time and submit in advance of the deadline to ensure they have time to make any corrections that might be necessary for successful submission. This includes the time necessary to complete the application resubmission process that may be necessary, if errors are identified during validation by Grants.gov and the NIH eRA systems. The application

package is not complete until it has passed the Grants.gov and NIH eRA Commons submission and validation processes. Applicants will use a platform or system to submit applications.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Due Date for Applications 12/16/2022

12/16/2022
Electronically submitted applications must be submitted no later than 11:59 p.m., ET, on the listed application due date.

10. Funding Restrictions

Expanded Authority:

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

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

Public Health Data:

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

Data Management Plan:

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

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

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

Human Subjects:

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

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

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

11. Other Submission Requirements and Information

Risk Assessment Questionnaire Requirement

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

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

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

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

Duplication of Efforts

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

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

Application Submission

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

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

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

Important reminders:

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

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

The applicant organization must ensure that the UEI number it provides on the application

is the same number used in the organization's profile in the eRA Commons and for the System for Award Management (SAM). Additional information may be found in the SF424 (R&R) Application Guide.

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

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

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

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

Section V. Application Review Information

1. Criteria

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

Overall Impact

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

Scored Review Criteria

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

Significance

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

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

Reviewers will use the criteria stated below in their evaluation of the scientific and technical merit of the application to this NOFO. The application is expected to describe the research plans and accomplishments of Component A and the research plans of Component B as described in this NOFO. Reviewers will assign a single impact score for the entire application. These review criteria will also serve as the basis of the criteria to evaluate the scientific and technical merit of the Component A Progress Report / Component B Application to complete the full-scale, rigorous evaluation.

- Describe the extent to which the application aligns with the stated purpose and Research Objectives described in the FOA.
- To what extent will the successful completion of the proposed activities significantly advance current knowledge and build the evidence base on the effectiveness of programs, policies, or practices to prevent sexual violence?
- To what extent will the proposed project address one or more of the outer layers of the social ecological model (http://www.cdc.gov/violenceprevention/overview/social-ecologicalmodel.html); e.g., community-, or societal-level)?
- To what extent will the proposed project address the needs of communities experiencing disproportionate burden of sexual violence (including but not limited to, people with disabilities, non-English speaking populations, tribal populations, rural communities and other geographically underserved areas, racial/ethnic minorities, sexual and gender minorities, and people with limited health literacy)?
- To what extent will the proposed project rigorously evaluate programs, policies, or practices with demonstrated theoretical or empirical support for impact on SV outcomes?

Investigator(s)

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

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?

Reviewers will use the criteria stated below in their evaluation of the scientific and technical merit of the application to this NOFO. The application is expected to describe the research plans and accomplishments of Component A and the research plans of Component B as described in this NOFO. Reviewers will assign a single impact score for the entire application. These review

criteria will also serve as the basis of the criteria to evaluate the scientific and technical merit of the Component A Progress Report / Component B Application to complete the full-scale, rigorous evaluation.

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

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 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?

Reviewers will use the criteria stated below in their evaluation of the scientific and technical merit of the application to this NOFO. The application is expected to include the research plans for both Component A and Component B as described in this NOFO. Reviewers will assign a single impact score for the entire application. These review criteria will also serve as the basis of the criteria to evaluate the scientific and technical merit of the Component A Progress Report / Component B Application to complete the full-scale, rigorous evaluation. Reviewers will use the criteria stated below in their evaluation of the scientific and technical merit of the application to this NOFO. The application is expected to describe the research plans and accomplishments of Component A and the research plans of Component B as described in this NOFO. Reviewers

will assign a single impact score for the entire application. These review criteria will also serve as the basis of the criteria to evaluate the scientific and technical merit of the Component A Progress Report / Component B Application to complete the full-scale, rigorous evaluation.

- To what extent is the proposal innovative and promising for advancing the field of violence prevention and adding to the current evidence base?
- To what extent does the applicant propose to evaluate a program, policy or practice that has never been and is currently not being rigorously evaluated for impact on sexual violence outcomes? If the proposed program, policy, or practice has been evaluated for other violence outcomes previously, to what extent does the proposed research address a particular gap (i.e., extending evidence to sexual violence outcomes) such that it will not be duplicative of previous or current research?
- To what extent is the proposed program, policy, or practice for the prevention of sexual violence well-supported by the Theory of Change with a strong theoretical basis and program model consistent with the best available evidence for prevention practice, behavioral interventions, and sexual violence etiology? To what extent does the Theory of Change delineate the hypothesized causal relationships between the program, targeted mediators or moderators (i.e., risk and protective factors) and the primary behavioral outcomes (i.e., sexual violence outcomes)?
- To what extent does the proposed research describe an appropriate experimental or quasi-experimental evaluation strategy that will lead to a firm conclusion (i.e., causal inference) about the effectiveness of the proposed program, policy, or practice on sexual violence outcomes?
- To what extent were the Component A activities completed within the previous 3 year project period?
- To what extent are the Component B innovative yet balanced with a well described research strategy that is likely to be completed within the 2-year project period?

Approach

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

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

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? If the project involves clinical research, are there plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed? Reviewers will use the criteria stated below in their evaluation of the scientific and technical merit of the

application to this NOFO. The application is expected to describe the research plans and accomplishments of Component A and the research plans of Component B as described in this NOFO. Reviewers will assign a single impact score for the entire application. These review criteria will also serve as the basis of the criteria to evaluate the scientific and technical merit of the Component A Progress Report / Component B Application to complete the full-scale, rigorous evaluation.

- To what extent does the proposed RPE-funded program, policy, or practice focus on the primary prevention of sexual violence?
- To what extent does the proposed program, policy, or practice to be evaluated address at least one of the three required strategies from the *STOP SV* technical package outlined in the NOFO?
    - ***Promoting Social Norms that Protect Against Violence***: focuses on changing social norms that accept or allow indifference to violence or represent restrictive gender norms.
    - ***Provide Opportunities to Empower and Support Girls and Women***: emphasizes approaches that strengthen education, employment, and income outcomes in women and girls that have been established as protective factors against risk for sexual violence victimization.
    - ***Create Protective Environments***: focuses on modifying characteristics of communities, such as changes to policies, institutional structures, or the social and physical environment, in order to create conditions that promote community protective factors and reduce risk for violence.
- To what extent does the applicant clearly describe the current implementation plan of the RPE-funded organization, or their locally-funded partner (with an established timeline for initiating implementation)?
- To what extent does the applicant demonstrate how the proposed evaluation of the program, policy, or practice will expand on, and not replicate or adapt, the existing evidence base for sexual violence prevention?
- Describe the extent to which the proposed evaluation is based on a rigorous research design (i.e., an experimental or quasi-experimental design) and well described and appropriate to meet the objectives of the NOFO and the applicant's proposed study. Research design considerations include, for example, inclusion of baseline and appropriate follow-up assessments for the approach being evaluated, a description of sampling methods, sample size, power estimates, and data collection methods, and a data analytic plan appropriate to the study design and level of intervention.
- To what extent does the applicant demonstrate sufficient capacity and completed formative research (e.g., both quantitative and qualitative research) to generate practice-based evidence?
- To what extent does the applicant demonstrate ability to recruit and retain an adequate study population to demonstrate significant intervention effects, as well as ability to access relevant data over an adequate amount of time (consistent with the proposed evaluation design) to rigorously evaluate the proposed program, policy, or practice?
- To what extent does the evaluation plan include valid and reliable measures of sexual violence outcomes and plans to measure actual behavior, including multiple forms of

sexual violence perpetration and/or victimization for all perpetrator types and not limited to a particular victim-perpetrator relationship?

- To what extent is the proposed study feasible and the timeline sufficiently detailed, complete and realistic for completing Component B activities within a 2-year project period?

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?

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? Reviewers will use the criteria stated below in their evaluation of the scientific and technical merit of the application to this NOFO. The application is expected to describe the research plans and accomplishments of Component A and the research plans of Component B as described in this NOFO. Reviewers will assign a single impact score for the entire application. These review criteria will also serve as the basis of the criteria to evaluate the scientific and technical merit of the Component A Progress Report / Component B Application to complete the full-scale, rigorous evaluation.

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

or how the research coincides with community input into the program, policy, or practice to ensure the relevance, appropriateness, and feasibility of the proposed research?

2. Additional Review Criteria

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

Protections for Human Subjects

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

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

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

Inclusion of Women, Minorities, and Children

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

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following four points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 4) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section (https://grants.nih.gov/grants/olaw/VAChecklist.pdf).

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

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

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

3. Additional Review Considerations

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

Applications from Foreign Organizations
N/A

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

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

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

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

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

- A description of the data to be collected or generated in the proposed project;
- Standards to be used for the collected or generated data;
- Mechanisms for, or limitations to, providing access to and sharing of the data (include a description of provisions for the protection of privacy, confidentiality, security,

intellectual property, or other rights - this section should address access to identifiable and de-identified data);

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

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

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

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

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

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

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

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

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

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

4. Review and Selection Process

Applications will be evaluated for scientific and technical merit by an appropriate peer review group, in accordance with CDC peer review policy and procedures, using the stated review

criteria.
As part of the scientific peer review, all applications:

- Will undergo a selection process in which 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.
- Balance and distribution of the sexual violence prevention approaches proposed for evaluation align with the three STOP SV: A Technical Package to Prevent Sexual Violence strategies described in the Background and Approach sections of this NOFO (***Promoting Social Norms that Protect Against Violence***, ***Provide Opportunities to Empower and Support Girls and Women,*** and ***Create Protective Environments***).
- Potential for the approach to impact population-wide changes by addressing the outer layers of the social ecological model.
- Potential for the evaluation to demonstrate empirical support for impact on sexual violence outcomes.
- Potential for the approach to address needs of a vulnerable population; populations and communities that disproportionately bear the burden of sexual violence. These include, but are not limited to, people with disabilities, non-English speaking populations, tribal populations, rural communities and other geographically underserved areas, sexual and gender minorities, and people with limited health literacy.
- Consideration for applications proposing to evaluate a primary prevention strategy using measures of sexual violence as the primary outcomes.
- Consideration for applications that demonstrate the capacity and scientific rigor, as determined by scientific peer review, to complete Component B (i.e., a rigorous evaluation of a program, practice or policy that meets the requirements of this NOFO) as evidenced by the Research Strategy section of the application's research plan.

Review of risk posed by applicants.
Prior to making a Federal award, CDC is required by 31 U.S.C. 3321 and 41 U.S.C. 2313 to review information available through any OMB-designated repositories of government-wide eligibility qualification or financial integrity information as appropriate. See also suspension and debarment requirements at 2 CFR parts 180 and 376.

In accordance with 41 U.S.C. 2313, CDC is required to review the non-public segment of the OMB-designated integrity and performance system accessible through SAM (currently the

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

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

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

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

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

5. Anticipated Announcement and Award Dates

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

Section VI. Award Administration Information

1. Award Notices

Any applications awarded in response to this NOFO will be subject to the UEI, SAM Registration, and Transparency Act requirements. If the application is under consideration for funding, HHS/CDC will request "just-in-time" information from the applicant as described in

the HHS Grants Policy Statement (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

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

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

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

2. CDC Administrative Requirements

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

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

Specific requirements that apply to this NOFO are the following:

AR-1: Human Subjects Requirements

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

AR-3: Animal Subjects Requirements

AR-9: Paperwork Reduction Act Requirements

AR-10: Smoke-Free Workplace Requirements

AR-11: Healthy People 2030

AR-12: Lobbying Restrictions

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

AR-14: Accounting System Requirements

AR-16: Security Clearance Requirement

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

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

AR-22: Research Integrity

AR-24: Health Insurance Portability and Accountability Act Requirements

AR-25: Data Management and Access

AR-26: National Historic Preservation Act of 1966

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

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

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

AR-31: Research Definition

AR-32: Appropriations Act, General Provisions

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

AR-36: Certificates of Confidentiality

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

Organization Specific ARs:

AR-8: Public Health System Reporting Requirements

AR-15: Proof of Non-profit Status

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

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

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

3. Additional Policy Requirements

The following are additional policy requirements relevant to this NOFO:

Should you successfully compete for an award, recipients of federal financial assistance (FFA) from HHS will be required to complete an HHS Assurance of Compliance form (HHS 690) in which you agree, as a condition of receiving the grant, to administer your programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, age, sex and disability, and agreeing to comply with federal conscience laws, where applicable. This includes ensuring that entities take meaningful steps to provide

meaningful access to persons with limited English proficiency; and ensuring effective communication with persons with disabilities. Where applicable, Title XI and Section 1557 prohibit discrimination on the basis of sexual orientation, and gender identity. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider- obligations/index.html and https://www.hhs.gov/civil-rights/for- individuals/nondiscrimination/index.html.

- For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on your specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment, see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html.
- For guidance on administering your project in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

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

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

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

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

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

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

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

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

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

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

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

Data Management Plan(s)

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

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

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

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

award. See Additional Requirement 36 to ensure compliance with this term and condition. The link to the full text is at: https://www.cdc.gov/grants/additional-requirements/ar-36.html.

4. Cooperative Agreement Terms and Conditions

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

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

CDC staff has substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

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

Areas of Joint Responsibility include:

- The recipient and CDC will establish a schedule for regular phone calls to discuss ongoing progress. This schedule will be agreed on by both the recipient and CDC.

5. Reporting

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

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

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

that continued funding is in the best interest of the Federal government.

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

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

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 appropriate, described 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 due within 90 days following the end of each budget period. The Annual Report is to be submitted electronically via email to the assigned Scientific Program Officer.

The Annual Report should include:

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

A. Submission of Reports

The Recipient Organization must submit:

1. **Yearly Non-Competing Grant Progress Report** is due 90 to 120 days before the end of the current budget period. The RPPR form (https://grants.nih.gov/grants/rppr/index.htm; https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf) is to be completed on the eRA Commons website. The progress report

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

2. **Annual Federal Financial Report (FFR) SF 425 (**Reporting | Grants | CDC) is required and must be submitted to the Payment Management System accessed through the FFR navigation link in eRA Commons or directly through PMS **within 90 days after the budget period ends.**
3. **A final progress report**, invention statement, equipment/inventory report, and the final FFR are required **90 days after the end of the period of performance.**

B. Content of Reports

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

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

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

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

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

    - How will the scientific findings be translated into public health practice or inform public health policy?

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

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

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

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

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

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

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

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

- Additional Reporting Requirements:

2. Annual Federal Financial Reporting The Annual Federal Financial Report (FFR) SF 425 is required and must be submitted through the Payment Management System (PMS) within 90 days after the end of the budget period. The FFR should only include those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) cash transaction data.

Failure to submit the required information in a timely manner may adversely affect the future funding of this project. If the information cannot be provided by the due date, you are required to submit a letter explaining the reason and date by which the Grants Officer will receive the information.

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

Recipients must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, recipients must submit a final FFR, final progress report, and Final Invention Statement and Certification within 90 days of the period of performance. Failure to submit timely and accurate final reports may affect future funding to the organization or awards under the direction of the same Project Director/Principal Investigator (PD/PI).

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

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

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

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

6. Termination

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

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

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

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

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

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

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

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

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

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

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

3) Terms: For purposes of this clause:

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

"Foreign government" includes any foreign government entity;

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

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

5) Contents of Reports: The reports must contain:

a. recipient name;

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

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

d. reporting period;

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

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

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

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

Section VII. Agency Contacts

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

Application Submission Contacts

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

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

Scientific/Research Contact(s)

Amanda Garcia-Williams, PhD
National Center for Injury Prevention and Control (NCIPC)

Telephone: 770.488.3936
Email: GVL8@cdc.gov

Peer Review Contact(s)

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

Financial/Grants Management Contact(s)
Angie Willard
CDC, Office of Financial Resources
Telephone: 770-488-2863
Email: AEN4@cdc.gov

Section VIII. Other Information

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

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

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

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

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

Applicants are encouraged to pay close attention to the Data Management Plan requirements listed in the NOFO and to keep these in mind while preparing their proposals.

Successful recipients will be permitted expanded authorities in the administration of this awards as provided for in the Code of Federal Regulations, Title 2, Subtitle A, Chapter II, Part 200, Subpart D, Paragraph 200.308(d)(4).