Centers for Disease Control and Prevention

NATIONAL CENTER FOR INJURY PREVENTION AND CONTROL

Research Grants to Identify Effective Community-Based Strategies for Overdose Prevention (R01)

RFA-CE-24-013

02/08/2024

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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 Identify Effective Community-Based Strategies for Overdose Prevention (R01)

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-24-013

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, Injury Center) is soliciting investigator-initiated research to partner with communities to develop and rigorously evaluate the effectiveness of new, innovative, under-developed, or untested community-based strategies/interventions/programs/practices to reduce overdose. Strategies/interventions/programs/practices may include but are not limited to, those that focus on preventing drug use initiation and drug use, reducing non-infectious harms related to drug use, reducing stigma or other barriers to harm reduction or substance use disorder treatment, and increasing linkage to and retention in care. Research should focus on groups experiencing a disproportionate burden of overdose and/or groups that are at greater risk of experiencing adverse outcomes related to substance use due to social determinants of health. Research should also involve engaging individuals in the focus population (e.g., people with lived experience with drug use).

Key Dates

Publication Date:

To receive notification of any changes to RFA-CE-24-013, 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:

The LOI date will generate once the Synopsis is published if Days or a Date are entered. Although a letter of intent is not required, is not binding, and does not enter into the review of an application, the information that it contains assists NCIPC with planning for scientific and technical merit peer review.

Application Due Date:

12/01/2023
12/01/2023

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:
03/01/2024
This is an estimated date.

Secondary Review:
04/01/2024
This is an estimated date

Estimated Start Date:
09/30/2024
This is an estimated date

Expiration Date:
02/01/2024

Required Application Instructions

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

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

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

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

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

Executive Summary

Purpose
The Centers for Disease Control and Prevention’s (CDC) National Center for Injury Prevention and Control (NCIPC, Injury Center) is soliciting investigator-initiated research to partner with communities to develop and rigorously evaluate the effectiveness of new, innovative, under-developed, or untested (hereafter referred to as “untested”) community-based strategies/interventions/programs/practices (hereafter referred to as “strategies”) to reduce overdose. Strategies may include, but are not limited to, those that focus on preventing drug use initiation and drug use, reducing non-infectious harms related to drug use, reducing stigma or other barriers to harm reduction or substance use disorder treatment, and increasing linkage to and retention in care. Research should focus on groups experiencing a disproportionate burden of

overdose and/or groups that are at greater risk of experiencing adverse outcomes related to substance use due to social determinants of health. Research should also involve engaging individuals in the focus population (e.g., people with lived experience with drug use).

Mechanism of Support: The funding mechanism for this Notice of Funding Opportunity (NOFO) will be a research grant (R-01).

Funds Available and Anticipated Number of Awards: CDC/NCIPC intends to commit up to $3,750,000 in FY 2024 to fund up to five (5) applications. Awards issued under this NOFO are contingent upon the availability of funds and a sufficient number of meritorious applications.

Budget and Project Period: The maximum award amount will be $750,000 per award for the first 12-month budget period. This includes both direct and indirect costs. Applicants may request a project period of up to five (5) years. The maximum total project funding is $3,750,000 (direct and indirect) per award, over the project period. The project period is expected to be 09/30/2024 to 09/29/2029. The total award will depend upon the project quality, duration, and cost proposed.

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

Eligible Institutions/Organizations: Institutions/organizations listed in *Section III. Eligibility Information 1. Eligible Applicants* are eligible to apply.

Eligible Project Directors/Principal Investigators (PDs/PIs):

CDC does not make awards to individuals directly. 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. Individuals from underrepresented racial and ethnic groups, as well as individuals with disabilities, are always encouraged to apply.

Applications in which the contact Eligible PD/PI meets NIH Early Stage Investigator (ESI) status, as verified via the NIH Determination of Investigator Status process, and whose application has a meritorious peer review score, may be considered for prioritization during the second level of review (see Section V. Application Review Information 4. Review and Selection Process). For the contact PD/PI Determination of Investigator Status: Before application submission, PD/PIs are encouraged to verify and/or enter the date of their terminal research degree or the end date of their post-graduate clinical training in their eRA Commons Profile to ensure the correct identification. NIH systems will automatically calculate the status of each investigator and display it within their eRA Commons personal profile. The ESI status of the PD/PIs on any R01 or R01 equivalent application will be flagged at the time of submission. Investigators should make sure their status is correctly marked in their profile. If your status is incorrect, please contact the NIH eRA Service Desk.

Number of PDs/PIs:

An application may name more than one PD/PI; their names must appear on the face page of the application. However:

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

Number of Applications: 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 before 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. Applicant institutions submitting multiple applications with essential y the same proposed research to this announcement will not be funded more than once.

Application Type: NEW

Special Date(s)
A pre-application teleconference call will be conducted on October 24, 2023 to address questions from prospective applicants regarding NOFO RFA-CE-24-013. The call will begin at 2:00pm Eastern Standard Time (EST) and end at 3:00pm 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 24, 20203
- Call Start Time: 2:00pm Eastern Standard Time (EST)
- Call End Time: 3:00pm Eastern Standard Time (EST)
- Call Leader: **Amanda Garcia-Williams, PhD, Scientific Program Official**
- Toll-Free Number: 1-866-600-6035
- Use Passcode 23198543# when prompted

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

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

Section I. Funding Opportunity Description

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

1. Background and Purpose

Despite efforts to address the overdose crisis, drug overdose deaths are at historic levels, and the U.S. has continued to have year-over-year increases in overdose deaths (1, 2). The proliferation of fentanyl in the illicit drug supply has driven increases in overdose deaths and challenged efforts to address it (3, 4). For example, the Drug Enforcement Agency (DEA) reports of increases in counterfeit prescription medications that contain fentanyl have raised concerns about overdose deaths among those who attempt to obtain prescription medications from illicit sources, including youth (4, 5).

Overdose deaths accelerated during the COVID-19 pandemic, with rapid increases in deaths involving synthetic opioids and increases in overdose deaths involving stimulants such as methamphetamine and cocaine (6). In 2021, 70,601 (66%) of the 106,699 drug overdose deaths involved synthetic opioids such as illicitly manufactured fentanyl, 24,486 (23%) involved cocaine, and 32,537 (30%) involved psychostimulants with abuse potential, such as methamphetamine (2). Deaths involving stimulants often occur in combination with synthetic opioids (7). Moreover, recent increases in overdose deaths have disproportionately affected non-Hispanic Black and American Indian and Alaska Native (AI/AN) persons (8).

Reducing the burden of drug overdose amidst a rapidly evolving overdose epidemic requires addressing drug use from multiple fronts, including preventing initiation or continuation of use and preventing nonfatal and fatal overdose through harm reduction strategies and linkage to evidence-based clinical treatment. Moreover, to improve health equity, prevention strategies need to be tailored for populations at greatest risk of overdose or with least access to care.

State, local, and tribal communities are implementing a variety of innovative strategies to address the crisis, but there is limited knowledge of the effectiveness of many of these strategies. Furthermore, there is a need to develop and evaluate new strategies in response to the evolving epidemic, including the evolving illicit drug supply.

To address the overdose crisis, additional research is needed to identify effective and scalable community-based strategies to reduce drug use initiation, drug use, and address barriers to care within the context of the evolving drug overdose crisis, and to tailor those strategies to those at greatest risk of overdose or with least access to care.

Purpose:

The Centers for Disease Control and Prevention’s (CDC) National Center for Injury Prevention and Control (NCIPC, Injury Center) is soliciting investigator-initiated research to partner with communities to develop and rigorously evaluate the effectiveness of untested community-based

strategies to reduce overdose. Strategies may include, but are not limited to, those that focus on preventing drug use initiation and drug use, reducing non-infectious harms related to drug use, reducing stigma or other barriers to harm reduction or substance use disorder treatment, and increasing linkage to and retention in care. Research should focus on groups experiencing a disproportionate burden of overdose and/or groups that are at greater risk of experiencing adverse outcomes related to drug use. Research should also involve engaging individuals in the focus population (e.g., people with lived experience with drug use).

Of particular interest is research focusing on groups experiencing a disproportionate burden of overdose and/or groups that are at greater risk of experiencing adverse outcomes related to drug use due to social determinants of health.

Research is intended to directly improve the ability of state, tribal, and local health departments or community groups to implement strategies to prevent overdose.

References

1. Ahmad FB, Cisewski JA, Rossen LM, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. 2023. Designed by LM Rossen, A Lipphardt, FB Ahmad, JM Keralis, and Y Chong: National Center for Health Statistics. https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm

2. Spencer MR, Miniño AM, Warner M. Drug overdose deaths in the United States, 2001–2021. NCHS Data Brief, no 457. Hyattsville, MD: National Center for Health Statistics. 2022. DOI: https://dx.doi.org/10.15620/cdc:122556.

3. US Department of Justice Drug Enforcement Administration. 2020 National Drug Threat Assessment. March 2021. https://www.dea.gov/documents/2021/03/02/2020-national-drug-threat-assessment

4. Drug Enforcement Administration. DEA Issues Public Safety Alert on Sharp Increase in Fake Prescription Pills Containing Fentanyl and Meth. 2021; September 17. https://www.dea.gov/press-releases/2021/09/27/dea-issues-public-safety-alert

5. Tanz LJ, Dinwiddie AT, Mattson CL, O'Donnell J, Davis NL. Drug Overdose Deaths Among Persons Aged 10–19 Years — United States, July 2019–December 2021. MMWR Morb Mortal Wkly Rep 2022;71:1576–1582. DOI: http://dx.doi.org/10.15585/mmwr.mm7150a2

6. Centers for Disease Control and Prevention. Increase in fatal drug overdoses across the United States driven by synthetic opioids before and during the COVID-19 pandemic. *CDC Health Action Network*. 2020; December 17. https://emergency.cdc.gov/han/2020/han00438.asp

7. O'Donnell J, Gladden RM, Mattson CL, Hunter CT, Davis NL. Vital Signs: Characteristics of Drug Overdose Deaths Involving Opioids and Stimulants — 24 States and the District of Columbia, January–June 2019. MMWR Morb Mortal Wkly Rep 2020;69:1189–1197. DOI: http://dx.doi.org/10.15585/mmwr.mm6935a1external icon.

8. Kariisa M, Davis NL, Kumar S, et al. Vital Signs: Drug Overdose Deaths, by Selected Sociodemographic and Social Determinants of Health Characteristics — 25 States and the

District of Columbia, 2019–2020. MMWR Morb Mortal Wkly Rep 2022;71:940–947. DOI: http://dx.doi.org/10.15585/mmwr.mm7129e2.

9. Guidance for Federal Departments and Agencies on Indigenous Knowledge. https://www.whitehouse.gov/wp-content/uploads/2022/12/OSTP-CEQ-IK-Guidance.pdf

10. Dankwa-Mullan I, Rhee KB, Stoff DM, Pohlhaus JR, Sy FS, Stinson Jr N, Ruffin J. Moving toward paradigm-shifting research in health disparities through translational, transformational, and transdisciplinary approaches. American journal of public health. 2010 Apr;100(S1):S19-24.

Healthy People 2030 and other National Strategic Priorities

This research addresses the **Healthy People 2030** focus areas of Substance Use and Injury Prevention as described in: https://health.gov/healthypeople. Specifically, this NOFO supports the Healthy People Substance Use (SU) areas of SU-03 Reduce drug overdose deaths, SU-07 Reduce the proportion of adults reporting use of any illicit drugs during the past 30 days, and SU-15 Reduce the proportion of people with illicit drug use disorder in the past year. This research also supports the Healthy People Injury Prevention (IVP) area of IVP-20 Reduce overdose deaths involving opioids, and IVP-03 Reduce unintentional injury deaths. Additionally, this research addresses the Healthy People health equity related goal of SU-01: Increase the proportion of people with a substance use disorder who got treatment in the past year.

Public Health Impact

The proposed research is expected to expand the evidence base for the effectiveness of untested community-based strategies to reduce overdose. Strategies evaluated as a result of this NOFO have the potential to prevent drug use initiation and drug use, reduce harms related to drug use, reduce stigma or other barriers to harm reduction or substance use disorder treatment, and increase linkage to and retention in care.

Research is intended to directly improve the ability of state, tribal, and local health departments or community groups to implement strategies to prevent overdose, especially among those most at risk for drug use and overdose, including those impacted by health disparities and social determinants of health. Further, by conducting research that involves partnering with communities and engaging with those who will be affected by the strategies, such as people with lived experience with drug use, the goal is to identify strategies that are effective, tailored, sustainable, scalable, and acceptable and feasible for persons with lived experiences.

Relevant Work

The strategic plan for the Division of Overdose Prevention includes the goal: Reduce opioid overdose now. The current concept applies to this goal. The Division of Overdose Prevention research priorities can be found on CDC's website: www.cdc.gov/injury/pdfs/researchpriorities/Research-Priorities-Overdose.pdf#page=1

This proposal also aligns with the current research priorities of the Division of Overdose Prevention. This project addresses the following research priority: Develop and evaluate innovative prevention strategies designed to prevent overdose, including among those at greatest risk.

The following publications from Division of Overdose Prevention authors have been recently

released and are of relevance for this NOFO:

1. Haegerich T, Jones C, Cote PO, Robinson A, Ross L. Evidence for State, Community and Systems-Level Prevention Strategies to Address the Opioid Crisis. *Drug and Alcohol Dependence*. 2019; doi:10.1016/j.drugalcdep.2019.107563
2. O'Donnell J, Tanz LJ, Gladden RM, Davis NL, Bitting J. Trends in and Characteristics of Drug Overdose Deaths Involving Illicitly Manufactured Fentanyls— United States, 2019–2020. MMWR Morb Mortal Wkly Rep. ePub: 14 December 2021.
3. Kariisa M, Davis NL, Kumar S, et al. *Vital Signs*: Drug Overdose Deaths, by Selected Sociodemographic and Social Determinants of Health Characteristics — 25 States and the District of Columbia, 2019–2020. *MMWR Morb Mortal Wkly Rep*. ePub: 19 July 2022. DOI: http://dx.doi.org/10.15585/mmwr.mm7129e2
4. Kariisa, M., Seth, P., Scholl, L., Wilson, N. O., & Davis, N. L. (2021). Drug overdose deaths involving cocaine and psychostimulants with abuse potential among racial and ethnic groups – United States, 2004–2019. *Drug and Alcohol Dependence*, *227*, 109001. https://doi.org/10.1016/j.drugalcdep.2021.109001

CDC funded 66 jurisdictions as part of its Overdose Data to Action (OD2A) Program (https://www.cdc.gov/drugoverdose/od2a/index.html), a cooperative agreement that began in September 2019. The program is focused on the complex and changing nature of the drug overdose epidemic, including stimulant overdoses, and highlights the need for an interdisciplinary, comprehensive, and cohesive public health approach to preventing overdoses.

In 2023, CDC built on this program with two new funding opportunities, one designed for states (Overdose Data to Action in States) and one designed specifically for localities and territories (Overdose Data to Action: Limiting Overdose through Collaborative Actions in Localities), to help ensure broad resources and support to respond to the evolving overdose crisis at all levels of government. Both awards support 5-year cooperative agreements to expand and strengthen overdose surveillance and prevention efforts to reduce nonfatal and fatal overdoses involving opioids and/or stimulants and polysubstance use. https://www.cdc.gov/drugoverdose/od2a/funding-announcements.html.

In partnership with the Office of National Drug Control Policy (ONDCP), CDC supports more than 700 community coalitions across the country to prevent and reduce substance use among youth through its Drug-Free Communities Support Program (https://www.cdc.gov/drugoverdose/drug-free-communities/about.html).

2. Approach

NCIPC intends to fund applications evaluating the effectiveness of untested community-based strategies to reduce overdose. Strategies may include, but are not limited to, those that focus on preventing drug use initiation and drug use, reducing non-infectious harms related to drug use, reducing stigma or other barriers to harm reduction or substance use disorder treatment, and increasing linkage to and retention in care. **Applications that do not propose to evaluate the effectiveness of untested (i.e., innovative new, under-developed, or untested) community-based strategies (i.e., intervention, program, practice) to reduce overdose, as evidenced in**

the Research Strategy section of the application's research plan, will be considered nonresponsive and <u>will not</u> be forwarded for peer review.

Primary outcomes of interest include, but are not limited to, nonfatal and fatal drug overdose, drug use, drug use initiation, substance use disorders (SUDs) and secondary outcomes of interest include, but are not limited to linkage to SUD care, and retention in SUD care. Process outcomes include stigma or other barriers to SUD care. Care includes harm reduction or evidence-based clinical treatment. Applicants are expected to include at least one primary outcome.

Applications that propose an evaluation of an untested strategy only for its impact related to *infectious disease* as the main outcomes, without also including a primary outcome that will directly contribute to our understanding of community-based strategies <u>to reduce overdose</u> do not meet the scientific intent of this NOFO. These applications <u>will not</u> be recommended for funding consideration during the NCIPC second-level review (see *Section V. Application Review Information*).

For this NOFO, the term "substance use" includes prescription drug misuse, illicit drug use, and cannabis/cannabinoid use. For this NOFO this term does NOT apply to nicotine and alcohol. Applications proposing to evaluate the effectiveness of untested community-based strategies on nicotine and alcohol as the only outcomes of interest do not meet the scientific intent of this NOFO. Measures of nicotine and/or alcohol use can be included as outcomes along with at least one primary outcome of interest including nonfatal and fatal drug overdose, drug use, drug use initiation, and substance use disorders (SUDs). **Applications that propose an evaluation of a strategy only for its impact on nicotine/and/or alcohol related outcomes without also including one of the primary outcomes listed above do not meet the scientific intent of this NOFO. These applications <u>will not</u> be recommended for funding consideration during the NCIPC second level review (see *Section V. Application Review Information*).**

For this NOFO, an "untested" strategy is theoretically justified but has not been developed or has not been implemented in the participating community or another community. **A "new", "innovative" or "under-developed", strategy (i.e., "untested") has been implemented in the participating community or another community but has not been rigorously evaluated for effectiveness overall or for a specific population, setting, or a primary outcome, and evaluating such a strategy is consistent with the intent of this NOFO.** Applicants must demonstrate that the proposed strategy is untested and justify why the proposed research is needed and likely to have substantial implications for addressing the drug overdose epidemic.

This NOFO is intended to support rigorous evaluation of untested community-based strategies to reduce overdose. **An application that proposes to develop or implement a strategy (i.e., intervention, program, practice) without also conducting a rigorous evaluation of the strategy (i.e., intervention, program, practice) as evidenced in the Research Strategy section of the application's research plan, will be considered nonresponsive and <u>will not</u> be forwarded for peer review.**

Additionally, for this announcement community-based strategies are defined as strategies that take place in community-based settings.

Examples of community-based settings include, but are not limited to:

- syringe services programs

- public health departments
- social services organizations
- neighborhood groups
- faith-based organizations
- community-based organizations and other places in communities that may serve people at risk of overdose, as well as public places within a community where overdoses can be prevented (e.g., public parks, restrooms, libraries, schools).

The community-based strategies listed above are examples and are not an exhaustive list.

Applicants are encouraged to rigorously evaluate strategies with the potential for population-wide effects. Applicants are expected to examine a range of outcomes from the community-based strategies evaluated, including potential unintended negative effects such as costs or consequences. Applicants should describe how the proposed research is innovative, advances the field of overdose prevention, and adds to the current evidence base.

As a public health agency, CDC focuses on public health responses to overdose prevention. While overdose prevention strategies may collaborate with law enforcement agencies, **applications that propose to focus on law enforcement policies without the inclusion of a strong public health component or focus,** as evidenced in the Research Strategy section of the application's research plan, **will be considered nonresponsive and will not be forwarded for peer review.**

The proposed research must focus on human subjects. **Applications proposing research using non-human species, as evidenced in the Research Strategy section of the application's research plan, will be considered nonresponsive and will not be forwarded for peer review.**

Applicants are asked to indicate in the applications Abstract what NCIPC Research Priority (https://www.cdc.gov/injury/researchpriorities/index.html) the research proposal intends to address.

Research Design

This funding opportunity is intended to support evaluations that are designed to detect whether any measured changes in outcomes can be attributed to the untested strategy. Applicants are expected to use the most objective and rigorous study designs possible to answer the proposed research questions. For this announcement, rigorous evaluation designs include those that utilize experimental (i.e., randomized controlled trials) or quasi-experimental designs (e.g., comparative interrupted time series design, difference-in-differences, instrumental variable methods, regression discontinuity, regression point displacement, stepped wedge, designs using propensity-score matching, designs involving matched comparison groups). Randomized trials are not feasible for some prevention strategies and alternative quasi-experimental designs are appropriate and acceptable. Applicants are expected to justify that the proposed design and data analysis plans (including attention to statistical power and baseline measures) are appropriate for evaluating the impacts of the strategy.

Applications may also include Indigenous knowledge methods and approaches. Indigenous Knowledge is "a body of observations, oral and written knowledge, innovations, practices, and

beliefs developed by Tribes and Indigenous Peoples through interaction and experience with the environment, and related practices, if not yet rigorously evaluated, are considered innovative community-based strategies. Indigenous Knowledge is based in ethical foundations often grounded in social, spiritual, cultural, and natural systems that are frequently intertwined and inseparable, offering a holistic perspective" (9) and including an extensive array of activities (e.g., traditional, healing, and spiritual practices such as ceremonies and rituals, talking circles, and drumming; wellness practices such as learning and speaking a traditional language, engaging in traditional practices, and developing connectedness through community and family activities).

The research proposal should include appropriate outcome measures of primary outcomes of interest (e.g., nonfatal and fatal drug overdose, drug use, drug use initiation, substance use disorders (SUDs)) and any secondary outcomes of interest (e.g., linkage to SUD care, and retention in SUD care). Process outcomes can include stigma or other barriers to SUD care. Care includes harm reduction or evidence-based clinical treatment. Applicants are expected to measure at least one primary outcome. The research proposal should also include data analytic plans that are appropriate to the community-based 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 project period.

Community-based strategies examined are expected to be theoretically justified and supported with epidemiological and behavioral research. Development of community-based strategies should also be informed by community partners and input from the focus population (e.g., people with lived experience with drug use). Applicants should include the theoretical background or framework, literature support for the strategy including formative research or application in other contexts, or a description of past input from the community and population of focus or plans to collect this information as part of the project.

Examples of outcome and impact data sources include, but are not limited to, vital statistics data, police records, criminal justice data, morbidity data including hospital or emergency department data or emergency medical services (EMS) data, or relevant self-report survey data. The research proposal should appropriately anticipate, conceptualize, and measure the intended benefits and potential unintended negative outcomes relevant to the study proposed. The use of multiple data sources is encouraged to improve the validity and reliability of each outcome or other measure selected. The proposal should also describe appropriate indicators of the strategy implementation process and success.

This NOFO is not intended to support applications that solely evaluate strategies in healthcare settings without also connecting to community resources (e.g., an intervention in a primary care or emergency department setting for youth treated for an overdose). The proposed research may include an evaluation of strategies involving a collaboration between healthcare settings and community-based partners (e.g., a brief intervention in a healthcare setting to treat for overdose that then links patients to community programs). **Applications proposing the evaluation** of an untested strategy to reduce overdose in healthcare settings without also connecting to community resources **do not meet the scientific intent of this NOFO. These applications will not be recommended for funding consideration during the NCIPC second-level review** (see *Section V. Application Review Information*).

Further, research funds are not available to evaluate the effectiveness of medications or a clinical behavioral-based intervention (e.g., contingency management, cognitive behavioral therapy

[CBT]). **Those that propose to evaluate the effectiveness of a pharmacological intervention approach or propose to evaluate a clinical behavioral-based intervention approach (e.g., contingency management, cognitive behavioral therapy [CBT]) for substance use or substance use disorders as evidenced in the Research Strategy section of the application's research plan, will be considered nonresponsive and <u>will not</u> be forwarded for peer review.**

Applications must be scientifically responsive to NOFO RFA-CE-24-013 to be forwarded for peer review. Additional responsiveness criteria are listed in Section III. Eligibility Information 5. Responsiveness of this NOFO. It is the applicant's responsibility to ensure that the submitted research proposal meets <u>all</u> responsiveness criteria listed in *Section III. Eligibility Information 5. Responsiveness*.

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 project period. The proposed processes, partnerships, and resources required to accomplish data collection and management should be detailed.

Applications should clearly describe and justify the proposed sampling methods, sample size, power estimates, and data collection methods for the primary outcome(s), at a minimum, and other proposed secondary measures and subgroup analyses. The timeline for data acquisition (requests for extant data and or primary data collection) must be specified. Numerous data sources can be used for the outcome data, including emergency department data, law enforcement data, self-report data, and other sources of data. In addition, administrative data from relevant agencies and survey data collected before or in the context of the evaluation are potential sources.

Applications should include the data analytic plan, timeline, and resources necessary for success.

Protection of Human Subjects and Personally Identifiable Information

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.

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 includes 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.

Objectives/Outcomes
The primary goal of this research is to determine the effectiveness of untested **community-based** strategies to reduce overdose. Strategies may include, but are not limited to, those that focus on:

- preventing drug use initiation and drug use
- reducing non-infectious harms related to drug use (i.e., nonfatal or fatal overdose)
- reducing stigma or other barriers to harm reduction or substance use disorder treatment
- increasing linkage to and retention in care

Primary outcomes of interest can include, but are not limited to:

- nonfatal and fatal drug overdose
- drug use
- drug use initiation (e.g., among youth)
- substance use disorders (SUDs)

Primary outcomes to be achieved with funded research should directly contribute to our understanding of community-based strategies **to reduce overdose**. Applicants are expected to include at least one primary outcome.

Secondary outcomes of interest can include, but are not limited to:

- linkage to SUD care (including harm reduction or evidence-based clinical treatment)
- retention in SUD care (including harm reduction or evidence-based clinical treatment)
- factors that decrease the likelihood of the primary outcomes listed above (i.e., protective factors) such as community cohesion or norm change
- sense of community or social connectedness
- sense of cultural connectedness

Process outcomes of interest can include, but are not limited to:

- Barriers and facilitators to implementation of the strategy, such as stigma
- Extent to which the strategy was implemented as enacted
- Acceptability by the population impacted by the strategy
- Activities (e.g., total number, frequency and duration, content)
- Reach (e.g., number of participants, number of people served in the community)
- Capacity building (e.g., number and types of partnerships such as new or ongoing, number of staff trained)

Outcomes are expected to be measured during the project period and outcome selection should be justified by the theoretical background or framework, literature support for the strategy including formative research or application in other contexts, or description of past input from the community and population of focus or plans to collect this information as part of the project.

Target Population

The target population includes those experiencing a disproportionate burden of substance use disorders and overdose, and/or groups are at greater risk of experiencing adverse outcomes related to drug use including people underserved by treatment for substance use disorders or harm reduction services.

This includes those at increased risk of overdose due to the changing illicit drug supply, such as youth or others who may be exposed to counterfeit prescription medications and people who use stimulants that may be adulterated with opioids such as fentanyl. These populations may be harder to reach via syringe services programs, which may be more focused on the injection of opioids.

Other groups experiencing a disproportionate burden of substance use disorders and overdose or that may be at greater risk of experiencing adverse outcomes related to drug use may include but are not limited to people in underserved socio-demographic groups (e.g., non-English speaking populations, tribal populations, rural communities and other geographically underserved areas, racial/ethnic minority groups, and sexual and gender minority groups), people experiencing social determinants of health (e.g., reduced economic stability; limited educational attainment; limited healthcare access, including those who have been historically underserved or are uninsured; limited health literacy), and people experiencing certain social or physical health conditions or experiences (e.g., recent incarceration, homelessness, a mental health condition, chronic pain, a disability, adverse childhood experiences, a history of suicidal ideation or suicide attempt or a history of substance use disorders and/or overdose).

Research that examines the effectiveness of strategies in high burden areas (e.g., identified through high overdose rates or vulnerability assessments) or that addresses health equity and is tailored for populations at greatest risk or with least access is also encouraged.

Applications must clearly describe how they have identified the target population and how the proposed research will improve health equity among those at greatest risk of overdose or with the least access to care.

Collaboration/Partnerships

It is expected that for all applications, the applicant organization and contact PI will provide the scientific and technical leadership necessary to conduct the proposed research throughout the entire project period. It is expected that the proposed research work plan described in the Research Strategy section of the application and the SF-424 Research and Related Budget will demonstrate the applicant organization’s leadership and involvement throughout the entirety of

the project period. The applicant organization cannot serve as a “pass-through" to fund another entity to conduct the majority of the research or provide the scientific or technical leadership necessary to complete the proposed research project.

As stated in the Background of this NOFO, NCIPC recognizes the importance of community involvement in research to reduce overdose. Recognizing that the development of partnerships takes time, the timeframe for this NOFO is up to 5 years to support the involvement of communities and the development of community partnerships.

Applicants are encouraged to seek and include the meaningful involvement of communities throughout the development and conduct of the proposed research and in the translation and dissemination of research results, including, but not limited to state, local, and or tribal health departments, local governmental agencies and/or businesses, faith-based organizations, tribal communities, and community-based organizations that serve individuals that are disproportionately burdened by drug use and overdose. This includes engagement and 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). By conducting research that involves partnering with communities and engaging with those who will be affected by the strategies, such as people with lived experience with drug use, the goal is to identify strategies that are effective, tailored, sustainable, scalable, and acceptable and feasible for persons with lived experiences.

Research is intended to directly improve the ability of state, tribal, and local health departments or organizations and community groups to implement evidence-based and effective strategies to prevent overdose, and applicants are encouraged to collaborate with state, local, tribal, and community partners, including but not limited to those implementing programmatic work funded by CDC’s Overdose Data to Action in States, Overdose Data to Action: Limiting Overdose through Collaborative Actions in Localities, or Drug-Free Communities (DFC) recipients (see Relevant Work section).

The Research Strategy section of the application is expected to clearly describe the roles and responsibilities of all partnering entities necessary to complete the proposed project. This includes describing how the partnership will allow the applicant to complete the proposed work (e.g., demonstration of the applicant’s access to planned data sources for proposed analyses and study populations). The Research Strategy section of the application must clearly 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, the nature and extent of the involvement to be provided by the applicant institution and outside entity, and how the partnership will ensure implementation of the proposed evaluation.

The roles and responsibilities described for each partnering entity must be substantiated with a signed Data Sharing Agreement, Letter of 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).

Applications will be evaluated during peer review on (under Approach and Environment):

- 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 extent to which the Research Strategy clearly describes the existing working relationships between the applicant institution and all partner organizations.
- The extent to which the Research Strategy clearly describes the involvement and scope of work each partner is willing to complete, including data access for all proposed analyses if applicable, to ensure the success of the proposed research within the proposed project period.
- The extent to which the Research Strategy includes partnering with community-based collaborators, including activities focused on building relationships with community partners.
- The extent to which the Research Strategy involves the engagement of individuals in the focus population (e.g., people with lived experience with drug use).
- The extent to which 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 delineates the intent and capabilities of each partnership.

It is incumbent on the applicant to clearly describe each contribution of each partnership to the proposed research in the Research Strategy and document the intent and capabilities of each partnership with a signed Data Sharing Agreement, Letter of Support, or Memorandum of Understanding.

Applications proposing to partner with Native American tribal governments and/or Native American tribal organizations are expected to include a signed letter of support signed by the Tribe(s)/Village(s) leadership, which may vary by Tribe(s)/Village(s), and may include the Tribal/Village Council, President, or other designated executive leader. The signed letter of support from the Tribe(s)/Village(s) leadership must: (1) Be on the Tribal/Village letterhead; (2) Specifically mention the name of the applicant (e.g., Tribal Organization, University) if applying on behalf of the Tribe(s)/Village(s); (3) Specifically state that the Tribe(s)/Village(s) approves of the applicant (e.g., Tribal Organization, University) if applying on their behalf; (4) Specifically indicate that the Tribe(s)/Village(s) intends to fully participate in the project activities, and (5) Include the name, title, and signature of the tribal leader.

This NOFO seeks diversity among applicant institutions, research investigators, and partnering organizations to ensure researcher experience and research outcomes are applicable and beneficial to all segments of our population and social ecology. Applicant organizations from or conducting research in collaboration or partnership with institutions that have a demonstrated record of or historical commitment to serving underrepresented students, including racial and ethnic minorities, individuals from disadvantaged backgrounds and individuals with disabilities may be considered during the second level of review (see *Section V. Application Review Information, 4. Review and Selection Process*). Applicants may indicate this the Research

Strategy of their application.

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

Collaborations/partnerships with investigators and/or organizational entities that are from underrepresented backgrounds, such as underrepresented racial and ethnic groups are encouraged.

Applications should demonstrate that the research staff has the necessary skills and experience to ensure the 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 are expected to 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. In addition, the degree to which a funded project meets its goals will be aided by a detailed project workplan and timeline.

Measures of effectiveness must relate to the goals stated in the "Purpose" section of this announcement and be able to measure the intended process measures and outcomes described. Outcomes to be evaluated should be specified. The purpose of this NOFO is to partner with communities to develop and rigorously evaluate the effectiveness of innovative community-based strategies to reduce overdose, thus most of the application should be dedicated to describing the approach proposed for developing the strategy, the evaluation plan including appropriate outcome measures, and measurement issues.

Applicants are encouraged to engage community partners and the focus population (e.g., people with lived experience with substance use) in the development and implementation of their evaluation/performance measurement plans.

Translation Plan
Applicants should describe how research findings can be used to improve state, tribal, and local health departments' or community groups' ability to implement strategies to prevent overdose. 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 how the applicant will disseminate results from effectiveness studies to enhance the implementation and dissemination of the proposed strategy.

Applicants are encouraged to engage community partners and the focus population (e.g., people with lived experience with drug use) in the development and implementation of their translation plans.

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:
$18,750,000

Anticipated Number of Awards:
5
Awards issued under this NOFO are contingent on the availability of funds and submission of a sufficient number of meritorious applications.

Award Ceiling:
$750,000
Per Budget Period

Award Floor:
$0
Per Budget Period

Total Period of Performance Length:
5 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

See *Section III. Eligibility Information.*

4. Justification for Less than Maximum Competition

Not Applicable (N/A)

5. Responsiveness

It is the applicant's responsibility to ensure that the application meets all 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. There must be an overall match between the proposed research objectives as described in the applicant's abstract and the research objectives of this announcement as described in Section I under the heading, "Objectives/Outcomes."

1. Applicant must propose to evaluate the effectiveness of untested community-based strategies (i.e., intervention, program, practice) to reduce overdose
    - **Applications that do not propose to evaluate the effectiveness of untested (**i.e., innovative new, under-developed, or untested**) community-based strategies** (i.e., intervention, program, practice) **to reduce overdose, as evidenced in the**

Research Strategy section of the application's research plan, will be considered nonresponsive and will not be forwarded for peer review.

2. Applications must propose to develop or implement a strategy without also conducting a rigorous evaluation of the strategy.
    - **An application that proposes to develop or implement a strategy** (i.e., intervention, program, practice) **without also conducting a rigorous evaluation of the strategy** (i.e., intervention, program, practice) **as evidenced in the Research Strategy section of the application's research plan, will be considered nonresponsive and will not be forwarded for peer review.**

3. The proposed research must not focus on law enforcement policies without the inclusion of a strong public health component or focus.
    - **Applications that propose to focus on law enforcement policies without inclusion of a strong a public health component or focus,** as evidenced in the Research Strategy section of the application's research plan, **will be considered nonresponsive and <u>will not</u> be forwarded for peer review.**

4. The proposed research must focus on human subjects.
    - **Applications proposing research using non-human species, as evidenced in the Research Strategy section of the application's research plan, will be considered nonresponsive and <u>will not</u> be forwarded for peer review.**

5. The proposed research must not focus on the effectiveness of a pharmacological intervention approach or propose to evaluate a clinical behavioral based intervention approach for substance use or substance use disorders.
    - **Applications that propose to evaluate the effectiveness of a pharmacological intervention approach or propose to evaluate a clinical behavioral based intervention approach (e.g., contingency management, cognitive behavioral therapy [CBT]) for substance use or substance use disorders as evidenced in the Research Strategy section of the application's research plan, will be considered nonresponsive and <u>will not</u> be forwarded for peer review.**

6. The SF-424 Biographical Sketch for the PI or Co-Investigator(s) must include documentation of expertise in the area of illicit substance use, substance use disorders, or overdose or by serving as the contact PD/PI on a research grant in the area of illicit substance use, substance use disorders, or overdose. 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 illicit substance use, substance use disorders, or overdose prevention, or by serving as a principal investigator on a research grant in in the area of illicit substance use, substance use disorders, or overdose research. Experience requirements may be demonstrated through the combined experiences of a Principal and Co-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 nonresponsive and <u>will not</u> be forwarded for peer review.**

6. Required Registrations

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

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

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

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

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

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

All applicant organizations **must obtain** a Unique Entity Identifier (UEI) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The UEI number is a twelve-digit number assigned by SAM.gov. An AOR should be consulted to

determine the appropriate number. If the organization does not have a UEI number, an AOR should register through SAM.gov. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a UEI number.

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

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

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

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

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

9. Cost Sharing

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

10. Number of Applications

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

Eligible applicant organizations may submit more than one application to this NOFO, provided that each application is scientifically distinct. To avoid duplication, please ensure the project titles are 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 (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. Applicant institutions submitting multiple applications with essentially the same proposed research to this announcement will not be funded more than once.

Section IV. Application and Submission Information

1. Address to Request Application Package

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

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

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

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

2. Content and Form of Application Submission

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

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

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

When using ASSIST, all mandatory forms will appear as separate tabs at the top of the

Application Information screen; applicants may add optional forms available for the NOFO by selecting the Add Optional Form button in the left navigation panel.

Please use the form and instructions for SF 424 (R&R) FORMS-H for applications due on or after January 25, 2023.

3. Letter of Intent

Due Date for Letter Of Intent 11/01/2023

11/01/2023
Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows NCIPC staff to estimate the potential review workload and plan the review. By the date listed above and in *Part 1. Overview Information*, prospective applicants are asked to submit a letter of intent that includes the following information:

- Name of the applicant (organization)
- Description of the research topic
- Descriptive title of the proposed research
- Name, address, and telephone number of the contact PD/PI
- Name of other key personnel
- Participating institutions
- Number and title of this notice of funding opportunity announcement (NOFO)

The letter of intent should be sent electronically to:

Aisha L. Wilkes, MPH
Scientific Review Official
Extramural Research Program Operations
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention (CDC)
Email: awilkes@cdc.gov

4. Required and Optional Components

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

5. PHS 398 Research Plan Component

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

Research Plan components as directed in Part 2, Section 1 (Notice of Funding Opportunity Description).

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

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

Other Research Plan Sections

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

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

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

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

- A description of the data to be collected or generated in the proposed project;
- Standards to be used for the collected or generated data;

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

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

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

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

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

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

Please use the form and instructions for SF424 (R&R) FORMS-H for applications due on or after January 25, 2023.

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.

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

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

Please use the form and instructions for SF424 (R&R) FORMS-H for applications due on or after January 25, 2023.

9. Submission Dates & Times

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Due Date for Applications 12/01/2023

12/01/2023

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

10. Funding Restrictions

Expanded Authority:

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

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

Public Health Data:

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

Data Management Plan:

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

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

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

Human Subjects:

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

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

and Human Services (DHHS) Regulations (45 CFR Part 46), or a restriction may be placed on the award. For more information, please contact the scientific/research contact included on this NOFO.

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

Protection of Human Subjects and Personally Identifiable Information
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.

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 includes 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.

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 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 project period.

Indirect Cost Rate Agreement
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.

11. Other Submission Requirements and Information

Risk Assessment Questionnaire Requirement
CDC is required to conduct pre-award risk assessments to determine the risk an applicant poses to meeting federal programmatic and administrative requirements by taking into account issues such as financial instability, insufficient management systems, non-compliance with award conditions, the charging of unallowable costs, and inexperience. The risk assessment will include an evaluation of the applicant's CDC Risk Questionnaire, located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, as well as a review of the applicant's history in all available systems; including OMB-designated repositories of government-wide eligibility and financial integrity systems (see 45 CFR 75.205(a)), and other

sources of historical information. These systems include, but are not limited to: FAPIIS (https://www.fapiis.gov/), including past performance on federal contracts as per Duncan Hunter National Defense Authorization Act of 2009; Do Not Pay list; and System for Award Management (SAM) exclusions.

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

When uploading supporting documentation for the Risk Questionnaire into this application package, clearly label the documents for easy identification of the type of documentation. For example, a copy of Procurement policy submitted in response to the questionnaire may be labeled using the following format: Risk Questionnaire Supporting Documents _ Procurement Policy.

Duplication of Efforts

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

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

Application Submission

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

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

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

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

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

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

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

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

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

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

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the CDC mission (https://www.cdc.gov/about/organization/mission.htm), all applications submitted

to the CDC in support of public health research are evaluated for scientific and technical merit through the CDC peer review system.

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

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

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

- To what extent does the proposed research objective match that of this funding announcement?
- To what extent will the successful completion of the proposed activities significantly advance our understanding of what works to prevent nonfatal and fatal overdose death in community-based settings through the evaluation of untested strategies?
- To what extent will the proposed project inform strategies to decrease health inequities and address social and structural conditions that impact health?
- To what extent does the application demonstrate the capability to efficiently transition research results into public health practice?
- Does the application propose research that, regardless of the scientific or technical merit, will be excluded from funding consideration? This includes the following types of applications:
    - Evaluation of an untested strategy only for its impact related to *infectious disease* as the main outcome, without also including a primary outcome that will directly contribute to our understanding of community-based strategies to reduce overdose.
    - Evaluation of an untested strategy only for its impact on nicotine and/or alcohol related outcomes identified as primary overdose-related outcomes.
    - Evaluation of an untested strategy to reduce overdose in healthcare settings without also connecting to community resources.

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?

- Does the PI/co-I Team have sufficient prior experience in the area of overdose or related outcomes (e.g., drug use, drug use initiation, harm reduction, substance use disorder treatment stigma related to substance use disorder)?
- Does the PI/co-I Team have sufficient prior experience and knowledge in conducting empirical research using the methods proposed in the research plan?
- Is the plan for coordinating project activities, including roles and responsibilities, realistic and clear?
- To what extent is there evidence of past collaboration between the proposed research team and external partners to support the success of the proposed research?

Innovation

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

- Is the proposed research innovative and yet offer a reasonable potential of meeting the Purpose and Research Objective of this NOFO?
- To what extent does the applicant describe how the proposed research is innovative, advances the field of overdose prevention, and adds to the current evidence base?
- To what extent does the proposed research leverage state, tribal, local, or community-based programmatic efforts to build the evidence for selected strategies?

Approach

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

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

- Are the study design, evaluation design, and overall research plan and proposed analytic techniques rigorous and appropriate for the specific research objective(s), including assessment of at least one primary outcome of interest (i.e., nonfatal and fatal drug overdose, drug use, drug use initiation, substance use disorders (SUDs))?
- To what extent is the proposed study feasible and the timeline sufficiently detailed, complete, and realistic for completing the proposed activities within the 5-year project period?

- To what extent is the application's proposed community-based strategies to reduce overdose adequately supported by theory or empirical evidence?
- To what extent does the application address health inequities in its approach (e.g., strategies, measures, populations at increased risk)?
- To what extent does the approach demonstrate the ability to access the necessary data for the evaluation and a clear data analysis plan based on their approach? For both approaches, are these data appropriate for documenting the expected changes in the project period proposed for the study?
- Does the application's proposed strategy assure sample recruitment and retention and adequate statistical power to produce meaningful results, including for subpopulations?
- Does the strategy include an adequate recruitment plan?
- How well does the application adequately address population selection criteria, ways to reach and follow-up with the target population, and methods for obtaining and retaining a sufficient sample?
- To what extent does the design address threats to validity and the ability to identify the key components?
- To what extent does the Research Strategy section of the application clearly describe the roles and responsibilities of each partner organization involved in data collection and/or the effectiveness evaluation?
- To what extent does the Research Strategy include partnering with community-based collaborators, including activities focused on building relationships with community partners?
- To what extent does the applicant justify the selection of the population of focus?
- To what extent does the Research Strategy engage individuals in the focus population (e.g., people with lived experience with drug use)?

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?

- 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 applicant describe whether or how the community was engaged or will be engaged in choosing or designing the strategy and whether or how the research coincides with community input into the strategy/intervention/program/practice to ensure the relevance, appropriateness, and feasibility of the proposed research?
- To what extent does the application clearly describe the existing working relationships between the research institution and all partner organizations? Does the application clearly describe the involvement and scope of work of relevant partners including community organizations, community leaders, people in the focus population (e.g., persons with lived experience with drug use), and other partners are willing to commit to ensuring the successful implementation and evaluation of the prevention strategies, including providing or facilitating access to relevant study participants, as well as

implementation and outcome data necessary to complete the proposed research within the proposed period of performance?

- To what extent does the applicant provide evidence of access to and support from systems and organizations in which the strategies are being implemented?
- 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 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).

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

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

Vertebrate Animals
The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following four points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) procedures for limiting discomfort,

distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 4) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section (https://grants.nih.gov/grants/olaw/VAChecklist.pdf).

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

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

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

3. Additional Review Considerations

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

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

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

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

The DMP should be developed during the project planning phase prior to the initiation of collecting or generating public health data and will be submitted with the application. The

submitted DMP will be evaluated for completeness and quality at the time of submission.

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

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

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

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

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

Budget and Period of Support
Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research. The applicant can obtain 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 applications including signed Data Sharing Agreements, Letters of Support, or Memorandum of Understanding for each partnership described in the Research Strategy section of the application clearly describing the support to be provided to conduct the proposed research.
- Consideration of research conducted in collaboration/ partnership with the community, as evidenced by the Letters of Support section of the application. This may include state and/or local health departments, local governmental agencies and/or businesses, and community-based organizations.
- Consideration for meritorious applications that contribute to a diverse mix of strategies in proposed research to evaluate untested community-based strategies to reduce overdose (e.g., balance of settings and focus populations).
- Consideration for meritorious applications that contribute to a geographic balance of proposed projects, as evidenced by the congressional district of the applicant organization, to broaden the distribution of awards.
- Consideration for applicant organizations from or conducting research in collaboration or partnership with institutions that have a demonstrated record of or historical commitment to serving underrepresented students, including racial and ethnic minorities, individuals from disadvantaged backgrounds and individuals with disabilities. Applicants may indicate this in the Research Strategy of their application.

- Consideration for applications in which the contact Eligible PD/PI meets NIH Early Stage Investigator (ESI) status, as verified by the NIH Determination of Investigator Status process.
- Exclusion from funding consideration, regardless of the scientific or technical merit of the proposed project, as evidenced by the Research Strategy section of the application's research plan:
    - Evaluation of an untested strategy only for its impact related to *infectious disease* as the main outcomes, without also including a primary outcome that will directly contribute to our understanding of community-based strategies to reduce overdose.
    - Evaluation of an untested strategy only for its impact on nicotine and/or alcohol related outcomes identified as primary overdose-related outcomes
    - Evaluation of an untested strategy to reduce overdose in healthcare settings without also connecting to community resources

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

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

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

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

(1) Financial stability;
(2) Quality of management systems and ability to meet the management standards prescribed in this part;
(3) History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting

requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;
(4) Reports and findings from audits performed under 45 CFR Part 75, subpart F, or the reports and findings of any other available audits; and
(5) The applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

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

5. Anticipated Announcement and Award Dates

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

Section VI. Award Administration Information

1. Award Notices

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

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

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

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

2. CDC Administrative Requirements

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

If you receive an award, you must follow all applicable nondiscrimination laws. You agree to

this when you register in SAM.gov. You must also submit an Assurance of Compliance (HHS-690). To learn more, see the HHS Office for Civil Rights website.

AR-1: Human Subjects Requirements
AR-2: Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR-3: Animal Subjects Requirements
AR-9: Paperwork Reduction Act Requirements
AR-10: Smoke-Free Workplace Requirements
AR-11: Healthy People 2030
AR-12: Lobbying Restrictions
AR-14: Accounting System Requirements
AR-16: Security Clearance Requirement
AR-21: Small, Minority, And Women-owned Business
AR-22: Research Integrity
AR-24: Health Insurance Portability and Accountability Act Requirements
AR-25: Data Management and Access
AR-26: National Historic Preservation Act of 1966
AR-28: Inclusion of Persons Under the Age of 21 in Research
AR-29: Compliance with EO13513, "Federal Leadership on Reducing Text Messaging while Driving", October 1, 2009
AR-30: Information Letter 10-006, - Compliance with Section 508 of the Rehabilitation Act of 1973
AR-31: Research Definition
AR-32: Appropriations Act, General Provisions
AR-33: United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern
AR-34: Accessibility Provisions and Non-Discrimination Requirements
AR-36: Certificates of Confidentiality
AR-37: Prohibition on certain telecommunications and surveillance services or equipment for all awards issued on or after August 13, 2020.

Organization Specific ARs:
AR-8: Public Health System Reporting Requirements
AR-15: Proof of Non-profit Status
AR 23: Compliance with 45 C.F.R. Part 87

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

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

Additional CDC Award Requirements

The following Additional Requirements, some of which emphasize and expand upon those

above, will be required for all recipients funded under this NOFO.

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

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

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

3. Additional Policy Requirements

The following are additional policy requirements relevant to this NOFO:

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

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

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

Employee Whistleblower Rights and Protections Employee Whistleblower Rights and Protections: All recipients of an award under this NOFO will be subject to a term and condition that applies the requirements set out in 41 U.S.C. § 4712, "Enhancement of contractor protection

from reprisal for disclosure of certain information" and 48 Code of Federal Regulations (CFR) section 3.9 to the award, which includes a requirement that recipients and subrecipients inform employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. § 4712. For more information see: https://oig.hhs.gov/fraud/whistleblower/.

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

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

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

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

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

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

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

Data Management Plan(s)

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

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

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

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

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

4. Cooperative Agreement Terms and Conditions

Not Applicable (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/rppr/index.htm; https://grants.nih.gov/grants/forms/report_on_grant.htm) and financial statements as required in the HHS Grants Policy Statement.

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

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

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

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

Technical Review and Summary Statement Response Requirements
Recipients will be required to electronically submit a response to the peer reviewers' comments and/or concerns, as 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.

A. Submission of Reports

The Recipient Organization must submit:

1. **Yearly Non-Competing Grant Progress Report** is due 90 to 120 days before the end of the current budget period. The RPPR form (https://grants.nih.gov/grants/rppr/index.htm; https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf) is to be completed on the eRA Commons website. The progress report will serve as the non-competing continuation application. Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.
2. **Annual Federal Financial Report (FFR) SF 425 (**Reporting | Grants | CDC) is required and must be submitted to the Payment Management System accessed through the FFR navigation link in eRA Commons or directly through PMS **within 90 days after the budget period ends.**
3. **A final progress report**, invention statement, equipment/inventory report, and the final FFR are required **90 days after the end of the period of performance.**

B. Content of Reports

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

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

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

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

    - Translation of Research (1 page maximum). When relevant to the goals of the research project, the PI should describe how the significant findings may be used to promote, enhance, or advance translation of the research into practice or may be used to inform public health policy. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers, and other potential users. The PI should identify the research findings that were translated into public health policy or practice and how the findings

have been or may be adopted in public health settings. Or, if they cannot be applied yet, this section should address which research findings may be translated, how these findings can guide future research or related activities, and recommendations for translation. If relevant, describe how the results of this project could be generalized to populations and communities outside of the study. Questions to consider in preparing this section include:

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

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

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

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

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

- Publications/Presentations: Include publications/presentations resulting from this CDC grant only during this budget period. If no publication or presentations have

been made at this stage in the project, simply indicate "Not applicable: No publications or presentations have been made."

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

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

- Additional Reporting Requirements:

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, 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 project period.

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

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

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

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

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

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

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

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

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

6. Termination

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

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

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

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

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

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

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

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

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

1) Annual Report: The recipient must submit a report on or before November 16 for each foreign country on the amount of foreign taxes charged, as of September 30 of the same year, by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant during the prior United States fiscal year (October 1 – September 30), and the amount reimbursed and unreimbursed by the foreign

government. [Reports are required even if the recipient did not pay any taxes during the reporting period.]

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

3) Terms: For purposes of this clause:

“Commodity” means any material, article, supplies, goods, or equipment;

“Foreign government” includes any foreign government entity;

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

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

5) Contents of Reports: The reports must contain:

a. recipient name;

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

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

d. reporting period;

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

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

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

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

Section VII. Agency Contacts

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

Application Submission Contacts

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

eRA Commons Help Desk (Questions regarding eRA Commons registration, tracking application status, post submission issues, FFR submission)

Phone: 301-402-7469 or 866-504-9552 (Toll Free)
TTY: 301-451-5939
Email: commons@od.nih.gov
Hours: Monday - Friday, 7am - 8pm U.S. Eastern Time

Scientific/Research Contact
Amanda Garcia-Williams, PhD, MPH
Scientific Program Official
Extramural Research Program Operations
National Center for Injury Prevention and Control (NCIPC)
Email: NCIPC_ERPO@cdc.gov

Peer Review Contact
Aisha Wilkes, MPH
Scientific Review Official
Extramural Research Program Operations
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention (CDC)
Email: awilkes@cdc.gov

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

Manal Ali
Grants Management Specialist
CDC Office of Grants Services
Email: hfo8@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.

Application Submission Process
Applications must be successfully submitted and complete all validation actions before 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 before 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.