

Centers for Disease Control and Prevention

NATIONAL CENTER FOR INJURY PREVENTION AND CONTROL

Research Grants to Rigorously Evaluate Innovative and Promising Strategies to Prevent Firearm-Related Violence and Injuries

RFA-CE-25-030

12/02/2024

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Overview

Participating Organization(s)

Centers for Disease Control and Prevention

Components of Participating Organizations

Components of Participating Organizations:

National Center for Injury Prevention and Control

Notice of Funding Opportunity (NOFO) Title

Research Grants to Rigorously Evaluate Innovative and Promising Strategies to Prevent Firearm-Related Violence and Injuries

Activity Code

Applications in response to this Notice of Funding Opportunity (NOFO) will be funded using the R01 activity code for a research grant.

Notice of Funding Opportunity Type

New

Agency Notice of Funding Opportunity Number

RFA-CE-25-030

Assistance Listings Number(s)

93.136

Category of Funding Activity

HL - Health

NOFO Purpose

The Centers for Disease Control and Prevention's (CDC) National Center for Injury Prevention and Control (NCIPC or the Injury Center) is soliciting investigator-initiated research to

rigorously evaluate the effectiveness of innovative and promising strategies to prevent all forms of firearm-related injuries, deaths, violence, or crime. For this announcement such forms include:

- mass shooting incidents
- other firearm homicides/assaults
- firearm suicides/self-harm
- unintentional firearm deaths and injuries
- firearm-related crime

This announcement supports research to evaluate the effectiveness of strategies to keep individuals, families, schools, and communities safe from firearm-related injuries, deaths, violence, or crime.

Key Dates

Publication Date:

To receive notification of any changes to RFA-CE-25-030, return to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notification Emails" link. An email address is needed for this service.

Letter of Intent Due Date:

11/01/2024

Application Due Date:

12/02/2024

On-time submission requires that electronic applications be error-free and made available to CDC for processing from the NIH eRA system on or before the deadline date. Applications must be submitted to and validated successfully by Grants.gov no later than 11:59 PM U.S. Eastern Time.

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

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

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

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

Scientific Merit Review:

03/18/2025

This date is an estimate.

Secondary Review:

05/01/2025

This date is an estimate.

Estimated Start Date:

09/30/2025

Expiration Date:

01/02/2025

Required Application Instructions

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

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

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

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

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

Executive Summary

Research funded under this Notice of Funding Opportunity (NOFO) should rigorously evaluate the effectiveness of innovative and promising strategies to keep individuals, families, schools, and communities safe from firearm-related injuries, deaths, violence, or crime.

This NOFO offers **Funding Option A** or **B** to address the research objective. Applicants may submit a research proposal under either Funding Option A or B (not both).

- **Funding Option A** will support research projects that rely on existing data to evaluate effectiveness and that do not support implementing prevention activities. These projects will be funded up to \$350,000 per year (direct and indirect costs) for a period of performance for up to 2 years.
- **Funding Option B** will support research projects that require new data collection and/or implementing prevention activities to evaluate effectiveness. These projects will be funded up to \$650,000 per year (direct and indirect costs) for a period of performance for up to 3 years.

Applicants are requested to clearly indicate in the Abstract whether the research proposal falls under Funding Option A or Funding Option B. CDC will only consider one funding option for each applicant.

Special Date(s)

A pre-application webinar call will be conducted on October 22, 2024 to address questions from prospective applicants regarding NOFO RFA-CE-25-030. The call will begin at 2:00pm Eastern Standard Time (EST) and end at 2:50pm Eastern Standard Time (EST), or sooner if all questions are addressed. Questions and answers from the discussion will be included in an amended NOFO approximately 3 weeks after the call.

Participant Access Information:

- Call Date: October 22, 2024
- Call Start Time: 2:00pm Eastern Standard Time (EST)
- Call End Time: 2:50pm Eastern Standard Time (EST)
- Call Leader: Emiko Petrosky, MD, MPH, Scientific Program Official
- Webinar Link:
 - https://cdc.zoomgov.com/j/1605372272?pwd=NldPVFJ0TjdKSnBya0hjekU0VGdrdz09
- Webinar ID: 160 537 2272
- Passcode: Xk3&dyp1
- Call-In Numbers:
 - o +1 669 254 5252 US (San Jose)
 - o +1 646 828 7666 US (New York)
 - +1 646 964 1167 US (US Spanish Line)
 - o +1 551 285 1373 US (New Jersey)
 - o +1 669 216 1590 US (San Jose)
 - o +1 415 449 4000 US (US Spanish Line)
- Dial-In Passcode: 71672817

Section I. Funding Opportunity Description

Statutory Authority

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

1. Background and Purpose

Firearm-related injuries, deaths, violence, and crime, including mass shooting incidents, other firearm homicides/assaults, firearm suicides, and unintentional firearm injuries affect people in all stages of life. Firearm injuries are among the leading causes of death for young people. In 2022, 79% of all homicides and 55% of all suicides involved firearms. The impact of firearm-related injuries extends beyond deaths. Many more people suffer nonfatal firearm-related injuries. People hospitalized with nonfatal gunshot wounds often experience long-term consequences, including physical disabilities and chronic mental health problems from conditions such as post-traumatic stress disorder. The economic impact of firearm violence is also substantial and costs the United States billions of dollars each year, including medical and lost productivity costs.

The effects of firearm violence are pervasive and extend beyond victims and their families. Public mass shooting incidents and other firearm homicides and assaults can affect the sense of community safety and impact everyday decisions. For example, in a recent study, adolescents exposed to a high school shooting had a 20% greater odds of avoiding school because of feeling unsafe. Research that helps guide strategies to enhance safety and reduce risk for all forms of firearm-related injuries, deaths, violence, or crime is critical.

While firearm-related injuries can affect anyone, some populations experience more firearm injuries and deaths than others. For example, rates of firearm homicide are generally higher in urban than rural communities, whereas rates of firearm suicide are often higher in rural than in urban communities. Firearm suicide rates are highest among older adults and non-Hispanic American Indian/Alaskan Native and White populations. Firearm homicide rates are highest among adolescents and young adults and non-Hispanic Black, American Indian/Alaskan Native, and Hispanic populations. The firearm homicide rate rose nearly 35% between 2019 and 2020, with the highest rates and largest increases among young Black men and boys. Firearm homicide rates continued to rise in 2021 and remained high but decreased slightly in 2022. The firearm suicide rate rose substantially between 2019 and 2022, with the largest increase among the American Indian and Alaska Native population relative to other racial and ethnic groups.

Research can address inequities by considering the contextual conditions that contribute to variations in risk across communities and populations. Inequities in these social and structural determinants of health (e.g., concentrated poverty, structural racism, high rates of unemployment and community violence, weak social connectedness, limited access to high-quality education and/or affordable, high-quality childcare) contribute to health inequities including those seen in health status across population groups and communities. The COVID-19 pandemic worsened the effects of multiple stressors for some groups, particularly in racial/ethnic minority communities. Research is needed to better address inequities in risk for firearm-related injuries. This will include studies that inform or evaluate strategies to address social and structural conditions that contribute to these inequities.

In 2013, the Institute of Medicine (IOM) in collaboration with the National Research Council (NRC) released the report, *Priorities for Research to Reduce the Threat of Firearm-Related Violence*. CDC and the CDC Foundation asked the IOM/NRC to convene a committee to engage diverse partners. The task of this committee was to identify the most pressing research questions on firearm violence, including those with the greatest potential for public health impact. This research funding announcement draws on the priorities included in the *Priorities for Research to Reduce the Threat of Firearm-Related Violence* (see

https://www.nap.edu/catalog/18319/priorities-forresearch-to-reduce-the-threat-of-firearm-related-violence).

Purpose

The Centers for Disease Control and Prevention's (CDC) National Center for Injury Prevention and Control (NCIPC or the Injury Center) is soliciting investigator-initiated research to rigorously evaluate the effectiveness of innovative and promising strategies to prevent all forms of firearm-related injuries, deaths, violence, or crime. For this announcement, this includes mass shooting incidents, other firearm homicides/assaults, firearm suicides/self-harm, unintentional firearm deaths and injuries, and firearm-related crime. This announcement supports research to

evaluate the effectiveness of strategies to keep individuals, families, schools, and communities safe from firearm-related injuries, deaths, violence, or crime.

CDC's Injury Center has been the nation's leading authority on violence and injury prevention for 30 years. The impact of firearm-related injuries on the health and safety of Americans underscores the importance of a comprehensive public health approach to prevention. CDC's Injury Center emphasizes both preventing incidents of violence and suicide from happening in the first place and mitigating their effects through population-based approaches to achieve public health impact.

Toward this end, CDC supports research to understand the best ways to prevent violence and suicide. The results of this research are then applied to real-world solutions to keep people safe, healthy, and productive.

Healthy People 2030 and other National Strategic Priorities

This research addresses the "Healthy People 2030" focus on injury and violence prevention as described in www.healthypeople.gov. Specifically, this NOFO supports the Healthy People 2030 Injury and Violence Prevention (IVP) areas of IVP-09 Reduce homicides, IVP-13 Reduce firearm-related deaths, IVP-14 Reduce nonfatal firearm-related injuries, IVP-12 Reduce gun carrying by adolescents, and MHMD-01 Reduce the suicide rate.

Public Health Impact

Firearm violence and suicide are significant problems that affect the health of individuals, families, and communities. NCIPC is committed to preventing all forms of firearm-related injuries, deaths, violence, or crime. The results from the research funded under this announcement will directly benefit communities seeking to implement prevention strategies based on the best available evidence.

Relevant Work

CDC's approach involves three elements: 1) a focus on prevention, 2) a science-driven approach to understand risk and protective factors, and 3) multidisciplinary collaboration to address the problem and to keep people safe, healthy, and productive.

Descriptions of CDC's currently funded research on firearm violence and injury prevention are available on NCIPC's website: Funded Research | Firearm Injury and Death Prevention | CDC

Descriptions of CDC's violence prevention initiatives are available on NCIPC's website: Violence Prevention | Violence Prevention | CDC

Information about CDC's National Violent Death Reporting System is available at <u>About The</u> National Violent Death Reporting System | NVDRS | CDC

Information about CDC research priorities in violence prevention and examples of guiding questions are available at <u>Injury Research Priorities (cdc.gov)</u>

Information about CDC's Strategic Vision for violence prevention is available at <u>About the Division of Violence Prevention | Injury Center | CDC</u>

CDC's definition of youth violence is available at <u>About Youth Violence | Youth Violence | Prevention | CDC</u>

CDC's definition of child maltreatment is available at <u>About Child Abuse and Neglect | Child Abuse and Neglect Prevention | CDC</u>

CDC's definition of intimate partner violence is available at <u>Intimate Partner Violence</u> Prevention | CDC

CDC's suicide prevention homepage is available at:

Suicide Prevention | CDC

Facts About Suicide | Suicide Prevention | CDC

CDC has released a series of Resources for Action to help communities use the best available evidence for violence prevention. The Resources for Action describe general prevention strategies and provide examples of specific approaches and their supporting evidence. They are available at

Resources for Action | Violence Prevention | CDC

Suicide Prevention Resource for Action CDC

References

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- Solar O, Irwin A. A conceptual framework for action on the social determinants of health. Social Determinants of Health Discussion Paper 2 (Policy and Practice). Geneva, Switzerland: World Health Organization; 2010. https://www.who.int/publications/i/item/9789241500852. Retrieved on July 7, 2020.

2. Approach

CDC/NCIPC is soliciting investigator-initiated research to rigorously evaluate the effectiveness of innovative and promising strategies to prevent all forms of firearm-related injuries, deaths, violence, or crime.

Objectives/Outcomes

This funding announcement supports rigorously evaluating the effectiveness of innovative and promising strategies to keep individuals, families, schools, and communities safe from firearm-related injuries, deaths, violence, or crime. A firearm injury is defined as a gunshot wound or penetrating injury from a weapon that uses a powder charge to fire a projectile. This definition includes gunshot injuries sustained from handguns, rifles, and shotguns but excludes gunshot wounds from air- and gas-powered guns, BB guns, and pellet guns, and non-penetrating injuries associated with firearms (e.g., "pistol whipping").

Investigations could, <u>for example</u>, conduct research to evaluate the effectiveness and/or test the effects of scaling up or expanding strategies:

- To prevent firearm-related assaults and homicides, suicide/self-directed firearm injuries, mass shooting incidents, unintentional firearm deaths and injuries, and firearm-related crime;
- For different population groups (e.g., children, youth, young adults, active-duty military/veterans, rural/tribal populations, and those at risk of harming themselves or others, including in situations of family and intimate partner violence);
- For different settings (e.g., rural/urban, school, neighborhood, community, online) that can be leveraged to prevent firearm-related injuries and crime; and
- For addressing various individual, peer/family, community and societal risk and protective factors including strategies that address social and structural conditions that contribute to the risk of racial/ethnic inequities for firearm-related injuries and crime.

For this announcement, "strategies" can include programs, policies, or practices. Applicants are encouraged to rigorously evaluate those with the potential for population-wide effects. Applicants are also encouraged to rigorously evaluate factors that lead to effectiveness and barriers to implementation, sustainability, and/or the success of strategies.

Strategies can include broad policies related to healthcare, economic, housing, employment, or educational factors associated with risk for firearm-related injuries and inequities that contribute to disparities in firearm-related injuries. This could also include evaluating strategies specific to firearms, such as laws, programs, and education campaigns related to storage practices or the effects of minimum age requirements, extreme risk protection orders, background checks, mandatory waiting periods, or gun shop interventions on firearm-related injury and death. The prevention strategies listed above are examples and are not an exhaustive list.

Applicants are expected to examine the range of outcomes from the programs, policies, or practices evaluated, including potential unintended negative effects, such as costs or risks to firearm owners. Applicants should describe how the research proposed could inform efforts to reduce firearm-related injuries, deaths, violence, or crime.

Applicants are expected to use the most objective and rigorous study designs possible to answer the proposed research questions. Rigorous evaluations should use experimental (i.e., randomized controlled trials) or quasi-experimental designs (e.g., involve matched comparison groups, use propensity-score matching, instrumental variable methods, regression point displacement, regression discontinuity, or time series). Randomized trials are not feasible for some prevention strategies (e.g., policy evaluations), and alternative quasi-experimental designs are appropriate and acceptable. The proposed research can include qualitative and quantitative methods. Applicants are encouraged to consider using a combination of methods.

The research proposal should include:

- Appropriate outcome measures, such as firearm-related behavior (e.g., access, use, carrying, secure storage and other safety practices), victimization or perpetration, or fatal or nonfatal injury.
- Data analytic plans that are appropriate to the prevention strategy
- Research design and hypotheses; and
- Data collection measures that anticipate and evaluate the effects of threats to the internal and external validity of the specified research design within the period of performance.

Innovative methodologies, such as predictive analytics or machine learning, are also encouraged when appropriate to address the proposed hypotheses.

Prevention programs, policies, or practices examined should be theoretically justified (e.g., include a conceptual model or theory of change, with proposed mediators and moderators, and how the prevention approach is related to firearm injuries, deaths, violence, or crime) and supported with epidemiological and behavioral research.

Examples of outcome and impact data sources include:

- Information from vital statistics
- Police records

- Criminal justice data
- Injury-related hospital or emergency department data
- Relevant self-reported behaviors

The research proposal should anticipate, conceptualize, and measure the intended benefits and potential unintended negative outcomes relevant to the proposed study. The research proposal should also describe appropriate indicators of program, policy, or practice implementation process and success (e.g., coverage, participation, awareness, enforcement). Using multiple data sources is encouraged to improve validity and reliability of each outcome or other selected measures.

Prevention strategies may be categorized based on the timing of prevention efforts - for example, before violence occurs (primary prevention), immediately after violence occurs (secondary prevention), or over the longer term to address trauma or the consequences of violence (tertiary prevention). NCIPC seeks to support research to inform primary (before violence occurs) and secondary prevention strategies (e.g., hospital-based violence intervention programs to prevent escalation or revictimization from firearm violence among youth).

Data Collection, Acquisition, and Analysis

Applicants must identify and describe appropriate data sources and provide evidence of their ability to acquire and/or collect data of sufficient quantity and quality to conduct the proposed research within the period of performance.

At a minimum, applications should clearly describe and justify:

- The proposed sampling methods
- Sample size
- Power estimates
- Data collection methods for the primary outcome(s)
- The timeline for data acquisition (requests for extant data and or primary data collection)

Other proposed secondary measures and subgroup analyses may also be included. Numerous data sources can be used for the outcome data, including information from vital statistics, hospitals or emergency departments, law enforcement or criminal justice agencies, self-reports, and other sources. Administrative data from relevant agencies and survey data collected prior to or in the context of the evaluation are also potential sources. Appropriate data sources will vary by the proposed research approach and outcome measures. The implementation indicators (e.g., acceptability, coverage, participation, awareness, enforcement, and sustainability), and outcome(s) should be measured at the level consistent with the research focus (e.g., federal, state, local, or organizational), the population of interest, and the data sources available or collected for this project (e.g., administrative, survey, surveillance, hospital or emergency departments, detention facilities).

Protection of Human Subjects and Personally Identifiable Information

The Research Strategy section of the application should clearly describe the type, source, access to, and protections of the data and human subjects participating in the study. Access to non-publicly available, previously collected data must be clearly described in the Research Strategy and documented with a signed Data Sharing Agreement or Letter of Support. Access to publicly available, previously collected data must be clearly described in the Research Strategy.

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

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

Population of Focus

Funds are available to conduct studies focused on preventing firearm-related injuries, deaths, violence, or crime. Firearm-related injuries and deaths affect people across the lifespan and in all communities. However, some subgroups are at greater risk and patterns of risk vary by the intent of the injury (e.g., homicide, suicide). For example, firearm homicide rates are high in urban neighborhoods with high rates of crime, violence, and social disadvantage. Young people, particularly racial/ethnic minority male youth, are most at risk for firearm homicide. The most common perpetrator of firearm homicides of females are intimate partners. Firearm suicide rates are high in rural and tribal communities. Males and veterans are at elevated risk for firearm suicide. Applicants are encouraged to focus on populations disproportionately impacted by firearm-related injuries and to consider the underlying social and structural conditions that contribute to these inequities in risk.

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

Collaboration/Partnerships

The applicant organization and contact PI should provide the scientific and technical leadership to conduct the proposed research throughout the entire project. The proposed research work plan described in the Research Strategy section of the application and the SF-424 Research and Related Budget should demonstrate the applicant organization's leadership and involvement throughout the entirety of the project. The applicant organization cannot serve as a "pass through" to fund another entity to conduct most of the research or to provide the scientific or technical leadership to complete the proposed research project.

As stated in the Background of this NOFO, NCIPC recognizes that context matters. The conditions where people live, work, play and learn affect their overall health. As a result, it is important to evaluate innovative and promising prevention strategies that relate to addressing community conditions and ensuring community engagement to prevent firearm-related injuries, deaths, violence, or crime. Applicants are encouraged to seek and include the meaningful involvement of communities to develop and conduct the proposed research and to translate and disseminate results. Community partners include, but are not limited to, state and/or local health departments, local governmental and non-governmental agencies, businesses, firearm owners,

faith-based organizations, and other community-based organizations. Applicants are strongly encouraged to form strong partnerships with community members with lived experience who can participate throughout the project (e.g., developing study methods, collecting data, interpreting results, and disseminating findings). The goals of community involvement include ensuring the relevance of the research for the community and to efficiently and effectively translate results for community use.

Partnerships between the applicant institution and multiple outside entities may be necessary or advantageous to complete the proposed work. The application must describe roles and responsibilities of each partnering entity. This includes demonstrating the applicant's access to planned data sources and study populations and to all partnerships to complete the proposed project.

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

- The nature and extent of the proposed partnership, including the roles and responsibilities of the PI(s) and of the outside entities or partner agencies
- The existing working relationship
- Plans for the proposed research
- The outside entity's scope of work, and
- How the partnership will ensure implementation and sustainability of the proposed evaluation.

The Research Strategy section must describe all data sources and the partnerships that are in place to assure data access for all proposed analyses within the period of performance.

The roles and responsibilities described for each partnering entity must be substantiated with a signed Data Sharing Agreement, Letter or Support (LOS), or Memorandum of Understanding (MOU), and be included in the Letter of Support section of the application. The Data Sharing Agreement, Letter of Support (LOS), or Memorandum of Understanding (MOU) must describe the partner's commitment of resources, time, and personnel to the proposed research. Applications that do not include a signed Data Sharing Agreement, Letter of Support, or Memorandum of Understanding from each partnering entity may not be recommended for funding during the second level of review (see *Section V. Application Review Information 4. Review and Selection Process*).

Peer reviewers will evaluate applications on the extent to which:

- The Research Strategy section clearly describes the roles and responsibilities of each partner involved in data collection and/or the effectiveness evaluation.
- The Research Strategy clearly describes the working relationships between the applicant institution and all partner organizations.
- The Research Strategy clearly describes the involvement and scope of work each partner is willing to complete to ensure the success of the proposed research.

• The relationships and activities of the partnerships described in the Research Strategy are documented by a signed Data Sharing Agreement, Letter of Support, or Memorandum of Understanding that clearly delineates the intent and capabilities of each partnership.

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

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

Evaluation/Performance Measurement

Applicants should provide an evaluation and performance measurement plan with measures of effectiveness. The plan must be able to demonstrate the feasibility of accomplishing the proposed project objectives. Measures of effectiveness must relate to the goals stated in the "Purpose" section of this announcement and be able to measure the intended outputs and outcomes described. Evaluation outcomes should be clearly specified. If applicable, performance measures should include the number of participants recruited into the study, the participation rate, and types of samples collected.

For RFA-CE-25-030, applicants should include appropriate outcome measures, such as firearm-related behavior (e.g., access, use, and safety practices), self-harm/suicide, victimization or perpetration of violence or crime, fatal or nonfatal injury.

Examples of violence outcome and impact data sources include:

- Vital statistics data
- Police record
- Criminal justice data
- Injury-related hospital or emergency department data
- Relevant self-reported behaviors

Applicants are encouraged to use multiple data sources to improve validity and reliability of each outcome or other measure selected. The applicant should appropriately anticipate, conceptualize, and measure the intended benefits and potential unintended negative outcomes of the study proposed.

Translation Plan

Applicants should describe the potential for widespread use of the results from the research proposed and the potential to translate the results with and for community partners. This could include using the findings to promote, enhance, or advance implementation and dissemination of the proposed strategy to inform practice. Applicants should also include plans to appropriately document relevant policy or program implementation methods as well as lessons learned to

facilitate future replication in another research or non-research setting if the prevention strategy is found to be effective. This may include identifying the core components of policies or programs and documenting lessons learned from the study that might inform future adaptations of the strategy for other settings or populations.

Grant recipients may be required to attend one reverse site visit per year in Atlanta with CDC/NCIPC staff during the period of performance to review their progress and findings and to discuss opportunities for widespread dissemination of their research achievements and lessons learned. Travel costs for attending this meeting must be included in the application's travel budget submitted in response to this NOFO.

3. Funding Strategy

N/A

Section II. Award Information

Funding Instrument Type:

G (Grant)

A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.

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:

\$12,900,000

CDC/NCIPC intends to commit up to \$4,300,000 in FY 2025 to fund up to ten (10) applications. Awards issued under this NOFO are contingent upon availability of funds and a sufficient number of meritorious applications.

Anticipated Number of Awards:

10

For awards made under Funding Option A, the maximum award amount will be \$350,000 per award for the first 12-month budget period, including direct and indirect costs. The maximum total project funding amount is \$700,000 over a two (2) year period of performance length, with a maximum of \$350,000 per award per year. The period of performance for an award made under Funding Option A is expected to run from 9/30/2025 to 9/29/2027.

For awards made under Funding Option B, the maximum award amount will be \$650,000 per award for the first 12-month budget period, including direct and indirect costs. The maximum total project funding amount is \$1,950,000 over a three (3) year period of performance length, with a maximum of \$650,000 per award per year. The period of performance for an award made under Funding Option B is expected to run from 9/30/2025 to 9/29/2028.

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

Award Ceiling:

\$650,000

Per Budget Period

Award Floor:

\$0

Per Budget Period

Total Period of Performance Length:

3 year(s)

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

HHS/CDC grants policies as described in the HHS Grants Policy Statement (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf) will apply to the applications submitted and awards made in response to this NOFO.

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

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:

00 (State governments)

01 (County governments)

02 (City or township governments)

04 (Special district governments)

05 (Independent school districts)

06 (Public and State controlled institutions of higher education)

07 (Native American tribal governments (Federally recognized))

08 (Public housing authorities/Indian housing authorities)

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

- 12 (Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education)
- 13 (Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education)
- 20 (Private institutions of higher education)
- 22 (For profit organizations other than small businesses)
- 23 (Small businesses)
- 25 (Others (see text field entitled "Additional Information on Eligibility" for clarification))
- 99 (Unrestricted (i.e., open to any type of entity above), subject to any clarification in text field entitled "Additional Information on Eligibility")

Additional Eligibility Category:

The following types of Higher Education Institutions are always encouraged to apply for CDC support as Public or Private Institutions of Higher Education:

Hispanic-serving Institutions

Historically Black Colleges and Universities (HBCUs)

Tribally Controlled Colleges and Universities (TCCUs)

Alaska Native and Native Hawaiian Serving Institutions

Nonprofits (Other than Institutions of Higher Education):

Nonprofits (Other than Institutions of Higher Education)

Other:

Faith-based or Community-based Organizations

Regional Organizations

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

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

2. Foreign Organizations

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

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

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

3. Additional Information on Eligibility

Please see Section III. Eligibility Information.

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

It is the applicant's responsibility to ensure that the application meets <u>all</u> responsiveness criteria listed in this section. Applications that do not meet all of the following Responsiveness criteria will be considered nonresponsive and will not be forwarded for peer review. HHS/CDC will notify the applicant that the application did not meet the submission requirements.

- 1. The proposed budget for each fiscal year must be less than or equal to the budget ceiling of \$350,000 for Funding Option A or \$650,000 for Funding Option B as outlined in the *Executive Summary* of the NOFO. **Applications that exceed the budget in any year will be considered nonresponsive and will not be forwarded for peer review.**
- 2. Applications must propose a study within the stated objectives of the NOFO and propose rigorous evaluations (e.g., experimental, quasi-experimental designs) of a prevention strategy to prevent firearm-related injuries, deaths, violence, or crime, as evidenced in the Research Strategy section of the Research Plan. Applications that propose studies outside of the stated objective of this NOFO will be considered nonresponsive and will not be forwarded for peer review. Examples of studies that are considered nonresponsive include research to strengthen surveillance, proposals to study risk or protective factors, and proposals to conduct development and feasibility testing. In addition, applications that do not propose rigorous evaluation of a prevention strategy to prevent firearm-related injuries, deaths, violence, or crime, as evidenced by the Research Strategy section of the Research Plan, will be considered nonresponsive and will not be forwarded for peer review.
- 3. Applicants must propose research to inform primary prevention (before violence occurs) and secondary prevention (e.g., hospital-based violence intervention programs to prevent escalation or revictimization from firearm violence among youth) strategies to prevent firearm-related violence and injuries in the Research Strategy section of the Research Plan. Applications proposing to examine or evaluate tertiary response strategies will be considered nonresponsive and will not be forwarded for peer review. In addition, applications that do not focus on preventing future firearm-related injury or violence, as evidenced by the Research Strategy section of the Research Plan, will be considered non-responsive and will not be forwarded for peer review.
- 4. Applicants must include a SF-424 Biographical Sketch for the PI or Co-Investigator that documents expertise in firearm-related injury prevention (e.g., youth violence, intimate

partner violence, suicide), injury prevention, criminology or related discipline that is reflected in the application's research strategy section. The knowledge, experience, and expertise necessary to conduct this research and achieve proposed objectives must be documented with at least one first-authored, peer-reviewed publication as defined by the NIH National Library of Medicine in the relevant area of firearm-related injury prevention; or by serving as a principal investigator on a research grant in violence, suicide, injury, or crime prevention research. Experience requirements may be demonstrated through the combined experiences of a Principal and Co-Principal Investigator (if applicable). The citation of the relevant publication(s) or research experience must be clearly identified (by bold text or highlight) in the appropriate SF 424 Biographical Sketch. Applications that do not include documentation to meet this requirement will be considered non-responsive and will not be forwarded for peer review.

6. Required Registrations

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

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

(Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: NCAGE Tool / Products / NCS Help Center (nato.int).

System for Award Management (SAM) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, <u>SAM.gov</u>.

Grants.gov

eRA Commons

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

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

active eRA Commons Signing Official account in order to initiate the submission process. During the submission process, ASSIST will prompt the Signing Official to enter their Grants.gov Authorized Organizational Representative (AOR) credentials in order to complete the submission, therefore the applicant organization must ensure that their Grants.gov AOR credentials are active.

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

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

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

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

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

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

Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. CDC does not make awards to individuals directly. Individuals from organizations that are uniquely prepared to examine research relevant to undeserved groups, including sexual orientation and gender identity minorities as well as individuals with disabilities are always encouraged to apply.

9. Cost Sharing

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

10. Number of Applications

As defined in the HHS Grants Policy Statement, (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf), applications received in response to the same Notice of Funding Opportunity generally are

scored individually and then ranked with other applications under peer review in their order of relative programmatic, technical, or scientific merit. HHS/CDC will not accept any application in response to this NOFO that is essentially the same as one currently pending initial peer review unless the applicant withdraws the pending application.

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

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

Section IV. Application and Submission Information

1. Address to Request Application Package

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

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

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

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

2. Content and Form of Application Submission

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

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

required for submission of applications for this NOFO. Follow the instructions in the SF-424 <u>Application Guide</u> to ensure you complete all appropriate "optional" components.

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

3. Letter of Intent

Due Date for Letter Of Intent 11/01/2024

11/01/2024

The letter of intent should be sent electronically to:

Aisha Wilkes, MPH

Scientific Review Official

National Center for Injury Prevention and Control (NCIPC)

Email: ncipc-peer-review@cdc.gov

4. Required and Optional Components

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

5. PHS 398 Research Plan Component

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

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

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

4. **Progress Report Publication List** (for Continuation ONLY)

Other Research Plan Sections

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

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

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

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

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

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

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

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

tools/data-management/data-management-plans

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

6. Appendix

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

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

7. Page Limitations

All page limitations described in this individual NOFO must be followed. For this specific NOFO, the Research Strategy component of the Research Plan narrative is limited to 12 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 25 pages for all appendices. Pages that exceed page limits described in this NOFO will be removed and not forwarded for peer review, potentially affecting an application's score.

8. Format for Attachments

Designed to maximize system-conducted validations, multiple separate attachments are required for a complete application. When the application is received by the agency, all submitted forms and all separate attachments are combined into a single document that is used by peer reviewers and agency staff. Applicants should ensure that all attachments are uploaded to the system.

CDC requires all text attachments to the Adobe application forms be submitted as PDFs and that all text attachments conform to the agency-specific formatting requirements noted in the SF424 (R&R) Application Guide at .How to Apply - Application Guide.

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

9. Submission Dates & Times

Part I. Overview Information contains information about Key Dates. Applicants are strongly encouraged to allocate additional time and submit in advance of the deadline to ensure they have time to make any corrections that might be necessary for successful submission. This includes the time necessary to complete the application resubmission process that may be necessary, if errors are identified during validation by Grants.gov and the NIH eRA systems. The application package is not complete until it has passed the Grants.gov and NIH eRA Commons submission and validation processes. Applicants will use a platform or system to submit applications.

ASSIST is a commonly used platform because it provides a validation of all requirements prior to submission. If ASSIST detects errors, then the applicant must correct errors before their

application can be submitted. Applicants should view their applications in ASSIST after submission to ensure accurate and successful submission through Grants.gov. If the submission is not successful and post-submission errors are found, then those errors must be corrected and the application must be resubmitted in ASSIST.

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

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

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

Applicants who encounter problems when submitting their applications must attempt to resolve them by contacting the NIH eRA Service desk at:

Toll-free: 1-866-504-9552; Phone: 301-402-7469

http://grants.nih.gov/support/index.html

Hours: Mon-Fri, 7 a.m. to 8 p.m. Eastern Time (closed on Federal holidays)

Problems with Grants.gov can be resolved by contacting the Grants.gov Contact Center at:

Toll-free: 1-800-518-4726 https://www.grants.gov/support

support@grants.gov

Hours: 24 hours a day, 7 days a week; closed on Federal holidays

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

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

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

- 1. Track submission and verify the submission status (tracking should be done initially regardless of rejection or success).
 - a. If the status states "rejected," be sure to save time stamped, documented rejection notices, and do #2a or #2b

- 2. Check emails from both Grants.gov and NIH eRA Commons for rejection notices.
 - a. If the deadline has passed, he/she should email the Grants Management contact listed in the Agency Contacts section of this announcement explaining why the submission failed.
 - b. If there is time before the deadline, correct the problem(s) and resubmit as soon as possible.

Due Date for Applications 12/02/2024

12/02/2024

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

10. Funding Restrictions

Expanded Authority:

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

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

Public Health Data:

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

Data Management Plan:

Fulfilling the data-sharing requirement must be documented in a Data Management Plan (DMP) that is developed during the project planning phase prior to the initiation of generating or collecting public health data and must be included in the Other Plan(s) section of the PHS 398 Research Plan Component of the application.

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

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

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

Human Subjects:

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

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

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

The Research Strategy section of the application is expected to clearly describe the type, source, access to, and protections of the data and human subjects participating in the study. Access to non-publicly available, previously collected data must be clearly described in the Research Strategy and documented with a signed Data Sharing Agreement or Letter of Support. Access to publicly available, previously collected data must be clearly described in the Research Strategy.

Data Management Plan

Applicants should develop and include, as part of the application's Resource Sharing Plan section of the PHS 398 Research Plan Component, a data management plan that meets the requirements of AR-25 using their own template. Applicants funded under this NOFO will be required to use NCIPC's Data Management Plan Template, OMB NO: 0920-1301 (Exp. Date: 10/31/2026).

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

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

11. Intergovernmental Review

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

12. Other Submission Requirements and Information

Duplication of Efforts

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

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

Application Submission

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

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

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

Important reminders:

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

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

The applicant organization must ensure that the UEI number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management (SAM). Additional information may be found in the SF424 (R&R) Application Guide.

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

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

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

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

Section V. Application Review Information

1. Criteria

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

Overall Impact

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

Scored Review Criteria

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

Significance

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

• To what extent does the proposed research address a question that is important for reducing the burden of firearm-related injuries, deaths, violence, or crime? The focus

- can include mass shooting incidents, other firearm homicides/assaults, firearm suicides/self-harm, unintentional firearm deaths and injuries, and firearm-related crime.
- To what extent will successful completion of the proposed activities significantly advance our understanding of what works to keep individuals, families, schools, or communities safe from firearm-related injuries, deaths, violence, or crime?
- To what extent will the proposed research address the needs of communities experiencing disproportionate burden of firearm-related injuries, deaths, violence, or crime?
- To what extent does the application address inequities in firearm-related injuries, deaths, violence, or crime, including evaluation of strategies that address social and structural conditions (e.g., concentrated poverty, structural racism, high rates of unemployment and community violence, weak social connectedness, limited access to high-quality education and/or affordable, high-quality child-care) contributing to these inequities?
- To what extent does the application describe engagement with community partners and community members with lived experience throughout the research study?

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 PI/co-I Team have sufficient prior experience conducting empirical research in the area of firearm violence, violence prevention (e.g., youth violence, intimate partner violence), suicide, injury prevention, criminology, or related discipline consistent with what is proposed in the application?

Innovation

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

 To what extent is the proposed research innovative or novel and yet offer a reasonable potential of meeting the Purpose and Research Objective of this NOFO within the proposed period of performance?

Approach

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

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

research strategy proposed?

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

- To what extent is the research plan appropriate for the specific research objective proposed in the application?
- To what extent is the research plan appropriate for the period of performance proposed?
- To what extent does the proposal examine actual firearm-related behavior (e.g., access, use, carrying, secure storage and other safety practices), victimization or perpetration, or fatal or nonfatal injuries?
- To what extent are the primary prevention strategies proposed adequately supported by theory or empirical evidence?
- Recognizing that randomized designs are not always possible (e.g., when evaluating policies), to what extent does the applicant propose using an objective, rigorous design that includes appropriate data and analytic plans to address the research questions?
- To what extent does the applicant adequately explain how they will access the data necessary for the study (e.g., records from vital statistics agencies, hospitals or emergency departments, law enforcement or criminal justice agencies, self-report data, or other sources)?
- To what extent does the application clearly describe the roles and responsibilities of each partner involved in data collection and/or the effectiveness evaluation?
- To what extent does the applicant appropriately anticipate, conceptualize, and measure the intended benefits and potential unintended negative or harmful outcomes relevant to the study proposed?
- To what extent does the applicant propose a study with adequate sample size to test the proposed hypotheses and to detect effects from the prevention strategy being evaluated?
- If applicable, to what extent does the application specify how recruitment strategies will be sufficient to achieve the projected sample size?

Environment

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

To what extent will findings be disseminated to communities and populations of focus in an appropriate and accessible manner?

- To what extent are the partnerships necessary and critical for successfully completing the research clearly described in the Research Strategy section of the application?
- To what extent does the application clearly describe the working relationships between the research institution and all partner organizations? Does the application clearly describe the involvement and scope of work the community organizations, community

leaders, and other partners are willing to commit to ensure the successful implementation and evaluation of the prevention strategies, including providing or facilitating access to relevant study participants, implementation, or outcome data?

- To what extent does the application demonstrate access to the data, or include a plan for accessing the data, necessary to complete the proposed research within the proposed period of performance?
- To what extent does the Research Strategy clearly describe the working relationships between the applicant institution and all partner organizations, including community partners?
- To what extent does the Research Strategy clearly describe the involvement and scope of work each partner is willing to complete to ensure the success of the proposed research within the proposed period of performance?
- To what extent are the relationships and activities of the partnerships described in the Research Strategy documented by a signed Data Sharing Agreement, Letter of Support, or Memorandum of Understanding that clearly delineates the intent and capabilities of each partnership?

2. Additional Review Criteria

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

Protections for Human Subjects

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

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

Inclusion of Women, Minorities, and Children

When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the policy on the Inclusion of Women and Racial and Ethnic Minorities in Research (https://www.cdc.gov/women/research/index.htm) and the policy on the Inclusion of Persons Under 21 in Research (https://www.cdc.gov/grants/additional-requirements/ar-28.html).

Vertebrate Animals

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

Biohazards

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

Dual Use Research of Concern

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

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

3. Additional Review Considerations

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

Applications from Foreign Organizations

N/A

Resource Sharing Plan(s)

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

Budget and Period of Support

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

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

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

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

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

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

4. Review and Selection Process

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

As part of the scientific peer review, all applications:

- Will undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review), will be discussed and assigned an overall impact/priority score.
- Will receive a written critique.

Applications will be assigned to the appropriate HHS/CDC Center, Institute, or Office. Applications will compete for available funds with all other recommended applications submitted in response to this NOFO. Following initial peer review, recommended applications will receive a second level of review. The following will be considered in making funding recommendations:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.
- Consideration for meritorious applications that include signed Data Sharing Agreements, Letters of Support, or Memorandum of Understanding for each partnership described in the Research Strategy section of the application's research plan.
- Consideration for meritorious applications that contribute to a diverse mix of strategies in proposed research to address firearm-related violence, injuries, deaths, or crime, as evidenced by the Research Strategy section of the application's research plan.

- Consideration for meritorious applications that contribute to a geographic balance of proposed projects, as evidenced by the congressional district of the applicant organization, to broaden the distribution of awards.
- Consideration for meritorious applications that propose to address inequities in firearmrelated violence, injuries, deaths, or crime, including studies that inform or evaluate strategies that address social and structural conditions contributing to these inequities, as evidenced by the Research Strategy section of the application's research plan.
- Consideration for applications in which the contact PD/PI meets NIH Early Stage Investigator (ESI) status, as verified by the NIH Determination of Investigator process, to broaden distribution of awards.

Review of risk posed by applicants.

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

In accordance with 41 U.S.C. 2313, CDC is required to review the non-public segment of the OMB-designated integrity and performance system accessible through SAM prior to making a Federal award where the Federal share is expected to exceed the simplified acquisition threshold, defined in 41 U.S.C. 134, over the period of performance. At a minimum, the information in the system for a prior Federal award recipient must demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics. CDC may make a Federal award to a recipient who does not fully meet these standards if it is determined that the information is not relevant to the current Federal award under consideration or there are specific conditions that can appropriately mitigate the effects of the non-Federal entity's risk in accordance with 45 CFR §75.207. CDC's review of risk may impact award eligibility.

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

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

CDC must comply with the guidelines on government-wide suspension and debarment in 2 CFR

part 180, and require non-Federal entities to comply with these provisions. These provisions restrict Federal awards, subawards and contracts with certain parties that are debarred, suspended or otherwise excluded from or ineligible for participation in Federal programs or activities.

5. Anticipated Announcement and Award Dates

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

Section VI. Award Administration Information

1. Award Notices

Any applications awarded in response to this NOFO will be subject to the UEI, SAM Registration, and Transparency Act requirements. If the application is under consideration for funding, HHS/CDC will request "just-in-time" information from the applicant as described in the HHS Grants Policy Statement (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

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

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

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

2. CDC Administrative Requirements

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

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

Specific requirements that apply to this NOFO are the following:

AR-1: Human Subjects Requirements

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

AR-3: Animal Subjects Requirements

AR-9: Paperwork Reduction Act Requirements

AR-10: Smoke-Free Workplace Requirements

AR-11: Healthy People 2030

AR-12: Lobbying Restrictions

AR-14: Accounting System Requirements

AR-16: Security Clearance Requirement

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

AR-22: Research Integrity

AR-24: Health Insurance Portability and Accountability Act Requirements

AR-25: Data Management and Access

AR-26: National Historic Preservation Act of 1966

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

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

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

AR-31: Research Definition

AR-32: Appropriations Act, General Provisions

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

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

Organization Specific ARs:

AR-8: Public Health System Reporting Requirements

AR-15: Proof of Non-profit Status

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

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

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

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

"Additional Requirement - 13: Prohibition on Use of CDC Funds for Certain Gun Control Activities" (AR-13) - "None of the funds made available for injury prevention and control at the Centers for Disease Control and Prevention may be used [in whole or in part] to advocate or promote gun control." CDC interprets this to mean that "CDC funds may not be spent on political action or other activities designed to affect the passage of specific Federal, State, or local legislation intended to restrict or control the purchase or use of firearms."

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

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

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

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

3. Additional Policy Requirements

The following are additional policy requirements relevant to this NOFO:

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

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

Plain Writing Act: The Plain Writing Act of 2010, Public Law 111-274, was signed into law on October 13, 2010. The law requires that federal agencies use "clear Government communication that the public can understand and use" and requires the federal government to write all new

publications, forms, and publicly distributed documents in a "clear, concise, well-organized" manner. For more information on this law, go to: https://www.plainlanguage.gov/.

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

Copyright Interests Provision: This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. Applicants may include reasonable publication costs and costs associated with submission, curation, management of data, and special handling instructions as allowable expenses in all research budgets. Pursuant to applicable grant regulations and CDC's Public Access Policy, Recipient agrees to submit into the National Institutes of Health (NIH) Manuscript Submission (NIHMS) system an electronic version of the final, peer-reviewed manuscript of any such work developed under this award upon acceptance for publication, to be made publicly available without any embargo or delay after publication. Also at the time of submission, Recipient and/or Recipient's submitting author must also post the manuscript through PMC without any embargo or delay after publication. The recipient must obtain prior approval from the CDC for any exception to this provision.

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

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

Dual Use Research of Concern: On September 24, 2014, the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern was released. Recipients (foreign and domestic) receiving CDC funding on or after September 24, 2015, are subject to this policy. Research funded by CDC, involving the agents or toxins named in the policy, must be reviewed to determine if it involves one or more of the listed experimental effects and if so,

whether it meets the definition of DURC. This review must be completed by an Institutional Review Entity (IRE) identified by the funded institution.

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

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

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

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

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

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

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

4. Cooperative Agreement Terms and Conditions

N/A

5. Reporting

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

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

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

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

Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by recipients:

- 1) Information on executive compensation when not already reported through the SAM Registration; and
- 2) Similar information on all sub-awards/ subcontracts/ consortiums over \$25,000. It is a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipients of applicable CDC grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over \$25,000. See the HHS Grants Policy Statement

(https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

Technical Review and Summary Statement Response Requirements

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

Annual Report Requirements

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

- A description of the completion status of each Specific Aim and/or research objective or milestone for the budget period.
- A complete list of the publications planned or completed to date including status (e.g., published [include reference], in review, under development).
- A description of any changes made in the use of human subjects or IRB approval status.
- A description of any changes made in the Data Management Plan. Award recipients funded under this NOFO will be required to use NCIPC's Data Management Plan Template, OMB NO: 0920-1301 to make revisions to the DMP as required during the award's period of performance.

A. Submission of Reports

The Recipient Organization must submit:

Annual Performance Report (APR)/RPPR is due 120 days before the end of the current budget period, or the date identified in the guidance that CDC distributes. The RPPR form (https://grants.nih.gov/grants/rppr/index.htm;

https://grants.nih.gov/grants/rppr/rppr instruction guide.pdf) is to be completed on the eRA Commons website. The progress report will serve as the non-competing continuation application. Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.

Annual Federal Financial Report (FFR) SF-425 (<u>Reporting | Grants | CDC</u>) is required and must be submitted to the Payment Management System accessed through the FFR navigation link in eRA Commons or directly through PMS within 90 days after the budget period ends.

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

B. Content of Reports

- 1. Annual Performance Report (APR)/RPPR: The recipient's continuation application/progress report should include:
- Description of Progress during Annual Budget Period: Current Budget Period Progress reported on the RPPR form in eRA Commons (https://grants.nih.gov/grants/rppr/index.htm). Detailed narrative report for the current budget period that directly addresses progress towards the Measures of Effectiveness included in the current budget period proposal.
- Research Aims: list each research aim/project
 - a) Research Aim/Project: purpose, status (met, ongoing, and unmet), challenges, successes, and lessons learned
 - b) Leadership/Partnership: list project collaborations and describe the role of external partners.

- Translation of Research (1 page maximum). When relevant to the goals of the research project, the PI should describe how the significant findings may be used to promote, enhance, or advance translation of the research into practice or may be used to inform public health policy. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers, and other potential users. The PI should identify the research findings that were translated into public health policy or practice and how the findings have been or may be adopted in public health settings. Or, if they cannot be applied yet, this section should address which research findings may be translated, how these findings can guide future research or related activities, and recommendations for translation. If relevant, describe how the results of this project could be generalized to populations and communities outside of the study. Questions to consider in preparing this section include:
- How will the scientific findings be translated into public health practice or inform public health policy?
- How will the project improve or effect the translation of research findings into public health practice or inform policy?
- How will the research findings help promote or accelerate the dissemination, implementation, or diffusion of improvements in public health programs or practices?
- How will the findings advance or guide future research efforts or related activities?
- Public Health Relevance and Impact (1 page maximum). This section should address
 improvements in public health as measured by documented or anticipated outcomes from
 the project. The PI should consider how the findings of the project relate beyond the
 immediate study to improved practices, prevention or intervention techniques, inform
 policy, or use of technology in public health. Questions to consider in preparing this
 section include:
- How will this project lead to improvements in public health?
- How will the findings, results, or recommendations been used to influence practices, procedures, methodologies, etc.?
- How will the findings, results, or recommendations contribute to documented or projected reductions in morbidity, mortality, injury, disability, or disease?
- Current Budget Period Financial Progress: Status of obligation of current budget period funds and an estimate of unobligated funds projected provided on an estimated FFR.
- New Budget Period Proposal:
- Detailed operational plan for continuing activities in the upcoming budget period, including updated Measures of Effectiveness for evaluating progress during the upcoming budget period. Report listed by Research Aim/Project.
- Project Timeline: Include planned milestones for the upcoming year (be specific and provide deadlines).

- New Budget Period Budget: Detailed line-item budget and budget justification for the new budget period. Use the CDC budget guideline format.
- Publications/Presentations: Include publications/presentations resulting from this CDC grant only during this budget period. If no publication or presentations have been made at this stage in the project, simply indicate "Not applicable: No publications or presentations have been made."
- IRB Approval Certification: Include all current IRB approvals to avoid a funding restriction on your award. If the research does not involve human subjects, then please state so. Please provide a copy of the most recent local IRB and CDC IRB, if applicable. If any approval is still pending at time of APR due date, indicate the status in your narrative.
- Update of Data Management Plan: The DMP is considered a living document that will
 require updates throughout the lifecycle of the project. Investigators should include any
 updates to the project's data collection such as changes to initial data collection plan,
 challenges with data collection, and recent data collected. Applicants should update their
 DMP to reflect progress or issues with planned data collection and submit as required for
 each reporting period.
- Additional Reporting Requirements:
- **2. Annual Federal Financial Reporting** The Annual Federal Financial Report (FFR) SF-425 is required and must be submitted through the Payment Management System (PMS) within 90 days after the end of the budget period. The FFR should only include those funds authorized and disbursed during the timeframe covered by the report. The Final FFR (SF-425) must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the Final FFR expenditure data and the Payment Management System's (PMS) cash transaction data.

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

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

Recipients must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, recipients must submit a Final FFR (SF-425), final progress report, and Final Invention Statement and Certification within 120 days after the end of the period of performance. Failure to submit timely and accurate final reports may affect future funding to the organization or awards under the direction of the same Project Director/Principal Investigator (PD/PI).

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

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

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

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

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

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

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

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

6. Termination

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

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

- (1) By the HHS awarding agency or pass-through entity, if the non-Federal entity fails to comply with the terms and conditions of the award;
- (2) By the HHS awarding agency or pass-through entity for cause;
- (3) By the HHS awarding agency or pass-through entity with the consent of the non-Federal entity, in which case the two parties must agree upon the termination conditions, including the effective date and, in the case of partial termination, the portion to be terminated; or
- (4) By the non-Federal entity upon sending to the HHS awarding agency or pass-through entity written notification setting forth the reasons for such termination, the effective date, and, in the case of partial termination, the portion to be terminated. However, if the HHS awarding agency or pass-through entity determines in the case of partial termination that the reduced or modified portion of the Federal award or subaward will not accomplish the purposes for which the Federal award was made, the HHS awarding agency or pass-through entity may terminate the Federal award in its entirety.

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

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

- B. The U.S. Department of State requires that agencies collect and report information on the amount of taxes assessed, reimbursed and not reimbursed by a foreign government against commodities financed with funds appropriated by the U.S. Department of State, Foreign Operations and Related Programs Appropriations Act (SFOAA) ("United States foreign assistance funds"). Outlined below are the specifics of this requirement:
- 1) Annual Report: The recipient must submit a report on or before November 16 for each foreign country on the amount of foreign taxes charged, as of September 30 of the same year, by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant during the prior United States fiscal year (October 1 September 30), and the amount reimbursed and unreimbursed by the foreign government. [Reports are required even if the recipient did not pay any taxes during the reporting period.]
- 2) Quarterly Report: The recipient must quarterly submit a report on the amount of foreign taxes charged by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant. This report shall be submitted no later than two weeks following the end of each quarter: April 15, July 15, October 15 and January 15.
- 3) Terms: For purposes of this clause:
- "Commodity" means any material, article, supplies, goods, or equipment;
- "Foreign government" includes any foreign government entity;

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

- 4) Where: Submit the reports to the Director and Deputy Director of the CDC office in the country(ies) in which you are carrying out the activities associated with this cooperative agreement. In countries where there is no CDC office, send reports to VATreporting@cdc.gov.
- 5) Contents of Reports: The reports must contain:
- a. recipient name;
- b. contact name with phone, fax, and e-mail;
- c. agreement number(s) if reporting by agreement(s);
- d. reporting period;
- e. amount of foreign taxes assessed by each foreign government;
- f. amount of any foreign taxes reimbursed by each foreign government;
- g. amount of foreign taxes unreimbursed by each foreign government.
- 6) Subagreements. The recipient must include this reporting requirement in all applicable subgrants and other subagreements.

Section VII. Agency Contacts

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

Application Submission Contacts

Grants.gov Customer Support (Questions regarding Grants.gov registration and submission, downloading or navigating forms)

Contact Center Phone: 800-518-4726

https://www.grants.gov/support Email: support@grants.gov

Hours: 24 hours a day, 7 days a week; closed on Federal holidays

eRA Commons Help Desk (Questions regarding eRA Commons registration, tracking

application status, post submission issues, FFR submission)

Phone: 301-402-7469 or 866-504-9552 (Toll Free)

TTY: 301-451-5939

https://www.era.nih.gov/need-help Email: commons@od.nih.gov

Hours: Monday - Friday, 7am - 8pm U.S. Eastern Time; closed on Federal holidays

Scientific/Research Contact

Emiko Petrosky, MD, MPH

National Center for Injury Prevention and Control (NCIPC)

Email: ncipc_erpo@cdc.gov

Peer Review Contact

Aisha Wilkes, MPH

National Center for Injury Prevention and Control (NCIPC)

Email: ncipc-peer-review@cdc.gov

Financial/Grant Management Contact

Angie Willard

Grants Management Specialist

CDC Office of Grants Services

Email: AEN4@cdc.gov

Section VIII. Other Information

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

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

Authority and Regulations

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

Statutory Authority

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

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

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

Application Submission Process

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

to 11:59 PM U.S. Eastern Time of the application due date. HHS/CDC grant submission procedures do not provide a grace period beyond the grant application due date time to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems.

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

General Information

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

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

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