



Centers for Disease Control and Prevention

National Center for Injury Prevention and Control Extramural Research Program Office

Evaluating Practice-based Sexual Violence Primary Prevention Approaches from CDC's Rape Prevention and Education (RPE) Program

RFA-CE-16-005

Application Due Date: 06/01/2016

Evaluating Practice-based Sexual Violence Primary Prevention Approaches from CDC's Rape Prevention and Education (RPE) Program

RFA-CE-16-005

TABLE OF CONTENTS

[Part 1. Overview Information](#)

Key Dates

Required Application Instructions

Executive Summary

[Part 2. Full Text](#)

[Section I. Funding Opportunity Description](#)

[Section II. Award Information](#)

[Section III. Eligibility Information](#)

[Section IV. Application and Submission Information](#)

[Section V. Application Review Information](#)

[Section VI. Award Administration Information](#)

[Section VII. Agency Contacts](#)

[Section VIII. Other Information](#)

Part 1. Overview Information

Participating Organization(s)

Centers for Disease Control and Prevention

Components of Participating Organizations

National Center for Injury Prevention and Control Extramural Research Program Office (NCIPC ERPO)

National Center for Injury Prevention and Control (NCIPC)

Funding Opportunity Announcement (FOA) Title

Evaluating Practice-based Sexual Violence Primary Prevention Approaches from CDC's Rape Prevention and Education (RPE) Program

Activity Code

Applications in response to this FOA will be funded using the U01 activity code.

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.

Funding Opportunity Announcement Type

New

Funding Opportunity Announcement Number

RFA-CE-16-005

Catalog of Federal Domestic Assistance (CFDA) Number(s)

93.136

Category of Funding Activity:

Health

FOA Purpose

The purpose of this announcement is to support research to *rigorously evaluate* the effectiveness of **primary prevention** programs, policies, or practices implemented by Rape Prevention and Education (RPE) Programs to prevent the perpetration of sexual violence.

The proposed research will add to the limited existing literature on effective strategies for prevention of sexual violence perpetration by evaluating a diverse set of approaches currently implemented or planned for implementation by a RPE-funded organization that address immediate and divergent needs in the field. Research funded under this announcement will address these priorities by rigorously evaluating programs, policies or practices for their impact on sexual violence perpetration along with other types of violence. Research conducted with these funds should also provide an estimate of the cost of implementation to inform future economic evaluation of the strategy. Research to evaluate the most promising 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.

The purpose of this amended FOA is to provide additional clarifying information based on questions received from potential applicants as a result of direct communication with the Scientific Program Official. A summary of the "questions and answers" and a list of the changes made to the original FOA begins on page 39.

Key Dates

Publication Date: To receive notification of any changes to RFA-CE-16-005, 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: 04/22/2016

Letter of Intent is due April 22, 2016.

Application Due Date: 06/01/2016

Application is due June 01, 2016.

On-time submission requires that electronic applications be error-free and made available to CDC for processing from eRA Commons on or before the deadline date. Applications must be submitted to and validated successfully by Grants.gov/eRA Commons no later than 5:00 PM U.S. Eastern Time. Note: HHS/CDC grant submission procedures do not provide a period of time beyond the application due date 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: 07/12/2016

An approximate date, actual date may be between June and July 2016.

Secondary Review: 08/16/2016

An approximate date, actual date may be between July and August 2016.

Estimated Start Date: 09/15/2016

The estimated start date is September 15, 2016.

Expiration Date: 06/23/2016

Due Dates for E.O. 12372: Due no later than 60 days after the application receipt date.

Required Application Instructions

It is critical that applicants follow the instructions in the [SF 424 \(R&R\) Application Guide](#) except where instructed to do otherwise in this FOA. Conformance to all requirements (both in the Application Guide and the FOA) 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.

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

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

Executive Summary

Purpose. The purpose of this announcement is to support research to *rigorously evaluate* the effectiveness of **primary prevention** programs, policies, or practices implemented by Rape Prevention and Education (RPE) Programs to prevent the perpetration of sexual violence.

The proposed research will add to the limited existing literature on effective strategies for prevention of sexual violence perpetration by evaluating a diverse set of approaches currently implemented or planned for implementation by a RPE-funded organization that address immediate and divergent needs in the field. Research funded under this announcement will address these priorities by rigorously evaluating programs, policies or practices for their impact on sexual violence perpetration along with other types of violence.

Research conducted with these funds should also provide an estimate of the cost of implementation to inform future economic evaluation of the strategy. Research to evaluate the most promising 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.

Mechanism of Support. The funding mechanism will be by a cooperative agreement; an assistance mechanism used when there will be substantial Federal scientific or programmatic involvement.

Funds Available and Anticipated Number of Awards. NCIPC intends to commit approximately \$2,250,000 in FY 2016 to fund up to five applications. Awards issued under this FOA are contingent upon availability of funds and a sufficient number of meritorious applications. Because the nature and scope of the proposed research will vary from application to application, it is also anticipated that the size and duration of each award may vary. The total amount awarded and the number of awards will depend upon the number, quality, duration and cost of the applications received and approved.

Budget and Project Period. The maximum award amount will be \$450,000 per award for the first 12 month budget period. This includes both direct and indirect costs. An applicant may request a project period of up to four years. The maximum total project funding amount expected per award is \$1,800,000 (including both direct and indirect costs) over the expected project period length of four years, with a maximum of \$450,000 per award per year.

The project period for this award will run from 9/30/2016 to 9/29/2020.

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), and the determination that continued funding is in the best interest of the Federal government.

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

Eligible Institutions/Organizations. Institutions/organizations listed in Section III.1 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. See section *III. 3 Special Eligibility Requirements* for more specific information. 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.

Number of PDs/PIs. Co-principal investigators are allowed for this FOA; their names must appear on the face page of the application. However, one principal investigator must be designated as the contact PI. For institutions/organizations proposing multiple PDs/PIs, 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. Only one application per principal investigator will be 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 first application received based on the document's time and date stamp in Grants.gov (<http://www.grants.gov/>).

Application Type. New

Special Date(s).

- Letter of intent is due April 22, 2016.
- A pre-application teleconference call will be conducted on April 13, 2016, from 2:00 – 3:00 pm

Eastern Time to address prospective applicants' questions regarding FOA CE16-005, Evaluating Practice-based Strategies from CDC's Rape Prevention and Education (RPE) Program to Build Evidence for Primary Prevention of Sexual Violence

PARTICIPANT ACCESS INFORMATION

- CALL DATE: April 13, 2016
- CALL TIME: 2:00 pm Eastern Time
- CALL DURATION: 1 hour, unless all questions are addressed before then
- CALL LEADER: Susan Neurath, Ph.D.
- Toll-Free Number: 855-644-0229
- Passcode: 8636049#

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

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

Part 2. Full Text

Section I. Funding Opportunity Description

Statutory Authority

This program is authorized under:

Sections 317(k)(2) and 393B of the Public Health Service Act (42 U.S.C. Sections 247b and 280(b)a and 280b-1b), as amended.

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

1. Background and Purpose

Background:

An estimated 1.3 million women are raped each year in the U.S. with nearly 1 in 5 women and 1 in 59 men experiencing rape at some point in their lives, including completed forced penetration, attempted forced penetration, or alcohol/drug facilitated completed penetration (Breiding et al., 2014). In addition, about 2 in 5 women and 1 in 5 men will experience other forms of sexual violence in their lifetimes, including being made to penetrate someone else, sexual coercion, unwanted sexual contact, and non-contact unwanted sexual experiences (Breiding et al., 2014). 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 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 grantees are currently engaged in a range of activities that range from implementing prevention strategies that are culturally relevant and based on the best available evidence to conducting educational seminars, professional trainings, and leveraging resources through partnerships. 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.

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. In addition, the Center's research priorities highlight the need to evaluate the efficacy and effectiveness of programs, policies or practices across all levels of the social ecology, identify effective programs, policies or practices that might prevent multiple types of violence concurrently, including sexual violence, intimate partner violence, and other forms of violence, and evaluate the economic efficiency of such programs, policies or practices. The proposed research will add to the limited existing literature on effective strategies for prevention of sexual violence perpetration by evaluating a diverse set of approaches currently implemented or planned for implementation by a RPE-funded organization that address immediate and divergent needs in the field. Research funded under this announcement will address these priorities by rigorously evaluating programs, policies, or practices for their impact on sexual violence perpetration along with other types of violence. Research conducted with these funds should also provide an estimate of the cost of implementation to inform future economic evaluation of the strategy. 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.

Public health strategies are traditionally characterized in terms of three levels of prevention: *primary* prevention approaches, which aim to prevent violence before it occurs; *secondary* prevention approaches, which focus on the more immediate responses to violence, such as victim treatment or arrest strategies; and *tertiary* prevention approaches, which focus on long-term care, such as rehabilitation/reintegration, attempts to lessen trauma or reduce the long-term disability associated with violence. **Applicants proposing secondary or tertiary strategies will be considered nonresponsive.**

Sexual violence is associated with a number of individual, family, and peer characteristics that increase the risk of perpetration, including attitudes that support or condone violence, personality traits, risky sexual behavior, and childhood exposure to violence (Tharp et al., 2013). Less is known about community and societal characteristics that influence risk for sexual violence, but these contextual and environmental factors may also play an important role in the prevention of perpetration (DeGue et al., 2012; Tharp et al., 2013). Despite a growing evidence base on the etiology of sexual violence, few primary prevention interventions have been formally evaluated for their demonstrated effectiveness in reducing rates of sexually violent behavior.

To date, three programs, policies, or practices have been shown to reduce sexual violence perpetration using a rigorous methodology: *Safe Dates* (Foshee et al., 2004; Foshee et al., 2005), *Shifting Boundaries* building-level intervention (Taylor, Stein, Mumford, Woods, 2013), and *RealConsent* (Salazar, Vivolo-Kantor, Hardin, & Berkowitz, 2014). Two additional programs, policies, or practices have demonstrated some benefits for sexual violence prevention in existing evaluations: one in a non-rigorous evaluation: *GreenDot* (Coker et al., 2015; Coker et al., 2014) and one on general dating violence perpetration in a rigorous evaluation: *Coaching Boys into Men* (Miller et al., 2013). These programs, policies, or practices are currently undergoing evaluations which will contribute to our knowledge on their ability to reduce sexual violence. Together, these primary prevention strategies represent important advances in the sexual violence prevention field, but significant gaps remain.

Communities require a broader and more comprehensive “menu” of effective programs, policies, and practices that allow them to select approaches to meet their unique needs. The availability of a diverse set 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). Research funded under this announcement is expected to address these important gaps in the sexual violence prevention field. 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/violenceprevention/overview/social-ecologicalmodel.html>; e.g., community-, or societal-level) are strongly encouraged.

RPE grantees are currently working with rape crisis centers, state sexual assault coalitions, and others to implement primary prevention programs, policies, or practices to reduce sexual violence. These include those that are evidence-based and those that are locally-developed in the field but have not been rigorously evaluated. **The objective of this FOA is to add to the evidence base of effective sexual violence prevention programs, policies, and practices. Research conducted under this FOA will evaluate primary prevention programs, policies, or practices currently being implemented, or planned for implementation by RPE-funded organizations, yet lack a rigorous evaluation.**

This announcement seeks research to conduct rigorous, scientific evaluations of sexual violence primary prevention programs, policies, and practices that have been implemented at a RPE-funded organization, and have not yet been, or are not currently being formally evaluated. Programs, policies, and practices that are eligible for evaluation include: 1) those that were developed by an RPE-funded organization or partner (i.e., sometimes called “homegrown” programs, policies, or practices) 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. Programs, policies, or practices that are planned to be implemented should be part of a CDC- or state-approved RPE work plan.

Purpose:

The purpose of this announcement is to support research to *rigorously evaluate* the effectiveness of **primary prevention** programs, policies, or practices implemented by Rape Prevention and Education (RPE) programs to prevent the perpetration of sexual violence.

For the purpose of this announcement, a rigorous evaluation is one that measures the impact and effectiveness of a program, policy, or practice by comparing outcomes for participants with the outcomes for those who did not participate in the program, policy, or practice. A more detailed description of rigorous evaluation designs is available in the Research Objectives of this announcement.

The purpose of this amended FOA is to provide additional clarifying information based on questions received from potential applicants as a result of direct communication with the Scientific Program Official. A summary of the "questions and answers" and a list of the changes made to the original FOA begins on page 39.

References:

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Healthy People 2020 and other National Strategic Priorities

NCIPC is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2020" and to measuring program performance as stipulated by the Government Performance and Review Act (GPRA). This FOA addresses the "Healthy People 2020" priority area(s) of injury and violence goal(s) to conduct a targeted program of research to reduce injury-related death and disability. For more information, see www.healthypeople.gov and <http://www.whitehouse.gov/omb/mgmt-gpra/>.

Public Health Impact

Sexual violence is a significant public health problem; an estimated 1.3 million women are raped each year in the U.S. Nearly 1 in 5 women and 1 in 59 men experience rape at some point in their lives; about 2 in 5 women and 1 in 5 men will experience other forms of sexual violence in their lifetimes (Breiding et al., 2014). 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 perpetration by evaluating a diverse set of approaches currently implemented by a RPE-funded organization that address immediate and divergent needs in the field.

Relevant Work

The goal of CDC's 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 grantees are currently engaged in a range of activities that range from implementing prevention strategies that are culturally relevant and based on the best available evidence to conducting educational seminars, professional trainings, and leveraging resources through partnerships. 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>).

This research supports the NCIPC research priorities outlined in the updated CDC Injury Research Priorities. Additional information about the Center's research priorities is available at: <http://www.cdc.gov/injury/researchpriorities/>.

2. Approach

Research Objectives: The objective of this research announcement is to support rigorous evaluations of primary prevention programs, policies, or practices currently being implemented or planned for implementation by RPE-funded organizations. This research is expected to add to the limited existing literature on effective strategies for prevention of sexual violence perpetration by evaluating a diverse set of approaches that are currently implemented or planned to be implemented by RPE-funded organizations that address immediate and divergent needs in the field. The results of the evaluation are expected to expand on, and not replicate, the existing evidence base. **To be responsive to this FOA**, the application must propose a rigorous evaluation of a practice-based sexual violence primary prevention program, policy, or practice that is currently being implemented or planned for implementation by an RPE-funded organization for its impact on sexual violence perpetration (see the Responsiveness section for specific details.)

The focus on practice-based prevention approaches is expected to increase the evidence for sexual violence prevention approaches that are feasible to implement by practitioners and acceptable to communities. Additionally, the research is also expected to provide an estimate of the cost of implementation to inform economic evaluation of the program, policy, or practice considered.

To be responsive to this FOA, the primary prevention program, policy, or practice **must** meet the following criteria:

- Focus on the primary prevention of sexual violence perpetration;
- Have been implemented or planned for implementation at an RPE-funded organization or their locally-funded partner in the jurisdiction where the RPE-funded organization implements or plans to implement the program, policy, or practice;
- Have evidence that evaluation of the proposed program, policy, or practice will expand on, and not replicate, the existing evidence base;
 - Do not have existing evidence of effectiveness from a rigorous evaluation for reducing sexual violence perpetration;
 - Are not currently undergoing a rigorous evaluation of effects on sexual violence perpetration;

The proposed program, policy, or practice is expected to have a theoretical basis consistent with the best available evidence for prevention practice, behavioral interventions, and sexual violence etiology supported by a clear, well-supported theory of change that clearly describes the hypothesized causal relationships between the program, policy, or practice, targeted mediators or moderators (i.e., risk and protective factors), and the primary behavioral outcomes (i.e., sexual violence perpetration). Although it is not a requirement, programs, policies, or practices that address evidence-based risk and protective factors for one or more of the outer layers of the social ecological model (e.g., community-, or societal-level) are encouraged.

The proposed program, policy, or practice is expected to expand on, and not replicate, the existing evidence base for sexual violence prevention;

Additionally, the proposed program, policy, or practice must either have formalized intervention materials or procedures (for example, intervention curricula and/or facilitator guides or manuals) **or** the application must include a plan to develop formalized intervention materials based on the program, policy, or practice currently being implemented or planned for implementation. This is to enable implementation and fidelity training and monitoring and aid in wide-spread dissemination of the program, policy, or practice if found to be effective. **To be responsive to this FOA**, a summary of these materials must be properly located in the appendix (see the Responsiveness section for specific details.)

Programs, policies, or practices that have been, or are currently being evaluated will not be addressed in this announcement. For the purposes of this announcement, ***programs, policies, or practices that are not eligible*** include:

- Any form of a non-primary prevention program, policy, or practice;

- These include intervention strategies (e.g., arrest strategies, justice responses, victim treatment, community policing, advocacy efforts) designed to stop violence from continuing or progressing.
- Any of the following primary prevention programs, policies, or practices that have been or are currently being rigorously evaluated: Safe Dates, Shifting Boundaries, RealConsent, GreenDot, and Coaching Boys into Men.
- Programs, policies, or practices that replicate or make changes (adaptations) to any of the following established programs, policies, and practices: Safe Dates, Shifting Boundaries, RealConsent, GreenDot, and Coaching Boys into Men.

Applicants are expected to propose new rigorous outcome evaluations for sexual violence perpetration. A rigorous outcome evaluation is one that measures the impact and effectiveness of a program, policy, or practice by comparing outcomes for participants with the outcomes for those who did not participate in the program, policy or practice. For the purposes of this FOA, ***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 interrupted time series or regression discontinuity, for strategies where random assignment is not possible due to implementation restrictions (e.g., evaluation of policy).
- In other cases in which a policy or intervention 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).

Applicants that are not a state or local organization funded through the CDC's RPE Program must identify a program, policy, or practice that an RPE grantee or their locally-funded partner is currently implementing or planning to implement to evaluate for primary prevention of sexual violence perpetration outcomes. For a complete list of RPE grantees visit <http://www.cdc.gov/violenceprevention/rpe/states.html>. **To be responsive to this FOA**, applicants that are partnering with a state or local organization funded through CDC's RPE Program must clearly document the roles and responsibilities of each partner (see the Collaboration/Partnership Section and Responsiveness Section for specific details).

Primary and Secondary Outcome Measures

The intent of this FOA is to identify effective strategies currently implemented by RPE-funded organizations for the **primary prevention** of sexually violent behavior. Thus, all proposals are expected to *include valid and reliable measures of sexual violence perpetration* as the primary outcome of interest. The indicator of sexual violence used for outcome measurement purposes may vary depending on the intervention population (e.g., age, context) and data sources available (e.g., survey, administrative). An assessment of sexual violence perpetration is to include actual behavior, including physical forms of sexual violence (e.g., rape, unwanted sexual contact). Measurement of sexual violence perpetration is expected to include *any* perpetration during the assessed period, including sexual violence perpetrated against strangers, intimate/dating partners, peers, acquaintances, family members, or others and not be restricted to one or more types of victim-perpetrator relationship (e.g., sexual violence against an intimate partner). Although the central focus of research conducted with these funds should be on reducing sexual violence perpetration, the inclusion of *measures of dating or intimate partner violence perpetration outcomes* (e.g., physical, sexual, psychological, and stalking) is encouraged to examine the impact of the program, policy, or practice on these related outcomes.

As secondary outcomes, applicants are also encouraged to examine impacts of the program, policy, or practice on other violence 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. Measurement of key mediators and moderators addressed by the intervention is also strongly encouraged.

CDC's requirements of the research projects funded under the FOA.

The proposed program, policy, or practice selected for evaluation must be based on sufficient theoretical support to suggest that it may be effective in reducing sexual violence perpetration. The theoretical basis must be consistent with the best available evidence for prevention practice, behavioral interventions, and sexual violence etiology. Applicants are expected to submit a clear, well-supported theory of change that clearly describes the hypothesized causal relationships between the program, policy, or practice, targeted mediators or moderators (i.e., risk and protective factors), and the primary behavioral outcomes (i.e., sexual violence perpetration) (see Nation et al., 2013). The application is expected to clearly describe the plans for investigation of program fidelity and program exposure during the evaluation. Additionally, the application is expected to clearly describe the potential unintended or adverse consequences of the program, policy, or practice.

The proposed research design is expected to be well described and appropriate to meet the objectives of the FOA 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 objectives of this FOA. 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. The proposed study timeline should be sufficiently detailed, complete and realistic for a 4-year project period. The research design is expected to include the following characteristics:

- The evaluation plan is expected to include valid and reliable measures of sexual violence perpetration and plans to measure actual behavior, including physical forms of sexual violence perpetration for all perpetrator types and not limited to a particular victim-perpetrator relationship (e.g., sexual violence against an intimate partner only).
- The evaluation plan is expected to 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.
- The proposed study design should have at least one baseline and a minimum of a 6-month post-intervention follow-up assessment of the intervention and control/comparison groups. Research designs that allow for multiple follow-ups over a longer period of time are preferred.
- The proposed study design should include plans for measuring and monitoring implementation fidelity and participant exposure to the program, policy or practice.
- The application should describe a plan for sharing results with the public, funding agency 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. The application must describe the feasibility of the implementation of the policy or intervention 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. The application should clearly describe and justify the proposed sampling methods, sample size, power estimates and data collection methods. The proposed measures of sexual violence perpetration are expected to be valid and reliable and not limited to a particular victim-perpetrator relationship (e.g., sexual violence against an intimate partner only). Applicants are encouraged to include valid and reliable measures of other forms of violence, as appropriate. 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. A data analytic plan must appropriately consider the level of intervention, and data and study design.

Potential applicants that are not a state or local organization funded through the CDC's RPE Program must

partner with a RPE grantee or their locally-funded partner that is currently implementing or planning to implement a program, policy, or practice for primary prevention of sexual violence perpetration outcomes. 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 grantees visit (<http://www.cdc.gov/violenceprevention/rpe/states.html>). Applicants are encouraged to contact these grantees to identify RPE-funded organizations with which to collaborate. Applicants must develop a collaborative partnership with a state or local organization funded through CDC's Rape Prevention and Education (RPE) Program to conduct the planning and implementation of the proposed research. Applicants are encouraged to have significant connections to the community to ensure successful evaluation in the jurisdiction where the RPE-funded organization implements the promising practice-based program, policy, or practice.

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 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). To support wide-spread dissemination of programs, policies, or practices that are found to be effective, applicants must either have formalized intervention materials or procedures (for example, intervention curricula and/or facilitator guides or manuals) *or* plans to develop these materials based on the program, policy, or practice being implemented.

Applicants are encouraged to provide preliminary evidence of the proposed program, policy, or practice's potential to reduce sexual violence perpetration 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 FOA.

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 objective of this research FOA is to add to the evidence base of effective sexual violence primary prevention programs, policies, or practices currently being implemented by RPE-funded organizations. This research is expected to add to the limited existing literature on effective strategies for prevention of sexual violence perpetration by evaluating a diverse set of approaches currently implemented or planned for implementation by RPE-funded organizations that address immediate and divergent needs in the field, yet lack a rigorous evaluation.

Target Population

While the program, policy, or practice proposed for evaluation may involve any demographic group, it should not be intentionally restricted to a narrowly-defined demographic or target group (e.g., restricting to a single ethnicity or a sexual minority) in a way that would preclude the ability to generalize the effectiveness of the program, policy, or practice in a broader community setting or the US-based population.

Collaboration/Partnerships

Applicants are encouraged to have significant connections to the community to ensure successful implementation in the jurisdiction where the RPE-funded organization implements the promising practice-based program, policy, or practice. Applicants that are not a state or local organization funded through the CDC's RPE Program must partner and collaborate with one or more RPE Program awardees or their locally-funded partners in the planning and implementation of the proposed research. At least one of the partner RPE-funded organization(s) must have an established history of providing rape prevention and education services to their community. Each applicant **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. A list of current RPE grantees and state sexual assault coalitions are available at: <http://www.cdc.gov/violenceprevention/rpe/states.html>.

Applicants should 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.

Funding from this FOA does not include funding for ongoing implementation of the program, policy, or practice which is currently funded by CDC's RPE cooperative agreement. Hence, the proposed budget should include all costs incurred by the applicants and/or RPE grantees that are directly related to the conduct of rigorous evaluation research.

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 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 the completion of a rigorous evaluation of changes in sexual violence perpetration within the 4-year project period.

To be responsive to this FOA, the expectations for each partner must be clearly documented in a letter of support, memoranda of understanding, or memoranda of agreement and included in the appendix of the application (see the Responsiveness section of this FOA for location details). This documentation is expected to clearly describe the nature of the relationships, including the following:

- The anticipated extent of involvement and scope of work to which the 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 grantees 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 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.

To be responsive to this FOA, the application must include a letter from the Director of the RPE-funded organization(s) attesting 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. (See the Responsiveness section of this FOA for location details).

Community Engagement – Applicants are expected to discuss whether or how the community was engaged in 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 FOA, “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.

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. Applicants that are not a state or local organization funded through the CDC’s RPE Program must obtain and include in the proposal a detailed letter of support from the state health department RPE Program and/or state sexual assault coalition describing the nature of the proposed partnership. This memorandum between the applicant, state health department RPE Program and/or state sexual assault coalition must outline the roles and responsibilities of PI(s) and the RPE-funded state or local partners. A list of current RPE grantees and state sexual assault coalitions are available at: <http://www.cdc.gov/violenceprevention/rpe/states.html>.

Evaluation/Performance Measurement

This announcement is intended to support rigorous, scientific evaluations of sexual violence primary prevention programs, policies, and practices that have been implemented or planned at an RPE-funded organization, and have not yet been, or are not currently being formally evaluated. 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 policy or intervention 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).

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, applicants must either have formalized intervention materials or procedures (for example, intervention 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.

Section II. Award Information

Funding Instrument Type: Cooperative Agreement

A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, scientific or program staff will assist, guide, coordinate, or participate in project activities.

Application Types Allowed:

New - An application that is submitted for funding for the first time. Includes multiple submission attempts within the same round.

Estimated Total Funding: \$9,000,000

Anticipated Number of Awards: 5

NCIPC intends to commit approximately \$2,250,000 (direct and indirect) in FY 2016 to fund up to five applications. NCIPC intends to commit approximately \$9,000,000 (direct and indirect) to fund up to five applications over the 4-year project period.

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

Award Ceiling: \$450,000 Per Budget Period

Award Floor: \$350,000 Per Budget Period

Total Project Period Length: 4 year(s)

Throughout the project period, 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 (<http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf>) will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category: State governments
County governments
City or township governments
Special district governments
Independent school districts
Public and State controlled institutions of higher education
Native American tribal governments (Federally recognized)
Public housing authorities/Indian housing authorities
Native American tribal organizations (other than Federally recognized tribal governments)
Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education
Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education
Private institutions of higher education
For profit organizations other than small businesses
Small businesses
Others (see text field entitled "Additional Information on Eligibility" for clarification)
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:

- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

Other:

- Native American tribal organizations (other than Federally recognized tribal governments)
- 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" when submitting via www.grants.gov.

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://dap.dau.mil/acquipedia/Pages/ArticleDetails.aspx?aid=5e3079b8-44f2-43df-a0e7-9f379e8c48ed>

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. Special Eligibility Requirements

N/A

To be considered eligible for this announcement, the applicant must provide:

- Documentation that the Principal Investigator (PI), Co-Principal Investigator (Co-PI), or Co-Investigator has previous experience in conducting at least one rigorous outcome evaluation. Prior PI experience with violence-related outcome evaluation research, particularly sexual violence research, is preferred, but not required. 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 SFS 424 Biographical Sketch.
- Documentation that the PI, Co-PI, or Co-Investigator 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 SFS 424 Biographical Sketch.
- Documentation of effective and well-defined working relationships with any organization and/or outside entities expected to partner in the proposed research. This should include, at a minimum, **one** state- or local organization(s) funded through CDC's RPE Program. Documentation of these working relationships is to ensure implementation and sustainability of the proposed activities. Documentation can include letters of support or memoranda of understanding or agreement detailing the nature and extent of the involvement from the performing organization, RPE-funded organization, and any other outside entities. The letters of support or memoranda of understanding or agreement must include detailed information about the nature of the partnership. Expectations for the information to be included in this documentation are described in the Collaboration/Partnership section of this FOA.

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

- To be considered responsive, there must be an overall match between the proposed objectives as described in the applicant’s abstract and the Research Objective of this FOA:
 - To support rigorous evaluations of the effectiveness of **primary prevention** programs, policies, or practices that are implemented, or planned for implementation, by RPE-funded organizations to prevent the perpetration of sexual violence (see the Research Objectives Section of this FOA for the characteristics of a rigorous outcome evaluation).
 - Applicants proposing to evaluate secondary/tertiary strategies as defined in the Research Objectives section of this FOA will be considered nonresponsive.
- To be considered Responsive, **all** of the following items must be provided in the appropriate location:
 1. **Appendix 1** must contain the letter of support, memoranda of understanding, memoranda of agreement, or other formal documentation of the agreements between the applicant and the partner RPE-funded organization(s) with an established history of providing rape prevention and education services to their community. (See the Collaboration/Partnership section of this FOA for the information expected to be included in this documentation);
 2. **Appendix 2** must contain a letter from the Director of the RPE-funded organization(s) attesting 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.
 3. **Appendix 3** must contain the following statement signed by the PI and RPE-funded partner:
 - I hereby certify that, to the best of my knowledge, this application meets the following criteria:
 - The proposed practice-based program, policy, or practice for sexual violence prevention is a primary prevention strategy. It does not include secondary or tertiary prevention strategies as described in this FOA;
 - The proposed practice-based program, policy, or practice is not one of the established programs, policies, or practices listed above (i.e., Safe Dates, Shifting Boundaries, RealConsent, GreenDot, and Coaching Boys into Men);
 - The proposed practice-based program, policy, or practice does not replicate or make changes (adaptations) to any of **the** programs, policies, or practices listed above (i.e., Safe Dates, Shifting Boundaries, RealConsent, GreenDot, and Coaching Boys into Men).
 4. **Appendix 4** must contain a description of the intervention materials that are currently available such as a complete manual or other implementation materials, curricula, or facilitator guides, that accurately reflects the nature of the proposed program, policy, or practice that has been delivered by the RPE-funded organization. If the materials do not currently exist then a plan for how and when these will be developed should be included in the appendix.
- To be considered Responsive, the following information needs to be clearly identified in the appropriate biosketch:
 - The biosketch for the PI, Co-PI, or Co-Investigator must include evidence of previous experience in conducting at least one rigorous outcome evaluation. This 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 appropriate SFS 424 Biographical Sketch.
 - The biosketch for the PI, Co-PI, or Co-Investigator, must include evidence of experience conducting empirical research with direct relevance to **sexual violence- or other violence-related research**. This 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 relevant SFS 424 Biographical Sketch.

6. Required Registrations

Applicant organizations must complete the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. Applicants must have a valid Dun and Bradstreet Universal Numbering System (DUNS) number in order to begin each of the following registrations.

- (Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: <https://eportal.nspa.nato.int/AC135Public/Docs/US%20Instructions%20for%20NSPA%20NCAGE.pdf>
- System for Award Management (SAM) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, <https://www.sam.gov/portal/SAM/#1>.
- [Grants.gov](http://www.Grants.gov)
- [eRA Commons](http://www.eRA Commons)

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

All Program Directors/Principal Investigators (PD/Pis) **must** also work with their institutional officials to register with the **eRA Commons** or ensure their existing 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 registration process at least four (4) weeks prior to the application due date.

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

All applicant organizations **must obtain** a DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services. An AOR should be consulted to determine the appropriate number. If the organization does not have a DUNS number, an AOR should complete the [US D&B D-U-N-S Number Request Web Form](#) or contact Dun and Bradstreet by telephone directly at 1-866-705-5711 (toll-free) to obtain one. A DUNS number will be provided immediately by telephone at no charge. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a DUNS number.

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

If an award is granted, the grantee organization **must** notify potential sub-recipients that no organization may receive a subaward under the grant unless the organization has provided its DUNS number to the grantee 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 FOA does not require cost sharing as defined in the HHS Grants Policy Statement (<http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf>).

10. Number of Applications

As defined in the HHS Grants Policy Statement, (<http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf>), applications received in response to the same funding opportunity announcement 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 FOA 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 in response to this FOA, provided that each application is scientifically distinct. However, applicant institutions can submit only one application with the same principal investigator. Only one application per principal investigator will be 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 first application received based on the time and date stamp for submission in Grants.gov (<http://www.grants.gov/>).

Section IV. Application and Submission Information

1. Address to Request Application Package

Applicants must download the SF424 (R&R) application package associated with this funding opportunity from www.Grants.gov.

If access to the Internet is not available or if the applicant encounters difficulty accessing the forms on-line, contact the HHS/CDC Office of Grants Services (OGS) Technical Information Management Section (TIMS) staff at (770) 488-2700 or ogstims@cdc.gov for further instructions. Hours: Monday - Friday, 7am - 4:30pm U.S. Eastern Time. CDC Telecommunications for the hearing impaired or disabled is available at: TTY 1-888-232-6348.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf), except where instructed in this Funding Opportunity Announcement 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 forms package associated with this FOA includes all applicable components, mandatory and optional.

Please note that some components marked optional in the application package are required for submission of applications for this FOA. Follow the instructions in the SF 424 (R&R) Application Guide to ensure you complete all appropriate "optional" components.

In conjunction with the SF424 (R&R) components, CDC grants applicants should also complete and submit additional components titled "PHS398." Note the PHS398 should include assurances and certifications, additional data required by the agency for a complete application. While these are not identical to the PHS398 application form pages, the PHS398 reference is used to distinguish these additional data requirements from the data collected in the SF424 (R&R) components. A complete application to CDC will include SF424 (R&R) and PHS398 components. These forms can be downloaded from <http://grants.nih.gov/grants/forms.htm>

3. Letter of Intent

Due Date for Letter of Intent: **04/22/2016**

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

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

- Name of Applicant
- Description of the research topic
- Descriptive title of the proposed research
- Name, address, and telephone number of the PD(s)/PI(s)
- Names of the other key personnel
- Participating institutions
- Number and title of this funding opportunity announcement

The letter of intent should be sent to:

- M. Chris Langub, PhD
- 4770 Buford Hwy, NE MS F-63
- Atlanta, GA 30341

Telephone: 770-488-3585

Email: MLangub@cdc.gov

4. Required and Optional Components

A complete application has many components, both required and optional. The forms package associated with this FOA in Grants.gov includes all applicable components for this FOA, required and optional.

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 16 components. Not all 16 components of the Research Plan apply to all Funding Opportunity Announcements (FOAs). Specifically, some of the following 16 components are for Resubmissions or Revisions only. See Part I, Section 5.5 of the SF 424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf) for additional information. Please attach applicable sections of the following Research Plan components as directed in Part 2, Section 1 (Funding Opportunity Announcement Description).

Follow the page limits stated in the SF 424 unless otherwise specified in the FOA. As applicable to and specified in the FOA, 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 FOA.
- 2. Specific Aims** – state the problem the proposed research addresses and how it will result in public health impact and improvements in population health.
- 3. Research Strategy** – the research strategy should be organized under 3 headings: Significance, Innovation and Approach. Describe the proposed research plan, including staffing and timeline.
- 4. Inclusion Enrollment Report** (Renewal and Revision applications ONLY)
- 5. Progress Report Publication List** (for Continuation ONLY)

Human Subjects Section

- 6. Protection of Human Subjects**
- 7. Inclusion of Women and Minorities**
- 8. Targeted/Planned Enrollment Table** (for New Application ONLY)
- 9. Inclusion of Children**

Other Research Plan Sections

10. Vertebrate Animals 11. Select Agent Research 12. Multiple PD/PI Leadership Plan. 13. Consortium/Contractual Arrangements 14. Letters of Support 15. Resource Sharing Plan(s) 16. Appendix

Component 4 (Inclusion Enrollment Report) applies only to Renewal and Revision applications for clinical research. Clinical research is that which is conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies). Follow the page limits in the SF 424 **unless otherwise specified in the FOA.**

All instructions in the SF424 (R&R) Application Guide

(http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf) must be followed along with any additional instructions provided in the FOA.

Additional comments:

- Applicants should ensure that the proposed research plan clearly describes the methodology of the proposed evaluation.

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 publically available. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

7. Page Limitations

All page limitations described in this individual FOA must be followed. For this specific FOA, 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 10 PDF files with a maximum of 25 pages for all appendices.

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 (Part I, Section 2) (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf).

9. Submission Dates & Times

Part I. Overview Information contains information about Key Dates. Applicants are encouraged to submit in advance of the deadline to ensure they have time to make any application corrections that might be necessary for successful submission.

Organizations must submit applications via [Grants.gov](http://www.grants.gov) (<http://www.grants.gov>), the online portal to find and apply for grants across all Federal agencies. The eRA Commons systems retrieve the application from Grants.gov and check the application against CDC business rules. If no errors are found, the application will be assembled in the eRA Commons for viewing by the applicant before moving on for further CDC processing.

If errors are found, the applicant will be notified in the eRA Commons. They must make required changes to

the local copy of their application and submit again through Grants.gov.

Applicants are responsible for viewing their application in the eRA Commons to ensure accurate and successful submission.

Once you can see your application in the Commons, be sure to review it carefully as this is what the reviewer will see. Applicants must then complete the submission process by tracking the status of the application in the eRA Commons ([http:// grants.nih.gov/grants/guide/url_redirect.htm?id=11123](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123)).

Information on the submission process is provided in the SF424 (R&R) Application Guide.

Note: HHS/CDC grant submission procedures do not provide a period of time beyond the grant application due date 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).

The application package is not complete until it has passed the Grants.gov/eRA Commons validation process. This process and email notifications of receipt, validation or rejection may take two (2) business days.

Applicants are strongly encouraged to allocate additional time prior to the submission deadline to submit their applications and to correct errors identified in the validation process. Applicants are encouraged also to check the status of their application submission to determine if the application packages are complete and error-free. Applicants who encounter system errors when submitting their applications must attempt to resolve them by contacting the Grants.gov Contact Center (1-800-518-4726; support@grants.gov). If the system errors cannot be resolved, applicants must contact TIMS at 770-488-2700; ogstims@cdc.gov for guidance at least 3 calendar days before the deadline date.

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. This validation process may take as long as two (2) business days. A third and final e-mail message is generated once the applicant’s application package has passed validation and the grantor has confirmed receipt of the application.

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

1. Track his/her submission and verify the submission status (tracking should be done initially regardless of rejection or success).
 - a. If the status states “*rejected*,” do #2a or #2b.
2. Check his/her emails from both Grants.gov and eRA Commons for rejection notices.
 - a. If the deadline has passed, he/she should email the Grant Management Specialist listed in the FOA (pgotim@cdc.gov) explaining why the submission failed. b. If there is time before the deadline, he/she should correct the problem(s) and resubmit as soon as possible.

Due Date for Applications: **05/23/2016**

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

10. Intergovernmental Review (E.O. 12372)

Your application is subject to Intergovernmental Review of Federal Programs, as governed by Executive Order 12372 (<http://www.archives.gov/federal-register/codification/executive-order/12372.html>). This order sets up a system for state and local review of proposed federal assistance applications. You should contact your state single point of contact (SPOC) as early as possible to alert the SPOC to prospective applications, and to receive instructions on your state’s process. Click on the following link to get the current SPOC list: http://www.whitehouse.gov/omb/grants_spoc/.

11. Funding Restrictions

N/A

12. Other Submission Requirements and Information

Application Submission

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

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

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

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

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management (SAM). Additional information may be found in the SF424 (R&R) Application Guide. If the applicant has an FWA number, enter the 8-digit number. Do not enter the letters "FWA" before the number. If a Project/Performance Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the Project/Performance Site operates under and appropriate Federal Wide Assurance for the protection of human subjects and complies with 45 CFR Part 46 and other CDC human subject related policies described in Part II of the SF 424 (R&R) Application Guide and in the HHS Grants Policy Statement.

See more resources to avoid common errors and submitting, tracking, and viewing applications: http://grants.nih.gov/grants/ElectronicReceipt/avoiding_errors.htm or http://grants.nih.gov/grants/ElectronicReceipt/submit_app.htm

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?

- 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 of the effectiveness of programs, policies, or practices to prevent sexual violence perpetration?

Investigator(s)

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

- To what extent does the application clearly demonstrate the research team has the experience to conduct the proposed research?
- Describe the strength of the investigator(s) experience and knowledge in conducting rigorous evaluation outcome evaluations as evidenced in the biosketch of either the PI, Co-PI, or Co-Investigator and documented by at least one relevant first-authored, peer-reviewed journal article in this area.
- 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 in this area.
- To what extent do the applicant and/or its partner RPE-funded organization have the experience and capability to collect, manage, and analyze accurate data in an appropriate and timely manner?
- To what extent do the applicant and/or its partner RPE-funded organization have the experience and capability to implement culturally-relevant sexual violence prevention programs, policies, or practices with the proposed target population?
- Describe whether there is evidence of past collaboration with the proposed research team and collaborators to support the success of the proposed research.

Innovation

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

- To what extent does the proposed research describe an appropriate evaluation strategy for assessing effectiveness on sexual violence perpetration outcomes?
- Describe the extent to which the proposed research will generate results that will lead to a firm conclusion about the effectiveness of the proposed program, policy, or practice.
- Does the applicant propose to evaluate a program, policy or practice that has never been and is currently not being rigorously evaluated in a controlled trial?
- Is the proposed research design innovative and yet offer reasonable potential of meeting the purpose and Research Objectives of this FOA?

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?

- Describe the extent to which the proposed program, policy or practice aligns with the expectations for a sexual violence primary prevention program, policy and practice that has been implemented or is planned to be implemented at an RPE-funded organization but has not yet been, or is not currently being evaluated.
- Describe the extent to which the proposed primary prevention program, policy, or practice meets the stated criteria to be eligible for this research opportunity?
- Does the proposed program, policy, or practice have strong a theoretical basis and program model consistent with the best available evidence for prevention practice, behavioral interventions, and sexual violence etiology that clearly describes 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 perpetration)?
- Describe the extent to which the proposed evaluation is based on a rigorous research design, well described and appropriate to meet the objectives of the FOA and the applicant's proposed study. Research design considerations include: the inclusion of one baseline and a minimum of a 6-month post-intervention follow-up assessment; the description of sampling methods, sample size, power estimates and data collection methods; the plans for measuring and monitoring implementation fidelity and participant exposure to the program, policy or practice; the data analytic plan with respect to the level of intervention and data and study design.
- Describe the extent to which the proposed research design allows for a rigorous, scientific evaluation of the effectiveness of the program, policy, or practice for its impact on sexual violence perpetration along with other types of violence.
- Does the evaluation plan include valid and reliable measures of sexual violence perpetration and plans to measure actual behavior, including physical forms of sexual violence perpetration for all perpetrator types and not limited to a particular victim-perpetrator relationship (e.g., sexual violence against an intimate partner only)?
- If the evaluation of a community- or policy-level change strategy is proposed, does the applicant include plans to assess indicators or proxies for sexual violence at the community- or population-level?
- Are there adequate plans to estimate the costs of implementing the prevention program, policy, or practice?
- Does the proposed program, policy, or practice have either formalized intervention materials or procedures (for example, intervention curricula and/or facilitator guides or manuals) *or* does the application include a plan to develop formalized intervention materials that would enable successful implementation and wide-spread dissemination of the program, policy, or practice if found to be effective? (As a minimum, this information is expected to be included in the appropriate appendix, see the Responsiveness Criteria for details)
- Describe the extent to which the results of this research are likely to provide information on effectiveness of the proposed program, policy, or practice to reduce sexual violence perpetration.
- Is the proposed study feasible and is the timeline sufficiently detailed, complete and realistic for a 4-year project period?

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?

- Describe whether the partnerships necessary to complete the proposed work, are supported by letters of support or memoranda of understanding 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.
- Describe the evidence the applicant provides for the partnership and engagement with grantees of the RPE program, policy, or practice, state sexual assault coalitions, or their state health department and the quality of the relationship to support a rigorous and collaborative research effort.
- Describe the extent to which the letters of support or memoranda of understanding outline the roles and responsibilities of PI(s) and the RPE-funded state or local partners, including who will collect and analyze data, interpret results, and develop practice-based recommendations and presentation of findings, including developing products for dissemination. 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 give the applicant permission to conduct the rigorous evaluation? 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 presentation of the process and outcome data during the entire project? Does the applicant provide a description of the duties, percentage-of-time commitments, and responsibilities of project personnel including clear lines of authority and supervisory capacity over the behavioral, administrative, data management, and statistical aspects of the research? How adequate are the plans for facilities, equipment, assessment programming, data processing, analysis capacity, and procedures for management of data security and participant confidentiality to achieve the research objectives?
- Describe the extent to which the proposed partnership between the applicant and RPE-funded organization(s) are likely to allow the applicant to conduct a rigorous evaluation of the proposed program, policy, or practice.
- Does the proposed study benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is the proposed setting(s) for implementation appropriate to determine program effectiveness?

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

(<http://www.cdc.gov/grants/additionalrequirements/index.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 (http://www.cdc.gov/maso/Policy/Policy_women.pdf and <http://www.gpo.gov/fdsys/pkg/FR-1995-09-15/pdf/95-22950.pdf#page=1>) and the policy on the Inclusion of Persons Under 21 in Research (<http://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 five 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) adequacy of veterinary care; 4) 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 5) 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

(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11150).

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/dual-use/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.

Resource Sharing Plans 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: <http://www.cdc.gov/grants/additionalrequirements/index.html>. Investigators responding to this funding opportunity should include a plan on sharing research resources and data.

Budget and Period of Support Reviewers will consider whether the budget and the requested period

of support are fully justified and reasonable in relation to the proposed research. The applicant can obtain guidance for completing a detailed justified budget on the CDC website, at the following Internet address: <http://www.cdc.gov/grants/interestedinapplying/applicationresources.html>

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 FOA. Following initial peer review, recommended applications will receive a second level of review. The following will be considered in making funding decisions:

- 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.
- Pending the scientific merit and second level review of the applications, and the availability of funding, the following will also be considered in making funding decisions:
 - Diversity and balance across the programs, policies, or practices to achieve a broad base or breadth of RPE programs, policies, or practices that will be evaluated;
 - Balance between evaluations of programs, policies, and practices that have been established and operating for a longer period of time, with those that have been newly implemented;
 - Potential for the program, policy, or practice to impact population-wide changes by addressing the outer layers of the social ecological model;
 - Geographic diversity of the RPE-funded organization or partner that is implementing the program, policy, or practice.

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 FOA will be subject to the DUNS, SAM Registration, and Transparency Act requirements. If the application is under consideration for funding, HHS/CDC will request "just-in-time" information from the applicant as described in the HHS Grants Policy Statement (<http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf>).

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

Awardees 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

All HHS/CDC grant and cooperative agreement awards include the HHS Grants Policy Statement as part of the NoA. For these terms of award, see the HHS Grants Policy Statement Part II: Terms and Conditions of Award (<http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf>).

Awardees must comply with the administrative requirements (AR) outlined in 45 Code of Federal Regulations (CFR) Part 75, as appropriate, as well as any additional requirements included in the FOA. Specific requirements that apply to this FOA are the following:

Generally applicable ARs:

[AR-1: Human Subjects Requirements](#)

[AR-2: Inclusion of Women and Racial and Ethnic Minorities in Research](#)

[AR-7: Executive Order 12372 Review](#)

[AR-9: Paperwork Reduction Act Requirements](#)

[AR-10: Smoke-Free Workplace Requirements](#)

[AR-11: Healthy People 2020](#)

[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-21: Small, Minority, And Women-owned Business](#)

[AR-22: Research Integrity](#)

[AR-24: Health Insurance Portability and Accountability Act Requirements](#)

[AR-25: Release and Sharing of Data](#)

[AR-26: National Historic Preservation Act of 1966](#)

[AR-28: Inclusion of Persons Under the Age of 21 in Research](#)

[AR-29: Compliance with EO13513, “Federal Leadership on Reducing Text Messaging while Driving”, October 1, 2009](#)

[AR-30: Information Letter 10-006, - Compliance with Section 508 of the Rehabilitation Act of 1973](#)

[AR 31 - Distinguishing Public Health Research and Public Health Nonresearch](#)

[AR 32 –; FY 2012 Enacted General Provisions](#)

[AR 33 - United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern](#)

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](#)

For more information on the Code of Federal Regulations, visit the National Archives and Records Administration at: <http://www.archives.gov/>.

To view brief descriptions of relevant CDC requirements visit: http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm.

3. Additional Policy Requirements

The following are additional policy requirements relevant to this FOA:

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 apply to all new obligations and all funds appropriated by Congress. For more information, visit the HHS website

at: <http://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>.

Tobacco and Nutrition Policies

The CDC supports implementing evidence-based programs and policies to reduce tobacco use and secondhand smoke exposure, and to promote healthy nutrition. CDC encourages all awardees to implement the following *optional* evidence-based tobacco and nutrition policies within their organizations. These policies build on the current federal commitment to reduce exposure to secondhand smoke, which includes The Pro-Children Act, 20 U.S.C. 7181-7184 that prohibits smoking in certain facilities that receive federal funds.

Tobacco:

- Tobacco-free indoors – no use of any tobacco products (including smokeless tobacco) or electronic cigarettes in any indoor facilities under the control of the applicant.
- Tobacco-free indoors and in adjacent outdoor areas – no use of any tobacco products or electronic cigarettes in any indoor facilities, within 50 feet of doorways and air intake ducts, and in courtyards under the control of the applicant.
- Tobacco-free campus – no use of any tobacco products or electronic cigarettes in any indoor facilities and anywhere on grounds or in outdoor space under the control of the applicant.

Nutrition:

- Healthy food service guidelines that at a minimum align with Health and Human Services and General Services Administration Health and Sustainability Guidelines for Federal Concessions and Vending Operations for cafeterias, snack bars, and vending machines in any facility under the control of the recipient organization and in accordance with contractual obligations for these services. The following are resources for healthy eating and tobacco free workplaces:

- http://www.gsa.gov/graphics/pbs/Guidelines_for_Federal_Concessions_and_Vending_Operations.pdf
- <http://www.cdc.gov/nccdphp/dnpao/hwi/toolkits/tobacco/index.htm>
- <http://www.cdc.gov/obesity/strategies/food-serv-guide.html>

Applicants should state whether they choose to participate in implementing these two optional policies. However, no applicants will be evaluated or scored on whether they choose to participate in implementing these optional policies.

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 the 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.

4. Cooperative Agreement Terms and Conditions of Award

This FOA is for a cooperative agreement. Under the cooperative agreement mechanism, the Centers for Disease Control and Prevention's (CDC) purpose is to support the awardee's activities. Applicants are advised that any activities involving information collection (i.e., surveys, questionnaires, etc.) from 10 or more individuals funded by a cooperative agreement will be subject to a Paperwork Reduction Act (PRA) determination and may or may not be subject to approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. PRA applicability will depend on the level of CDC involvement with the development, collection and management of information/data.

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

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial CDC programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the HHS/CDC purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; CDC Project Officers are not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and HHS/CDC as defined below.

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

- Designing and conducting research to address the described research objectives of this cooperative agreement.
- Undertaking any data collection solely to meet the applicant's research needs. Retaining custody of and exercising primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and CDC policies.
- Partnering effectively with any outside entities expected to participate in the proposed research. Such partnerships should be well-defined and documented by letters of support or Memoranda of Understanding detailing the nature and extent of involvement.
- Establishing goals and objectives that are realistic, measurable, and time-oriented for all phases of the project.

- Developing a research protocol involving human subjects for Institutional Review Board (IRB) review and approval by all cooperating institutions participating in the research project, including CDC if applicable.
- Assuring that IRB approvals are current for research involving human subjects for all participating sites.
- 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 a kick-off meeting at CDC in Atlanta and at least one trip per year for a briefing on 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.

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

- Providing suggestions, as requested by the awardee, for improving research protocols (e.g., for sampling, recruitment, assessment, and data management), and participating in analysis, interpretation, and dissemination of study findings, including 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.
- Collaborating with the grantee 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.
- 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 awardee and CDC will establish a schedule for regular phone calls to discuss ongoing progress. This schedule will be agreed on by both the awardee and CDC.

For the applicants that are successfully funded under this FOA, the recipient agrees that upon award, their application and the summary of reviewers' comments will be shared with the CDC staff who will serve as collaborators on this research project and provide technical assistance 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.

The Paperwork Reduction Act of 1995 (PRA): Applicants should be advised that any activities involving information collection (i.e., posing similar questions or requirements via surveys, questionnaires, telephonic requests, focus groups, etc.) from 10 or more non-Federal entities/persons, including States, are subject to

PRA requirements and may require CDC to coordinate an Office of Management and Budget (OMB) Information Collection Request clearance prior to the start of information collection activities. This would also include information sent to or obtained by CDC via forms, applications, reports, information systems, and any other means for requesting information from 10 or more persons; asking or requiring 10 or more entities/persons to keep or retain records; or asking or requiring 10 or more entities/persons to disclose information to a third-party or the general public.

5. Reporting

Awardees will be required to submit the [Non-Competing Continuation Grant Progress Report \(PHS 2590\)](#) annually 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 awardees 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 awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable CDC grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsr.gov on all subawards over \$25,000. See the HHS Grants Policy Statement (<http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf>) for additional information on this reporting requirement.

A. Submission of Reports

The Recipient Organization must provide HHS/CDC with an original, plus one hard copy of the following reports:

1. **Yearly Non-Competing Grant Progress Report**, (use form PHS 2590, posted on the HHS/CDC website, www.grants.gov and at <http://grants.nih.gov/grants/funding/2590/2590.htm>, **is due 90 to 120 days prior to the end of the current budget period.** The progress report will serve as the non-competitive 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 is required and must be submitted through eRA Commons **within 90 days after the end of the calendar quarter in which the budget period ends.**
3. **A final progress report**, invention statement, equipment/inventory report, and the final FFR are required **90 days after the end of the project period.**

B. Content of Reports

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

- Description of Progress during Annual Budget Period: Current Budget Period Progress reported on the PHS 2590 ([http:// grants1.nih.gov/ grants/funding/ 2590/2590.htm](http://grants1.nih.gov/grants/funding/2590/2590.htm))
<http:// grants.nih.gov/grants/ funding/2590/2590.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 contributed 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.
- Additional Reporting Requirements:

N/A

2. Annual Federal Financial Reporting

The Annual Federal Financial Report (FFR) SF 425 is required and must be submitted through eRA Commons within 90 days after the end of the calendar quarter in which the budget period ends. 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. **All CDC Financial Expenditure data due on/after October 1, 2012 must be submitted using the FFR via the eFSR/FFR system in the eRA Commons.** All Federal Reporting in the Payment Management System is unchanged. All new submissions should be prepared and submitted as FFRs.

CDC's implementation of the FFR retains a financial reporting period that coincides with the budget period of a particular project. However, **the due date for annual FFRs will be 90 days after the end of the calendar quarter in which the budget period ends.** Note that this is a change in due dates of annual FFRs and may provide up to 60 additional days to report, depending upon when the budget period end date falls within a calendar quarter. For example, if the budget period ends 1/30/2012, the annual FFR is due 6/30/2012 (90 days after the end of the calendar quarter of 3/31/2012). Due dates of final reports will remain unchanged. The due date for final FFRs will continue to be 90 days after the project period end date.

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

FFR (SF 425) instructions for CDC grantees are now available at [http:// grants.nih.gov/ grants/forms.htm](http://grants.nih.gov/grants/forms.htm).

For further information, contact GrantsInfo@nih.gov. Additional resources concerning the eFSR/FFR system, including a User Guide and an on-line demonstration, can be found on the eRA Commons Support Page: https://era.nih.gov/registration_accounts.cfm

FFR Submission: The submission of FFRs to CDC will require organizations to register with eRA Commons (Commons) ([https:// commons. era.nih.gov/ commons/](https://commons.era.nih.gov/commons/)). CDC recommends that this one time registration process be completed at least 2 weeks prior to the submittal date of a FFR submission.

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/registration/registration_instructions.jsp 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: <http://era.nih.gov/commons/index.cfm>.

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 project period. 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.

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

CDC Technical Information Management Section (TIMS)

Telephone 770-488-2700

Email: ogstims@cdc.gov

Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Time

Scientific/Research Contact(s)

- Susan Neurath, Ph.D.
- National Center for Injury Prevention and Control
- Telephone: 770-488-3368
- Email: SNeurath@cdc.gov

Peer Review Contact(s)

- M. Chris Langub, Ph.D.
- National Center for Injury Prevention and Control
- Telephone: 770-488-3585
- Email: MLangub@cdc.gov

Financial/Grants Management Contact(s)

- Veronica H. Davis
- Centers for Disease Control and Prevention
- ONDIEH
- Telephone: 770-488-2743
- Email: VAD4@cdc.gov

Section VIII. Other Information

Other CDC funding opportunity announcements 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 Federal Regulations.

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

CE16-005; Amendment 1

April 18, 2016

Questions and Answers from the Pre-Application Call held on April 11, 2016.

Please note that the questions and answers below do not represent an actual transcript of the Pre-Application Call. The questions have been edited for accuracy and clarity.

Q1. My colleagues and I are considering submitting an application to evaluate a communication effort aimed at changing social norms among men thereby reducing sexual violence perpetration. Would an evaluation of the implementation of a communication-driven prevention strategy qualify as a “program, policy or practice” as long as the other elements of the FOA’s requirements are met?

A communication effort to change social norms as described in the question could qualify as a “program, policy, or practice”. Please remember that the communication effort, as with any other qualifying “program, policy, or practice” must be one that is currently implemented, or planned to be implemented by a CDC-funded RPE Program and must meet all of the other criteria described in this FOA. As with any other selected program, policy, or practice – it will be important to explain why the selected strategy is likely to be effective.

Q2. Could the proposed research evaluate a program, policy, or practice that is focused on the primary prevention of sexual violence against children?

The FOA does not preclude an evaluation of a program, policy, or practice that is focused on the primary prevention of sexual violence against children. It will be necessary that the selected program, policy, or practice be one that is implemented, or planned for implementation, by the participating RPE-funded organization and meets all of the criteria described in the FOA for an eligible program, policy, or practice (as described in the Approach and Eligibility sections of the FOA).

Q3. Could the RPE Partner be a Co-PI for this Cooperative Agreement?

The FOA does not preclude a staff member from a partnering RPE-funded organization(s) with an established history of providing rape prevention and education services to their community from serving as a Co-PI or Co-Investigator. Please note that even if a staff member from a partnering RPE-funded organization(s) serves as a Co-PI or Co-Investigator, the application will still need to provide the appropriate documentation described in the Special Eligibility Requirements and Responsiveness sections of the FOA, including the specific information required for Appendix 1, 2, 3, and 4.

Q4. *Should* an RPE Partner be a Co-PI for this Cooperative Agreement?

The FOA neither precludes nor requires that a staff member from a partnering RPE-funded organization(s) serves as a Co-PI or Co-Investigator. This FOA seeks research proposals that include strong and meaningful partnerships between all of the participating entities. Please note that the PI, Co-PIs or Co-Investigators must meet the specific qualifications outlined in the FOA under Special Eligibility Requirements.

Q5. Could an evaluation of a program, policy, or practice that was developed by an RPE-funded organization and implemented by other partner organizations be competitive for this funding opportunity?

The FOA requires that the program, policy, or practice proposed for evaluation be currently implemented or planned for implementation by the RPE-funded organization. Appendix 2 must contain a letter from the Director of the RPE-funded organization attesting 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. As long as the responsiveness criteria are met regarding the inclusion of the RPE-funded organization as an implementing partner and the evaluation occurring in the jurisdiction where the RPE-funded organization is implementing or planning to implement, it is possible to include additional sites in the sample to strengthen the study design (see response to #7).

Q6. If we (a non-RPE-funded organization) submit evidence of the partnering RPE-funded organization's work plans from prior years showing that they developed the program, policy, or practice, would this meet the requirements of the Responsiveness Criteria?

The work plans could be part of the evidence provided but it would still be necessary to address the other responsiveness criteria in *Section III. Eligibility Information, 5. Responsiveness*, including the formal documentation of the agreements between the applicant and the RPE-funded organization(s).

Q7. Are we able to include in our sample all of the universities who are implementing the program, policy, or practice via university personnel? Or are we limited to the one university who is implementing the

program, policy or practice via assistance from their local RPE funded organization?

As long as the responsiveness criteria are met regarding the inclusion of the RPE-funded organization as an implementing partner and the evaluation occurring in the jurisdiction where the RPE-funded organization is implementing or planning to implement the program, policy, or practice, it is possible to include additional universities in the sample to strengthen the study design.

Q8. I've noticed in several places in the FOA's Background and Approach sections there are references to information that must be included in the application for the application to be considered "responsive". What exactly does this mean?

As part of the evaluation process, all of the applications are initially screened against the criteria listed in *Section III. Eligibility Information, 5. Responsiveness*. Only those applications that meet all of the responsiveness criteria will be forwarded to Peer Review.

All of the responsiveness criteria must be completed as specified in the responsiveness section for the application to be considered "responsive" and moved forward to peer review.

Q9. What happens if, on an otherwise strong application, the applicant accidentally makes a mistake on one of the Responsiveness criteria?

If an application does not meet all of the specific requirements described in *Section III. Eligibility Information, 5. Responsiveness* – the application will be deemed "non-responsive" and will not be submitted for Peer Review.

Q10. Would an RPE-funded agency be eligible to apply to this FOA in partnership with the appropriate research entity or principal investigator?

See question 3 above for the response.

Q11. We and our local RPE program are currently conducting and evaluating Green Dot. Would this be a potential conflict of interest? Or are constituents encouraged to evaluate more than one program?

This FOA does not preclude an RPE-funded organization already evaluating one program, policy, or practice from submitting an application to this FOA. The application will reviewed as described in this FOA.

Q12. Two organizations have asked me to work with them on applications for this FOA. Would it meet the spirit of the guidelines if I were to serve as the PI on one, and as a consultant on the other?

It is acceptable to be the PI on one application and a consultant on another. The second paragraph of *Section III Eligibility Information, 10. Number of Applications* states “Only one application per principal investigator will be 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 first application received based on the document’s time and date stamp in Grants.gov.”

If an individual serves on two, or more, applications recommended for funding, CDC will review both applications to ensure that individual is not being compensated for more than 100% of their salary.

Q13. What is the maximum percentage of administrative costs allowed for the budget? Are subcontractors required to adhere to the same budget guidelines regarding the maximum percentage of administrative costs?

Please review the Direct and Indirect (F&A) Costs information in Title 45 Part 75 – Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards; Subpart E – Cost Principles. This section begins at §75.400 (An electronic version of this reference is available at: http://www.ecfr.gov/cgi-bin/text-idx?SID=5da2121f68a07eea5797b67544970610&:mc=true&:node=pt45.1.75&:rgn=div5#sg45.1.75_1411.sg12)

Q14. Will federally approved indirect cost rates be accepted from the applicant and/or the subcontractor?

Please review the Direct and Indirect (F&A) Costs information in Title 45 Part 75 – Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards; Subpart E – Cost Principles. This section begins at §75.400 (An electronic version of this reference is available at: http://www.ecfr.gov/cgi-bin/text-idx?SID=5da2121f68a07eea5797b67544970610&:mc=true&:node=pt45.1.75&:rgn=div5#sg45.1.75_1411.sg12)

Q15. The first paragraph of the Research Objectives states that “To be responsive to this FOA, the application must propose a rigorous evaluation of a practice-based sexual violence primary prevention program, policy, or practice that is currently being implemented or planned for implementation by an RPR-funded organization for its impact on sexual violence perpetration.” Please define “plan to implement”. Does this mean that the program, policy or practice has to be in the current work plan of the RPE-funded organization?

Please see the 5th paragraph in the Collaborations/Partnerships section. The final sentences state “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 the completion of a rigorous evaluation of changes in sexual violence perpetration within the 4-year project period.”

Q16. As a follow-up to #16, will there be time allowed for planning in the first year?

Applicants should propose a timeline that reflects all activities from planning, to implementation, to analysis, and dissemination. The Peer Reviewers will consider the appropriateness of the timeline.

Q17. If a state health department applies for this FOA, will they need MOUs from the RPE director?

Please see in *Section III. Eligibility Information, 5. Responsiveness*, the specific requirements for Appendix 1. It states “Appendix 1 must contain the letter of support, memoranda of understanding, memoranda of agreement, or other formal documentation of the agreements between the applicant and the partner RPE-funded organization(s) with an established history of providing rape prevention and education services to their community.”

Q18. In addition to the example designs listed, are you open to rigorous mixed method designs (i.e., qualitative component would be in addition to a quantitative component, not in place of)?

The 7th paragraph of the *Research Objectives* lists a number of rigorous outcome evaluations. This is a list of examples. A rigorous mixed method design that includes a qualitative component in addition to a quantitative component could be eligible. Applicants are expected to provide a proposal illustrating how the rigorous evaluation will be conducted/completed during the 4-year project period. Please also consider *Section V. Application Review Information, 1. Criteria, Scored Review Criteria, Approach*.

Reviewers will consider these criteria in the determination of scientific merit.

Q19. At what level does the CDC have the greatest interest in seeing research: the program/intervention level, community/practice level, or the policy level?

Although it is not a requirement, programs, policies, or practices that address evidence-based risk and protective factors for one or more of the outer layers of the social ecological model (e.g., community-, or societal-level) are encouraged.

Q20. If we are looking at the policy level, the RPE-funded grantees may not have a primary role in implementing an intervention/strategy. How would you like to see them included as a partner in that circumstance; for example, could they just serve on the RAB (research advisory board)?

The FOA requires that the program, policy, or practice proposed for evaluation be currently implemented or planned for implementation by the RPE-funded organization. In the case of a policy level intervention, it would be important to describe how RPE funding was used to facilitate implementation. For example, it would be appropriate to describe how RPE funding was used to provide education about the burden or risks for sexual violence to help inform the policy.

Q21. In the Approach section, the second paragraph of the Research Objectives states “Additionally, the research is also expected to provide an estimate of the cost of implementation to inform economic evaluation of the program, policy, or practice considered.” However the paragraph just above Objectives/Outcomes states “Applicants should include plans to estimate the implementation costs associated with the proposed program, policy, or practice during the course of 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.”

Please clarify if the cost of implementation is required and, if so, should it be one of the specific aims of the research? Or could we just address it in the body of the proposal?

It is important to describe how the implementation costs associated with the proposed program, policy, or practice will be documented in order to inform future economic evaluations of the approach (e.g., cost-effectiveness). There is flexibility regarding where in the application this information is described. The reviewers will be considering the applicant’s plan to estimate these costs when evaluating the application.

We recognize that cost of implementation and cost effectiveness are not the same. Do you recommend including both?

Applicants are expected to include a plan for estimating the costs of implementation. A plan for a cost-effectiveness evaluation is not required.

Q22. The first paragraph of the Primary and Secondary Outcome Measures states “Thus, all proposals are expected to include *valid and reliable measures of sexual violence perpetration* as the primary outcome of interest.”

Can we use victimization rates as a measure, or do we need self-reported rates of perpetration? The validity and reliability of self-reported perpetration is questionable, so are there other measures, such as arrest rates, that can be used?

Please see the next sentence of this paragraph. It states “The indicator of sexual violence used for outcome measurement purposes may vary depending on the intervention population (e.g., age, context) and data sources available (e.g., survey, administrative).” Applicants are expected to select, describe and justify their methodological design, including the choice of indicator data. Victimization rates can be used as an indicator of perpetration.

Q23. The FOA defines the primary outcome of interest as sexual violence perpetration and is to include actual behavior, including physical forms of sexual violence (e.g., rape, unwanted sexual contact).

Is CDC only looking for individual or relationship-level intervention studies, with some form of assignment (random preferred) to independent groups where the impact of the intervention upon sexual violence behaviors can be assessed? Where does this leave room for rigorous evaluation of outer-layer primary prevention RPE-funded strategies that may impact community-level risk or protective factors around conditions/context? For example, for a strategy with a focus on a large geographic area (e.g. multiple counties), would the proposal need to specifically demonstrate the effectiveness on reducing SV perpetration in that area, or could it aim to measure short and intermediate process and outcome measures (with theory of change leading to long-term outcome of decreased perpetration rates)?

Please see the 7th paragraph of the Background section. It states “Communities require a broader and more comprehensive “menu” of effective programs, policies, and practices that allow them to select approaches to meet their unique needs. The availability of a diverse set 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) Research funded under this announcement is expected to address these important gaps in the sexual violence prevention field. Programs, policies, or

practices that are designed to address one or more of the outer layers of the social ecology model (e.g., community- or societal-level) are strongly encouraged.” Applicants are expected to select, describe and justify their methodological design, including the choice of indicator data. The intent of this FOA is to identify effective strategies currently implemented or planned for implementation by RPE-funded organizations for the primary prevention of sexually violent behavior. Thus, all proposals are expected to include valid and reliable measures of sexual violence as the primary outcome of interest. The indicator of sexual violence used for outcome measurement purposes may vary depending on the intervention population (e.g., age, context) and data sources available (e.g., survey, administrative).

Q24. The FOA frames the purpose as, "research to rigorously evaluate the effectiveness of primary prevention programs, policies, or practices." Will proposals that fully embrace Community-Based Participatory Research (CBPR) principles be considered? If not, why not?

Applications that meet all of the responsiveness criteria described in *Section III. Eligibility Information, 5. Responsiveness* will be forwarded to Peer Review and reviewed for scientific merit using the criteria described in *Section V Application Review Information*. The goals and expectations for community engagement are described under *Community Engagement in the Approach* section.

Q25. The FOA says, “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 the completion of a rigorous evaluation of changes in sexual violence perpetration within the 4-year project period.” This is confusing- What other RPE-funded program, policies or practices are eligible besides those which are currently being implemented? Also, our state health department puts RPE sub-grantee contracts out to bid. We are currently under contract until 2017. Will we need to demonstrate a contract and funded workplan beyond that point in our application?

For this FOA, the only eligible RPE-funded programs, policies, or practices are those that are currently implemented or those planned for implementation with a timeframe that would allow for the completion of a rigorous evaluation of changes in sexual violence perpetration within the 4-year project period. For applications proposing to evaluate an RPE-funded program, policy, or practice that is planned for implementation, it is important to include documentation showing that the program, policy, or practice is part of a CDC- or state-approved RPE work plan. It is also important to describe how implementation of the prevention strategy to be evaluated will be sustained for the intervention period proposed in the application.

Q26. Are stipends or incentives for research participants allowed in the budget if they are directly related to the conduct of rigorous evaluation research?

Modest/nominal remuneration (incentives) for study participants may be allowed. Applicants will be expected to clearly describe and justify the need for remuneration costs in the budget and budget justification of the proposal. If remuneration for study participants is proposed, funded applicants are expected to include a copy of their institution’s internal policies on remuneration for study participants.

Q27. In light of the timeframe for sending answers to questions and the planned posting of the amended FOA, is the Letter of Intent deadline still April 22, 2016, or has that deadline changed?

The due date for the Letters of intent will still be April 22.

Q28. Can the Letter of Intent be submitted via email?

Yes; you may submit your Letter of Intent by email to Chris Langub at EEO6@cdc.gov.

Q29. My organization receives CDC RPE funds for a primary prevention program INDIRECTLY as a grantee of a state Dept. of Health (DOH) RPE program. We don’t receive the funds directly from the CDC.

Does receiving CDC RPE program funds through a grant from the DC Department of Health RPE program qualify my organization as a “locally funded ‘partner’” (as referenced on page 9 of the FOA) of a CDC RPE-funded organization?

For the purposes of this FOA, a “locally-funded partner” is an organization that receives funding from a state Department of Health that is an RPE-funded organization and uses the funds to implement the state Department of Health’s RPE program, policy, or practice within the state’s jurisdiction.

Could our state DOH RPE program-funded primary prevention program qualify as a suitable program for evaluation under this CDC FOA?

The program, policy, or practice would need to meet the characteristics of a program, policy, or practice described in the FOA – including the responsiveness criteria.

If so, would only the portion of our program that is conducted in the state providing the funds to us qualify for evaluation?

The evaluation is expected to occur in the jurisdiction where the RPE-funded organization is implementing or planning to implement, the program, policy, or practice to be evaluated.

It is possible to include similar programs that your organization conducts in other states - as long as the responsiveness criteria are met regarding the inclusion of the RPE-funded organization as an implementing partner and the evaluation occurring in the jurisdiction where the RPE-funded organization is implementing or planning to implement the program, policy or practice.

If our state Department of Health RPE program-funded program qualifies as a suitable program for evaluation under this CDC FOA, would we be required to include a letter of support from the Director of the DC Dept. of Health in our application?

It is important to include the letters of support described in the Responsiveness criteria for Appendix 1 and 2.

Q30. Can an organization whose primary prevention program is being proposed for evaluation be the applicant? If so, would that applicant be required to formally partner with another organization (a subgrantee) that would do the evaluation?

See Section III Eligibility Information for a description of eligible applicants. Regardless of the applicant category, all applications must meet all of the *Section III. Eligibility Information, 5. Responsiveness* criteria.

Q31. In *Section III. Eligibility Information, 5. Responsiveness*, the information describing the expectations for Appendix 3 states “Appendix 3 must contain the following statement signed by the PI and RPE-funded partner:

I hereby certify that, to the best of my knowledge, this application meets the following criteria:

- The proposed practice-based program, policy, or practice for sexual violence prevention is a primary-prevention strategy. It does not include secondary or tertiary prevention strategies as described in this FOA;
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- The proposed practice-based program, policy, or practice is not one of the established programs,

policies, or practices listed above (i.e., Safe Dates, Shifting Boundaries, RealConsent, GreenDot, and Coaching Boys into Men);

-
- The proposed practice-based program, policy, or practice does not replicate or make changes (adaptions) to any of [the] programs, policies, or practices listed above (i.e., Safe Dates, Shifting Boundaries, RealConsent, GreenDot, and Coaching Boys into Men).”

The program, policy, or practice that we are implementing is not on your list in an adapted mode. Would this program, policy, or practice be acceptable for this FOA?

The proposed program, policy, or practice must not be an adaption or replication of any of those listed above. Additionally, the proposed program, policy, or practice is also expected to meet all of the other responsiveness criteria as well.

We understand that our selected program, policy, or practice has been (or still maybe) under evaluation. If we adapt it and implement it as a part of a comprehensive approach, would it be acceptable for this FOA?

The intent of the FOA is to expand on, and not replicate, the existing evidence base. It will be important to describe the need for rigorous evaluation of the violence prevention program, policy, or practice proposed. The proposed program, policy, or practice is expected to meet all of the responsiveness criteria.

Applicants are expected to develop a proposal that meets the purpose, intent and Research Objectives described in this FOA.

Q32. Can there be more than one partnering local rape crisis center implementing the program, policy, or practice(s)?

As long as the responsiveness criteria are met regarding the inclusion of the RPE-funded organization as an implementing partner and that the evaluation will occur in the jurisdiction where the RPE-funded organization is implementing or planning to implement the program, policy, or practice, it is possible to include additional local rape crisis centers to strengthen the study design.

Q33. Can we compensate the schools for their additional time and effort needed to participate in this research

project?

Modest/nominal remunerative for the schools may be allowed. Applicants will be expected to clearly describe and justify remuneration costs in the budget and budget justification of the proposal. If remuneration of participating schools is proposed, clearly describe the funding amount and mechanism (e.g., sub-contract). If a sub-contract, this activity is expected to be included in the sub-contract agreements. Funded applicants are also expected to include a copy of their institution's relevant internal policies.

Q34. We are developing a process for identifying which of the state's local rape crisis centers are best prepared to partner with us in this research project. Do we need to have the specific local rape crisis center's identified before we submit our application? Or is it sufficient for us to describe our process for identifying our partnering local rape crisis center(s)?

Please see the *Section III. Eligibility Information, 5. Responsiveness*, criteria for Appendix 1. Applicants are expected to include formal documentation of the agreements between the applicant and the RPE-funded organization.

List of Changes:

- Page 18; added “the” to the final sub-bullet for “Appendix 3”.