

Centers for Disease Control and Prevention

NATIONAL CENTER FOR INJURY PREVENTION AND CONTROL

Grants to Support New Investigators in Conducting Research Related to Understanding Drug Use and Overdose Risk and Protective Factors (K01)

RFA-CE-24-011

12/01/2023

Table of Contents

Section I. Funding Opportunity Description 8
Section II. Award Information.....24
Section III. Eligibility Information 25
Section IV. Application and Submission Information.....32
Section V. Application Review Information 42
Section VI. Award Administration Information 50
Section VII. Agency Contacts 62
Section VIII. Other Information 62

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

Grants to Support New Investigators in Conducting Research Related to Understanding Drug Use and Overdose Risk and Protective Factors (K01)

Activity Code

K01 - Mentored Research Scientist Development Award

Notice of Funding Opportunity Type

Reissue of RFA-CE-23-002

Agency Notice of Funding Opportunity Number

RFA-CE-24-011

Assistance Listings Number(s)

93.136

Category of Funding Activity

HL - Health

NOFO Purpose

The purpose of the Centers for Disease Control and Prevention National Center for Injury Prevention and Control (NCIPC) Mentored Research Scientist Development Award (K01) is to provide support for an intensive, supervised/mentored career development experience in substance use and/or overdose prevention research leading to research independence. NCIPC supports K01 grants to help ensure the availability of an adequate number of trained scientists to address critical public health research questions to prevent polydrug use and overdose. This

funding would support research that aims to better understand and identify risk and protective factors related to any drug use/overdose (e.g., opioids including fentanyl and stimulants, etc.), substance use disorders (SUDs), and stigma (e.g., how do certain factors impact stigma). Research can focus on the examination of potential moderators or mediators between the relationship between risk and protective factors and drug use and outcomes. Research should be conducted among persons experiencing a disproportionate burden of substance use disorders and overdose, which may include but are not limited, to those **people in certain sociodemographic groups** (e.g. non-English speaking populations, tribal populations, rural communities, racial/ethnic minority groups, sexual and gender minority groups), **people experiencing social determinants of health** (e.g., reduced economic stability; limited educational attainment, access or quality; limited healthcare access or quality including those who have been historically underserved or are uninsured; limited access to substance use treatment; limited health literacy; those in geographically underserved areas), **people experiencing social or physical health conditions or experience**s (e.g., homelessness, a mental health condition, chronic pain, incarceration or recent release from incarceration, a disability, adverse childhood experiences, a history of suicidal ideation or suicide attempt, a history of substance use disorders and/or overdose).

Key Dates

Publication Date:

To receive notification of any changes to RFA-CE-24-011, return to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notification Emails" link. An email address is needed for this service.

Letter of Intent Due Date:

11/01/2023

Letters of Intent are requested by **11/01/2023**. 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

Please carefully review and follow the instructions in *Section IV. Application and Submission Information 9. Submission Dates and Times* in order to ensure timely receipt of your application by the application due date at 11:59 PM EST.

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:
03/05/2024
This is an estimated date.

Secondary Review:
05/01/2024
This is an estimated date.

Estimated Start Date:
09/30/2024
The estimated start date is September 30, 2024.

Expiration Date:
03/08/2024

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 purpose of the Centers for Disease Control and Prevention National Center for Injury Prevention and Control (NCIPC) Mentored Research Scientist Development Award (K01) is to provide support for an intensive, supervised/mentored career development experience in substance use and/or overdose prevention research leading to research independence. NCIPC supports K01 grants to help ensure the availability of an adequate number of trained scientists to address critical public health research questions to prevent polydrug use and overdose. This

funding would support research that aims to better understand and identify risk and protective factors related to any drug use/overdose (e.g., opioids including fentanyl and stimulants, etc.), substance use disorders (SUDs), and stigma (e.g., how do certain factors impact stigma). Research can focus on the examination of potential moderators or mediators between the relationship between risk and protective factors and drug use and outcomes.

Research should be conducted among persons experiencing a disproportionate burden of substance use disorders and overdose, which may include but are not limited, to those people in **certain sociodemographic groups** (e.g. non-English speaking populations, tribal populations, rural communities, racial/ethnic minority groups, sexual and gender minority groups), **people experiencing social determinants of health** (e.g., reduced economic stability; limited educational attainment, access or quality; limited healthcare access or quality including those who have been historically underserved or are uninsured; limited access to substance use treatment; limited health literacy; those in geographically underserved areas), **people experiencing certain social or physical health conditions or experiences** (e.g., homelessness, a mental health condition, chronic pain, incarceration or recent release from incarceration, a disability, adverse childhood experiences, a history of suicidal ideation or suicide attempt, a history of substance use disorders and/or overdose).

Applicants should propose to address one or more of the key research questions related to NCIPC's research priority to identify risk and protective factors for drug overdose listed below:

1. How do risk and protective factors and trajectories for use, misuse, substance use disorder, and/or overdose differ for prescription opioids, illicit opioids, and other emerging drug threats such as resurging methamphetamine and cocaine?
2. What are risk and protective factors and trajectories related to polydrug use and overdose, including co-use of opioid and non-opioid drugs, with a focus on methamphetamine, cocaine, and benzodiazepines?
3. How do these risk and protective factors and trajectories vary by sociodemographic and geographic characteristics at all levels of the social ecology (described in the Background section of this NOFO)?
4. How do risk and protective factors and trajectories related to drug use, misuse, substance use disorders, and overdose vary among populations experiencing a disproportionate burden of substance use disorders and overdose and intersectional social identities?
5. What are risk and protective factors for early drug use initiation (i.e., particularly during youth and adolescence as described in the Background section of this NOFO) and escalation of use? How do these vary among populations experiencing a disproportionate burden of substance use disorders and overdose?
6. What are the associations among adverse childhood experiences (ACEs), prescription opioid misuse and/or illicit drug use, and chronic pain, as well as moderators of these associations, including social determinants of health?
7. What are norms and behaviors surrounding prescription opioid misuse, illicit drug use, overdose, and related health and behavioral outcomes? What are norms and behaviors among people experiencing a disproportionate burden of substance use disorders and overdose and/or groups that are at greater risk of experiencing adverse outcomes related to substance use due to social determinants of health? What are the best strategies to tailor communication about risk such that messages related to these outcomes resonate

with all members of the public, particularly those disproportionately affected by overdose?

In developing cross-sectional or longitudinal analyses that correspond to aspects of these research questions, applicants are encouraged to examine mechanisms (e.g., mediation, moderation, applicability of theoretical frameworks), particularly questions that incorporate social determinants of health.

Mechanism of Support: The funding mechanism for this Notice of Funding Opportunity (NOFO) will be a K01 Mentored Research Scientist Development Award.

Funds Available and Anticipated Number of Awards: NCIPC intends to commit up to $450,000 (direct and indirect costs) in FY2024 to support up to three (3) applications for this NOFO. The total funding and the number of awards is contingent upon availability of funds and a sufficient number of meritorious applications.

Budget and Project Period: The maximum award amount will be $150,000 per award for the first 12-month budget period. This includes both direct and indirect costs. For this award, the indirect costs are limited to 8% of Modified Total Direct Cost. Applicants may request a project period of up to three (3) years. The maximum total project funding is $450,000 (direct and indirect) per award, over the project period. The project period is expected to be 09/30/2024 to 09/29/2027. 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: Individuals with the skills, knowledge, and resources necessary to carry out the proposed research as the contact PD/PI are invited to work with their institution/organization and mentor to develop an application for support. NOTE: CDC does not make awards to individuals directly.

The purpose of the NCIPC Mentored Research Scientist Development Award (K01) is to provide support for an intensive, supervised/mentored career development experience in substance use and/or overdose prevention research leading to research independence. NCIPC supports K01 grants to help ensure the availability of an adequate number of trained scientists to address critical public health research questions to prevent polydrug use and overdose:

- Applicant contact PD/PIs must have a qualifying (relevant to the field of study) research or health- professional doctoral or medical degree (such as PhD, ScD, DO, DrPH, MD, DVM, PharmD, DDS, DMD, PsyD, DPT), from an accredited institution of higher learning. Applications that do not demonstrate that the contact PD/PI has a qualifying (relevant to the field of study) research or health professional doctoral or medical degree (such as PhD, ScD, DO, DrPH, MD, DVM, PharmD, DDS, DMD, PsyD, DPT) from an

accredited institution of higher learning, as evidenced by their SF-424 Biographical Sketch, will be considered nonresponsive and will not be forwarded for peer review.

- At the time of the NOFO application due date, applicant contact PD/PIs must have less than five years of post-graduate research experience as a researcher in the substance use and overdose prevention field, as documented on the contact PD/PI's SF-424 Biographical Sketch. The 5-year period will be calculated from the completion of the qualifying degree (e.g., a research or health-professional doctoral or medical degree [such as PhD, ScD, DO, DrPH, MD, DVM, PharmD, DDS, DMD, PsyD, DPT] from an accredited institution of higher learning). The Positions and Employment section of SF-424 Biographical Sketch is expected to clearly document all of the contact PD/PI's relevant research experience. **Applications that do not demonstrate that the contact PD/PI has less than five years of post-graduate experience as a researcher in the substance use and overdose prevention field, as evidenced by their SF-424 Biographical Sketch, will be considered nonresponsive to the NOFO and will not be forwarded for peer review.**
- Time periods for significant breaks in employment or employment in areas unrelated to substance use and overdose prevention should be clearly documented. Only the years where any substance use and overdose prevention research was conducted **after** the completion of the qualifying degree will count towards the limit of five years of research experience. Research conducted during undergraduate or pre-graduate training does not count towards the five-year research time - even if the applicant contact PD/PI authored or co-authored a paper relevant to the research prior to completion of the qualifying degree.
- This funding opportunity may support individuals who propose to train in a new field or individuals who have had a hiatus in their research career due to circumstances such as, but not limited to, illness or pressing family circumstances. Applicant contact PD/PIs who are changing their career trajectory to the substance use and overdose prevention field must clearly document the start date of their post-graduate emphasis in substance use and overdose prevention in their SF-424 Biographical Sketch and must clearly demonstrate that they have less than five years of post-graduate experience as a researcher in the substance use and overdose prevention field. **Applications from contact PD/PIs who completed their qualifying degree prior to February 09, 2018 and do not clearly document their relevant post-graduate research experience in substance use and overdose prevention (including breaks in employment or research in other areas) will be considered nonresponsive to the NOFO and will not be forwarded for peer review.**
- Individuals who are identified as the contact PD/PI on a current and/or former CDC or National Institutes of Health (NIH) grant or cooperative agreement award from any of the following excluded independent research assistance mechanisms defined below, as documented by their eRA Commons PD/PI Grant History profile, are NOT eligible for funding under this NOFO. The excluded assistance mechanisms are: CDC or NIH research project (R01 or U01), program project (P01), center grant (R49, P50), sub-project of program project (P01), sub-project of center grant (R49, P50), or other major individual career development award (e.g., K01, K07, K08, K22, K23, K25, K76, K99/R00). Applications with a contact PD/PI eRA Commons Grant History profile that reflects a current or former award in any of the named excluded independent research

assistance mechanisms will be considered nonresponsive and will not be forwarded for peer review.

- Individuals with current or former funding on the following CDC or NIH training award assistance mechanisms ARE eligible to apply as contact PD/PIs to this NOFO: CDC or NIH Small Grant (R03), Exploratory/Developmental Grant (R21), Dissertation Award (R36 or R49), SBIR/STTR (R41, R42, R43, or R44), Transition Scholar (K38) awards, National Research Service Awards (F30, F31, F32) and individuals appointed to institutional K (K12, KL2) and T (T32) programs.
- At the time of award, the contact PD/PI must be a citizen, a non-citizen national of the United States, or have been lawfully admitted for permanent residence (i.e., possess a currently valid Permanent Resident Card USCIS Form I-551, or other legal verification of such status).
- At the time of the NOFO application due date, the contact PD/PI must have a full-time position at the eligible applicant institution. The application must include a Candidate Eligibility Statement (e.g., an institutional letter of attestation) that is signed by the eligible applicant institution's Authorized Representative that explicitly verifies the contact PD/PI's full time employment status. This should be included in the Institutional Commitment to Candidate's Research Career Development section of the application. The contact PD/PI is not required to have a tenure track appointment at the eligible applicant institution in order to be eligible for this NOFO. **Applications that do not include a Candidate Eligibility Statement that: (1) explicitly verifies the contact PD/PI's full time employment status and (2) is signed by the applicant institution's Authorized Representative will be considered nonresponsive and will not be forwarded for peer review.**
- Applicant contact PD/PIs are required to commit a minimum of 60% of full-time professional effort (i.e., a minimum of 7.3 person-months/year) to their research project and career development for the entirety of the project period. The budget, budget justification, and PHS 308 Career Development Award sections of the application must clearly describe the contact PD/PI's commitment. Applications that do not demonstrate contact PD/PI commitment to a minimum of 60% of full-time professional effort to their research project and career development for the entirety of the project period, as evidenced by the application's SF-424 Research and Related Budget effort of at least 7.3 person-months/year for the contact PD/PI, will be considered nonresponsive and will not be forwarded for peer review.

Number of PDs/PIs: There can be only one PD/PI listed in the SF-424 Senior/Key Personnel project role category. Additional Senior/Key Personnel project roles are limited to Mentor, Co-Investigator, Consultant and Other. Multiple PD/PI (i.e., M-PD/PI) and Co-Principal Investigators (Co-PD/PI) project roles are not allowed for this announcement.

Number of Applications: Eligible applicant organizations/institutions may submit more than one application, provided that each application is scientifically distinct. However, applicant institutions can submit only one grant application with the same contact PD/PI in response to this NOFO. Additionally, applicant institutions can submit only one grant application with the same individual designated in a Mentor project role in the application in response to this NOFO. Only one application per contact PD/PI will be reviewed or funded under this announcement; only one

application per Mentor will be reviewed or funded under this announcement. If two or more applications from the same contact PD/PI are received, the only application that will be submitted for review will be the last application received based on the document's time and date stamp in Grants.gov (http://www.grants.gov). If two or more applications identifying the same Mentor are received, the only application that will be submitted for review will be the last application received based on the document's time and date stamp in Grants.gov (http://www.grants.gov). 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. Contact PD/PIs submitting applications to this NOFO and any other CDC/ATSDR NOFO will not be funded under more than one NOFO.

Special Date(s)
A pre-application teleconference call will be conducted on October 10, 2023 to address questions from prospective applicants regarding NOFO RFA-CE-24-011. 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 10, 2023
- Call Start Time: 2:00pm Eastern Standard Time (EST)
- Call End Time: 3:00pm Eastern Standard Time (EST)
- Call Leader: Joyce Dieterly, MPH, 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

Background
Risk and protective factors for drug use, initiation, escalation, and overdose exist at multiple levels of the social ecology. At the **individual-level**, factors associated with risk span physical and mental health, and biological domains and include early initiation of drug use during youth and adolescence; experiencing pain and a number of mental health conditions; sex and race/ethnicity; and adverse childhood experiences.[1-9] Factors associated with some level of protection include such things as employment, affiliation with a religion and frequency of prayer, strong moral beliefs and values including cultural values of respect, and generally concepts of

positive youth development.[10-14] Some **relationship-level** factors that increase risk for drug use include a family history of substance use disorder and associating with peers who engage in drug use.[15, 16] Some relationship-level factors shown to protect against drug use are parental and peer attitudes and norms that are disapproving of drug use, positive family relationships, more parental monitoring and greater parental involvment.[16-20] At the **community-level**, the environment in which individuals live can impact their level of risk for drug use. For instance, lack of social cohesion, poverty, poor access to healthcare and treatment services, stigma within the community about seeking treatment for substance use disorder, and access to licit and illicit drugs within the community serve as factors that increase risk for drug use.[21] Factors associated with some level of protection include strength of adolescents' school bonds, or involvement and commitment to school, and engagement in prosocial activities at school and in the community.[19,22,23] At the **societal-level**, risk factors for drug use may include poor economic conditions and an/or expansive illicit drug supply while programs such as Prescription Drug Monitoring Programs (PDMPs) that track prescribing practices and patterns and policies limiting access to prescription drugs and enhancing access to substance use disorder treatment options and the life-saving opioid-reversing drug naloxone can serve as factors that protect against drug initiation, use, and overdose.[24-29] Research on protective factors at the societal-level has been limited; however, several laws and policies have been implemented to decrease alcohol use (e.g., alcohol taxes, drunk driving laws, minimum legal drinking age).[30,31] Importantly, risk may be either attenuated or exacerbated at each level of the social ecology based on various sociodemographic and geographic characteristics, including race/ethnicity, age, socioeconomic status, and rural, suburban, and urban community characteristics.

While prior research has documented these risk and protective factors spanning the social ecology, our understanding of the risk and protective factors for drug overdose is confounded by the complex and evolving nature of the drug overdose epidemic.[32] Changes in the illicit drug supply, mixing of drugs with or without the knowledge of the person using those drugs, and polydrug use are factors that contribute to the complexity of the drug overdose landscape and challenge our ability to identify and address risk and protective factors for drug use and overdose.[33,34] These factors also create challenges for developing and implementing response and intervention strategies.

Purpose

The purpose of the Centers for Disease Control and Prevention National Center for Injury Prevention and Control (NCIPC) Mentored Research Scientist Development Award (K01) is to provide support for an intensive, supervised/mentored career development experience in substance use and/or overdose prevention research leading to research independence. NCIPC supports K01 grants to help ensure the availability of an adequate number of trained scientists to address critical public health research questions to prevent drug use and overdose, substance use disorders (SUD), and stigma.

This funding would support up to 3 recipients for up to 3 years at up to $150,000 per year to conduct research that aims to better understand and identify risk and protective factors related to any drug use/overdose (e.g., opioids including fentanyl and stimulants, etc.), SUDs, and stigma (e.g., how do certain factors impact stigma). Research can focus on the examination of potential

moderators or mediators between the relationship between risk and protective factors and drug use and outcomes. Research should be conducted among persons experiencing a disproportionate burden of substance use disorders and overdose, which may include but are not limited, to those people in **certain sociodemographic groups** (e.g. non-English speaking populations, tribal populations, rural communities, racial/ethnic minority groups, sexual and gender minority groups), **people experiencing social determinants of health** (e.g., reduced economic stability; limited educational attainment, access or quality; limited healthcare access or quality including those who have been historically underserved or are uninsured; limited access to substance use treatment; limited health literacy; those in geographically underserved areas), **people experiencing certain social or physical health conditions or experiences** (e.g., homelessness, a mental health condition, chronic pain, incarceration or recent release from incarceration, a disability, adverse childhood experiences, a history of suicidal ideation or suicide attempt, a history of substance use disorders and/or overdose).

Applicants should propose a research project that addresses **at least one aspect of one key research question related to NCIPC's priority to identify risk and protective factors for drug overdose included in NCIPC's *Overdose Prevention Research Priorities* and listed below.**

Key research questions include:

1. How do risk and protective factors and trajectories for use, misuse, substance use disorders, and/or overdose differ for prescription opioids, illicit opioids, and other emerging drug threats such as resurging methamphetamine and cocaine?
2. What are risk and protective factors and trajectories related to polydrug use and overdose, including co-use of opioid and non-opioid drugs, with a focus on methamphetamine, cocaine, and benzodiazepines?
3. How do these risk and protective factors and trajectories vary by sociodemographic and geographic characteristics at all levels of the social ecology (described in the Background section of this NOFO)?
4. How do risk and protective factors and trajectories related to drug use, misuse, substance use disorders, and overdose vary among populations experiencing a disproportionate burden of substance use disorders and overdose and intersectional social identities?
5. What are risk and protective factors for early drug use initiation (i.e., particularly during youth and adolescence as described in the Background section of this NOFO) and escalation of use? How do these vary among populations experiencing a disproportionate burden of substance use disorders and overdose?
6. What are the associations among adverse childhood experiences (ACEs), prescription opioid misuse and/or illicit drug use, and chronic pain, as well as moderators of these associations, including social determinants of health?
7. What are norms and behaviors surrounding prescription opioid misuse, illicit drug use, overdose, and related health and behavioral outcomes? What are norms and behaviors among people experiencing a disproportionate burden of substance use disorders and overdose and/or groups that are at greater risk of experiencing adverse outcomes related to substance use due to social determinants of health? What are the best strategies to tailor communication about risk such that messages related to these outcomes resonate

with all members of the public, particularly those disproportionately affected by overdose?

Each of the key research questions outlined above is broad, multi-faceted, and often intended to highlight multiple gaps in the evidence base. As such, applicants for this NOFO may not anticipate being able to answer an entire key research question with their proposed project. However, meritorious proposals are expected to provide a thorough plan for addressing at least one aspect of one key research question identified here. For example, not all facets of substance use must be addressed (i.e., use, substance use disorder, overdose) and not all drugs must be studied. Still, applicants should clearly explain how their research will aim to answer one of the research questions above. The funded research projects will help directly address NCIPC's research priority to:

- Identify risk and protective factors for drug overdose, with a focus on overdoses involving opioids, emerging drugs, and polydrug combinations

References

1. Poudel A, Gautam S. Age of onset of substance use and psychosocial problems among individuals with substance use disorders. BMC Psychiatry. 2017;17:10.
2. Schepis TS, Hakes JK. Age of initiation, psychopathology, and other substance use are associated with time to use disorder diagnosis in persons using opioids nonmedically. Subst Abus. 2017;38(4):407-413.
3. Weiss RD, Potter JS, Griffin ML, et al. Reasons for opioid use among patients with dependence on prescription opioids: the role of chronic pain. J Subst Abuse Treat. 2014;47(20):140-5.
4. Conway KP, Compton W, Stinson FS, et al. Lifetime comorbidity of DSM-IV mood and anxiety disorders and specific drug use disorders: results from the National Epidemiologic Survey on Alcohol and Related Conditions. J Clin Psychiatry. 2006;67(2):247-57.
5. Sullivan MD, Edlund MJ, Zhang L, et al. Association between mental health disorders, problem drug use, and regular prescription opioid use. Arch Intern Med. 2006;166(19):2087-93.
6. Turk DC, Swanson KS, Gatchel RJ. Predicting opioid misuse by chronic pain patients: a systematic review and literature synthesis. Clin J. Pain. 2008;24(6):497-508.
7. Morley KI, Ferris JA, Winstock AR, et al. Polysubstance use and misuse or abuse of prescription opioid analgesics: a multi-level analysis of international data. Pain. 2017;158(6):1138-44.
8. Swendsen J, Le Moal M. Individual vulnerability to addiction. Ann NY Acad Sci. 2011;1216(1):73-85.
9. Merrick MT, Ford DC, Haegerich TM, et al. Adverse Childhood Experiences Increase Risk for Prescription Opioid Misuse. J Prim Prev. 2020 Apr;41(2):139-152.
10. Bachman JG, Freedman-Doan P, O'Malley PM, et al. Changing patterns of drug use among US military recruits before and after enlistment. Am J Public Health. 1999 May;89(5):672-7.

11. Resnick MD, Bearman PS, Blum RW, et al. Protecting adolescents from harm: findings from the National Longitudinal Study on Adolescent Health. JAMA. 1997 10;278(10):823-32.
12. Scales PC, Leffert N. Developmental assets. Minneapolis, MN: Search Institute; 1999.
13. Oman RF, Vesely S, Aspy CB, et al. The potential protective effect of youth assets on adolescent alcohol and drug use. AJPH. 2004 Aug;94(8):1425-30.
14. Spooner C, Hall W, Lynskey M. Structural determinants of youth drug use. ANCD Research Paper No. 2. Canberra: Australian National Council on Drugs; 2001.
15. Pickens RW, Preston KL, Miles DR, et al. Family history influence on drug abuse severity and treatment outcome. Drug Alcohol Depend. 2001;61(3):261-70.
16. Walters GD. Prosocial peers as risk, protective, and promotive factors for the prevention of delinquency and drug use. J Youth Adolesc. 2020;49(3):618-30.
17. Morojele NK, Brook JS. Adolescent precursors of intensity of marijuana and other illicit drug use among adult initiators. J Genet Psychol. 2001;162:430-450.
18. White HR, McMorris BJ, Catalano RF, et al. Increases in alcohol and marijuana use during the transition out of high school into emerging adulthood: The effects of leaving home, going to college, and high school protective factors. J Stud Alcohol. 2006;67(6):810-22.
19. Ford JA. Nonmedical prescription drug use among adolescents: The influence of bonds to family and school. Youth & Society. 2009 Mar;40(3):336-52.
20. Resnick MD, Bearman PS, Blum RW, et al. Protecting adolescents from harm: findings from the National Longitudinal Study on Adolescent Health. JAMA. 1997;10;278(10):823-32.
21. Substance Abuse and Mental Health Services Administration. Preventing prescription drug misuse. Overview of factors and strategies; 2016.
22. Voelkl KE, Frone MR. Predictors of substance use at school among high school students. J Educational Psychol. 2000;92(3):583.
23. King KA, Vidourek RA, Merianos AL. Sex and grade level differences in lifetime nonmedical prescription drug use among youth. J Prim Prev. 2013;34:237-49.
24. Rhodes T, Lilly R, Fernandez C, et al. Risk factors associated with drug use: the importance of 'risk environment.' Drugs: education, prevention, and policy. 2003;10(4):303-329.
25. Haffajee RL, Jena AB, Weiner SG. Mandatory use of prescription drug monitoring programs. JAMA. 2015:313(9):891-2.
26. McClellan C, Lambdin BH, Ali MM, et al. Opioid-overdose laws association with opioid use and overdose mortality. Addict Behav. 2018:86:90-5.
27. Gertner AK, Domino ME, Davis CS. Do naloxone access laws increase outpatient naloxone prescriptions? Evidence from Medicaid. Drug Alcohol Depend. 2018:190:37-41.
28. Strickler GK, Zhang K, Halpin JF, et al. Effects of mandatory prescription drug monitoring program (PDMP) use laws on prescriber registration and use and on risky prescribing. Drug Alcohol Depend. 2019;199:1-9.
29. Sharp A, Jones A, Sherwood J, et al. Impact of Medicaid expansion on access to opioid analgesic medications and medication-assisted treatment. Am J Public Health. 2018;108(5):642-8.

30. Voas RB, Tippetts AS, Fell JC. Assessing the effectiveness of minimum legal drinking age and zero tolerance laws in the United States. Accident Analysis and Prevention. 2003;35:579-587.
31. Elder RW, Lawrence B, Ferguson A, et al. Task Force on Community Preventive Services. The effectiveness of tax policy interventions for reducing excessive alcohol consumption and related harms. Am J Prev Med. 2010;38(2):217-29.
32. O'Donnell J, Gladden RM, Mattson C, et al. Vital Signs: Characteristics of drug overdose deaths involving opioids and stimulants — 24 states and the District of Columbia, January–June 2019. MMWR. 2020;69(35);1189–1197.
33. Drug Enforcement Administration. National Drug Threat Assessment, 2019.
34. Jones C, Olsen E, O'Donnell J, et al. Resurgent Methamphetamine Use at Treatment Admission in the United States, 2008-2017. Am J Public Health. *2020*;110(4):509-516.

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

Expanding the pool of public health researchers in the field of substance use and overdose prevention will increase opportunities for developing innovative and impactful solutions for overdose prevention. New investigators will contribute to our knowledge about the best ways to prevent and address drug use/overdose, SUD, and stigma, particularly with respect to populations who may be at increased risk of drug use initiation or overdose.

Relevant Work

For 30 years, NCIPC has been the nation's leading public health authority on violence and injury prevention. Preventing drug overdose, including opioid overdose, in the United States requires a comprehensive public health approach. To this end, CDC's efforts focus on the following areas:

- Conducting surveillance and research to monitor emerging trends, identify risk factors, and inform prevention activities;
- Strengthening state, local, territorial, and tribal capacity to improve data collection and implement evidence-based prevention strategies;
- Working with providers, health systems, and payers to support safer and more effective opioid prescribing and pain management;
- Coordinating with public safety and community-based partners to rapidly identify and respond to overdose threats; and
- Increasing public awareness about the risks of opioids and other drug overdoses and related harms and reduce stigma.

CDC's largest investment – Overdose Data to Action (OD2A) – supports funded jurisdictions in collecting high quality, comprehensive, and timely data on nonfatal and fatal overdoses and in using those data to inform prevention and response efforts. OD2A focuses on understanding and tracking the complex and changing nature of the drug overdose epidemic and highlights the need for seamless integration of data into prevention strategies. CDC launched the multiyear OD2A cooperative agreement in September 2019 with 66 recipients (referred to as jurisdictions) comprising state, territorial, county, and city health departments.

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 fatal and non-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

One of NCIPC's overall goals is to increase the number and diversity of experienced substance use and overdose prevention research professionals available to conduct independent substance use and overdose prevention research. The purpose of this research grant program is to support the development of new researchers who have not yet served as a contact PD/PI on a specified major CDC or NIH research award and address NCIPC's overdose prevention research priorities specifically related to understanding risk and protective factors associated with drug use and overdose, SUD, and stigma.

Contact PD/PI Requirements
Individuals who have a qualifying degree, less than five years of experience as a post-graduate researcher in the substance use and overdose prevention field, full time employment at the applicant organization at the time of the NOFO application due date and have not received current or former funding as contact PD/PI on the specified excluded research project mechanisms are eligible to apply. Excluded CDC or NIH research project award mechanisms are: (R01 or U01), program project (P01), center grant (R49, P50), sub- project of program project (P01), sub-project of center grant (R49, P50), or other major individual career development award (e.g., K01, K07, K08, K22, K23, K25, K76, K99/R00).

Applicant contact PD/PIs who have no prior CDC or NIH funding or who have current or former CDC or NIH funding from the following assistance mechanisms are eligible to apply to this NOFO: CDC or NIH Small Grant (R03), Exploratory/Developmental Grant (R21), Dissertation Award (R36 or R49), SBIR/STTR (R41, R42, R43, or R44), Transition Scholar (K38) awards, National Research Service Awards (F30, F31, F32) and individuals appointed to institutional K (K12, KL2) and T (T32) programs.

The contact PD/PI must meet **all** of the following criteria (see the ***Executive Summary, Eligible Project Directors/Principal Investigators (PDs/PIs)*** section for details):

- Applicant contact PD/PIs must have a qualifying (relevant to the field of study) research or health- professional doctoral or medical degree (such as PhD, ScD, DO, DrPH, MD, DVM, PharmD, DDS, DMD, PsyD, DPT), from an accredited institution of higher learning. Applications that do not demonstrate that the contact PD/PI has a qualifying (relevant to the field of study) research or health professional doctoral or medical degree (such as PhD, ScD, DO, DrPH, MD, DVM, PharmD, DDS, DMD, PsyD, DPT) from an accredited institution of higher learning, as evidenced by their SF-424 Biographical Sketch, will be considered nonresponsive and will not be forwarded for peer review.
- At the time of the NOFO application due date, applicant contact PD/PIs must have less than five years of post-graduate research experience as a researcher in the substance use and overdose prevention field, as documented on the contact PD/PI's SF-424 Biographical Sketch. The 5-year period will be calculated from the completion of the qualifying degree (e.g., a research or health-professional doctoral or medical degree [such as PhD, ScD, DO, DrPH, MD, DVM, PharmD, DDS, DMD, PsyD, DPT] from an accredited institution of higher learning). The Positions and Employment section of SF-424 Biographical Sketch is expected to clearly document all of the contact PD/PI's relevant research experience. **Applications that do not demonstrate that the contact PD/PI has less than five years of post-graduate experience as a researcher in the substance use and overdose prevention field, as evidenced by their SF-424 Biographical Sketch, will be considered nonresponsive to the NOFO and will not be forwarded for peer review.**
- Time periods for significant breaks in employment or employment in areas unrelated to substance use and overdose prevention should be clearly documented. Only the years where any substance use and overdose prevention research was conducted **after** the completion of the qualifying degree will count towards the limit of five years of research experience. Research conducted during undergraduate or pre-graduate training does not count towards the five-year research time – even if the applicant contact PD/PI authored or co-authored a paper relevant to the research prior to completion of the qualifying degree.
- This funding opportunity may support individuals who propose to train in a new field or individuals who have had a hiatus in their research career due to circumstances such as, but not limited to, illness or pressing family circumstances. Applicant contact PD/PIs who are changing their career trajectory to the substance use and overdose prevention field must clearly document the start date of their post-graduate emphasis in substance use and overdose prevention in their SF-424 Biographical Sketch and must clearly demonstrate that they have less than five years of post-graduate experience as a researcher in the substance use and overdose prevention field. **Applications from contact PD/PIs who completed their qualifying degree prior to February 09, 2018 and do not clearly document their relevant post-graduate research experience in substance use and overdose prevention (including breaks in employment or research in other areas) will be considered nonresponsive to the NOFO and will not be forwarded for peer review.**

- Individuals who are identified as the contact PD/PI on a current and/or former CDC or National Institutes of Health (NIH) grant or cooperative agreement award from any of the following excluded independent research assistance mechanisms defined below, as documented by their eRA Commons PD/PI Grant History profile, are NOT eligible for funding under this NOFO. The excluded assistance mechanisms are: CDC or NIH research project (R01 or U01), program project (P01), center grant (R49, P50), sub-project of program project (P01), sub-project of center grant (R49, P50), or other major individual career development award (e.g., K01, K07, K08, K22, K23, K25, K76, K99/R00). **Applications with a contact PD/PI eRA Commons Grant History profile that reflects a current or former award in any of the named excluded independent research assistance mechanisms will be considered nonresponsive and will not be forwarded for peer review.**
- Individuals with current or former funding on the following CDC or NIH training award assistance mechanisms ARE eligible to apply as contact PD/PIs to this NOFO: CDC or NIH Small Grant (R03), Exploratory/Developmental Grant (R21), Dissertation Award (R36 or R49), SBIR/STTR (R41, R42, R43, or R44), Transition Scholar (K38) awards, National Research Service Awards (F30, F31, F32) and individuals appointed to institutional K (K12, KL2) and T (T32) programs.
- At the time of award, the contact PD/PI must be a citizen, a non-citizen national of the United States, or have been lawfully admitted for permanent residence (i.e., possess a currently valid Permanent Resident Card USCIS Form I-551, or other legal verification of such status).
- At the time of the NOFO application due date, the contact PD/PI must have a full-time position at the eligible applicant institution. The application must include a Candidate Eligibility Statement (e.g., an institutional letter of attestation) that is signed by the eligible applicant institution's Authorized Representative that explicitly verifies the contact PD/PI's full time employment status. This should be included in the Institutional Commitment to Candidate's Research Career Development section of the application. The contact PD/PI is not required to have a tenure track appointment at the eligible applicant institution in order to be eligible for this NOFO. **Applications that do not include a Candidate Eligibility Statement that: (1) explicitly verifies the contact PD/PI's full time employment status and (2) is signed by the applicant institution's Authorized Representative will be considered nonresponsive and will not be forwarded for peer review.**
- Applicant contact PD/PIs are required to commit a minimum of 60% of full-time professional effort (i.e., a minimum of 7.3 person-months/year) to their research project and career development for the entirety of the project period. The budget, budget justification, and PHS 308 Career Development Award sections of the application must clearly describe the contact PD/PI's commitment. Applications that do not demonstrate contact PD/PI commitment to a minimum of 60% of full-time professional effort to their research project and career development for the entirety of the project period, as evidenced by the application's SF-424 Research and Related Budget effort of at least 7.3 person-months/year for the contact PD/PI, will be considered nonresponsive and will not be forwarded for peer review. Has a qualifying (relevant to the field of study) research or health- professional doctoral or medical degree (such as PhD, ScD, DO, DrPH, MD, DVM, PharmD, DDS, DMD, PsyD, DPT from an accredited institution of higher

learning, at the time of the NOFO application due date, as evidenced by their SF-424 Biographical Sketch.

Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for HHS/CDC support.

Mentor Requirements
Awards funded under NOFO RFA-CE-24-011 are expected to support the applicant contact PD/PI in conducting relevant and meaningful research in collaboration with an experienced research mentor or mentors that will lead to the applicant's research independence. **Applicant contact PD/PIs are expected to identify a primary mentor who will supervise the proposed career development and research experience funded under this NOFO. The primary mentor must be an active investigator in the area of the substance use or overdose prevention research proposed in the research strategy of the application and must be committed both to the career development of the contact PD/PI and to the direct supervision of the contact PD/PI's research throughout the entirety of the project period.** The mentor should clearly document the availability of sufficient research support and facilities for high-quality research.

Applicant contact PD/PIs are encouraged to identify more than one mentor, i.e., a mentoring team (or advisory committee), if this is deemed advantageous for providing expert advice in all aspects of the research career development program and research proposal. However, **only one individual can be identified as the primary mentor who will coordinate the contact PD/PI's research.** The contact PD/PI must work with the selected mentor(s) in preparing the application. The primary mentor and all members of the mentoring team should have a successful track record of mentoring individuals at the contact PD/PI's career stage. The mentor(s) must demonstrate appropriate expertise, experience, and ability to guide the contact PD/PI in the organization, management and implementation of the proposed research. The application must also include evidence that each member of the mentoring team has the commitment, experience and institutional support to provide both career development and research support to the candidate. The primary mentor and each co-mentor must be clearly identified in the Mentor project role category in the SF-424 Senior/Key Personnel section of the application.

The Plans and Statements of Mentor and Co-Mentor(s) section of the application should provide: 1) detailed information on each mentor's research qualifications and previous experience as a research supervisor; 2) a plan that describes the nature of the supervision and mentoring that will occur during the proposed award period; 3) a plan for career progression for the contact PD/PI to move from the mentored stage of his/her career to independent research investigator status during the project period of the award; 4) a plan for monitoring the contact PD/PI's research, publications, and progression towards independence; and 5) a plan to provide annual evaluations of the contact PD/PI's progress as required in the annual progress report.

The application must describe the relationship between the proposed research and each mentor's current research and research expertise. The mentor should be recognized as an accomplished investigator in the proposed substance use and overdose prevention research area and should have sufficient research support to cover the costs of the proposed research project in excess of the allowable costs of this award. **This award does not include funds for mentor research**

assistance support.

Mentor Letter(s) of Support: Each proposed mentor must provide a distinct Letter of Support in the Plans and Statements of Mentor and Co-Mentor(s) section of the application. Each mentor's Letter of Support must describe in detail the partnership between the contact PD/PI and mentor, the nature and extent of the relationship, and the specific roles and responsibilities of the contact PD/PI and the mentor. Applications that do not include a letter of support from the primary mentor in which the primary mentor commits to supporting the contact PD/PI throughout the entirety of the project period will be considered nonresponsive and will not be forwarded for peer review.

If more than one mentor is proposed, the respective areas of expertise and responsibility of each mentor must be described in the mentor's respective Letter of Support. Co-mentors should clearly describe how they will coordinate the mentoring of the applicant among all mentors. If the primary or co-mentor does not have an appointment at the applicant institution, a statement must be provided describing the mechanism(s) and frequency of communication with the contact PD/PI, including the frequency of face-to-face meetings.

Letters of Support from other participating collaborators or consultants, if applicable, should be included in the Letters of Support from Collaborators, Contributors, and Consultants section of the application. The Letter of Support should clearly document the role and responsibilities of the collaborator/consultant.

The application is expected to describe the institutional support of the applicant's career development plan and proposed research in the Description of Institutional Environment and Institutional Commitment to Candidate's Research Career Development.

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.

Research Strategy Requirements

Under NOFO RFA-CE-24-011, NCIPC intends to support meritorious research projects that aim to better understand and identify risk and protective factors related to any drug use/overdose (e.g., opioids including fentanyl and stimulants, etc.), SUD, and stigma (e.g., how do certain factors impact stigma). Research can focus on the examination of potential moderators or mediators between the relationship between risk and protective factors and drug use and outcomes. Research should be conducted among persons experiencing a disproportionate burden of substance use disorders and overdose, which may include but are not limited, to those people

in certain socio-demographic groups (e.g. non-English speaking populations, tribal populations, rural communities, racial/ethnic minority groups, sexual and gender minority groups), people experiencing social determinants of health (e.g., reduced economic stability; limited educational attainment, access or quality; limited healthcare access or quality including those who have been historically underserved or are uninsured; limited access to substance use treatment; limited health literacy; those in geographically underserved areas), people experiencing certain social or physical health conditions or experiences (e.g., homelessness, a mental health condition, chronic pain, incarceration or recent release from incarceration, a disability, adverse childhood experiences, a history of suicidal ideation or suicide attempt, a history of substance use disorders and/or overdose).

Applicants should propose a research project that addresses at least one aspect of one key research question related to NCIPC's priority to identify risk and protective factors for drug overdose included below. Key research questions include:

1. How do risk and protective factors and trajectories for use, misuse, substance use disorders, and/or overdose differ for prescription opioids, illicit opioids, and other emerging drug threats such as resurging methamphetamine and cocaine?
2. What are risk and protective factors and trajectories related to polydrug use and overdose, including co-use of opioid and non-opioid drugs, with a focus on methamphetamine, cocaine, and benzodiazepines?
3. How do these risk and protective factors and trajectories vary by sociodemographic and geographic characteristics at all levels of the social ecology (described in the Background section of this NOFO)?
4. How do risk and protective factors and trajectories related to drug use, misuse, substance use disorders, and overdose vary among populations experiencing a disproportionate burden of substance use disorders and overdose and intersectional social identities?
5. What are risk and protective factors for early drug use initiation (i.e., particularly during youth and adolescence as described in the Background section of this NOFO) and escalation of use? How do these vary among populations experiencing a disproportionate burden of substance use disorders and overdose?
6. What are the associations among adverse childhood experiences (ACEs), prescription opioid misuse and/or illicit drug use, and chronic pain, as well as moderators of these associations, including social determinants of health?
7. What are norms and behaviors surrounding prescription opioid misuse, illicit drug use, overdose, and related health and behavioral outcomes? What are norms and behaviors among people experiencing a disproportionate burden of substance use disorders and overdose and/or groups that are at greater risk of experiencing adverse outcomes related to substance use due to social determinants of health? What are the best strategies to tailor communication about risk such that messages related to these outcomes resonate with all members of the public, particularly those disproportionately affected by overdose?

The application must clearly state the Overdose Prevention Research Priority question to be addressed by the proposed research in the Specific Aims section of the application. **Applications**

that do not clearly propose to address at least one aspect of one key overdose prevention research priority question in the Specific Aims section of the application will be considered nonresponsive and will not be forwarded for peer review.

The application should clearly describe the proposed research approach including 1) the data source(s) and data access plans, 2) the planned analyses and how the analytic approach is well suited to the data source, 3) the research scope, and 4) the proposed study design. If the proposed research is related to a larger study, clearly describe the relationship between the two efforts.

Analytic plans should anticipate and evaluate the effects of threats to the internal and external validity of the specified research design. Rigorous research designs using quantitative or mixed methods that are appropriate to address the research questions are preferred. Applicants must propose studies that can feasibly be completed within the requested budget and project period.

Proposed research projects could include an expansion of a current investigation in which the researcher is involved or analyses of secondary data. Research plans must describe the research question(s) of interest and the proposed hypothesis for the study, the proposed aims and objectives, and research study design to test the hypothesis, as well as the expected outcomes to be evaluated. The use of any secondary data, proposed analytic strategy, and the estimated sample size and power for analysis for outcomes of interest must be clearly specified.

The budget, budget justification, and PHS 308 Career Development Award sections of the application must clearly describe the contact PD/PI's commitment to dedicating at least 7.3 person-months per year (60% effort) to the proposed research and career development and training activities for the entirety of the project period. The proposed activities should demonstrate a coordinated approach to prepare for conducting future independent research in the field of substance use and overdose prevention. **Applications that do not demonstrate contact PD/PI commitment to a minimum of 60% of full-time professional effort to their research project and career development throughout the entirety of the project period, as evidenced by the application's SF-424 Research and Related Budget effort of at least 7.3 person-months/year for the contact PD/PI, 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 will be considered nonresponsive and will not be forwarded for peer review.**

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

Applications must be responsive to NOFO RFA-CE-24-011 in order 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 all responsiveness criteria listed in *Section III. Eligibility Information 5. Responsiveness*.

Objectives/Outcomes

This funding would support research that aims to better understand and identify risk and protective factors related to any drug use/overdose (e.g., opioids including fentanyl and stimulants, etc.), SUDs, and stigma (e.g., how do certain factors impact stigma). Research can focus on the examination of potential moderators or mediators between the relationship between risk and protective factors and drug use and outcomes. Research should be conducted among persons experiencing a disproportionate burden of substance use disorders and overdose, which may include but are not limited, to those people in certain socio-demographic groups (e.g. non-English speaking populations, tribal populations, rural communities, racial/ethnic minority groups, sexual and gender minority groups), people experiencing certain social determinants of health (e.g., reduced economic stability; limited educational attainment, access or quality; limited healthcare access or quality including those who have been historically underserved or are uninsured; limited access to substance use treatment; limited health literacy; those in geographically underserved areas), people experiencing social or physical health conditions or experiences (e.g., homelessness, a mental health condition, chronic pain, incarceration or recent release from incarceration, a disability, adverse childhood experiences, a history of suicidal ideation or suicide attempt, a history of substance use disorders and/or overdose).

Applicants should propose a research project that addresses **at least one aspect of one key research question related to NCIPC's priority to identify risk and protective factors for drug overdose included below**. Key research questions include:

1. How do risk and protective factors and trajectories for use, misuse, substance use disorders, and/or overdose differ for prescription opioids, illicit opioids, and other emerging drug threats such as resurging methamphetamine and cocaine?
2. What are risk and protective factors and trajectories related to polydrug use and overdose, including co-use of opioid and non-opioid drugs, with a focus on methamphetamine, cocaine, and benzodiazepines?
3. How do these risk and protective factors and trajectories vary by sociodemographic and geographic characteristics at all levels of the social ecology (described in the Background section of this NOFO)?
4. How do risk and protective factors and trajectories related to drug use, misuse, substance use disorders, and overdose vary among populations experiencing a disproportionate burden of substance use disorders and overdose and intersectional social identities?
5. What are risk and protective factors for early drug use initiation (i.e., particularly during youth and adolescence as described in the Background section of this NOFO) and escalation of use? How do these vary among populations experiencing a disproportionate burden of substance use disorders and overdose?
6. What are the associations among adverse childhood experiences (ACEs), prescription opioid misuse and/or illicit drug use, and chronic pain, as well as moderators of these associations, including social determinants of health?
7. What are norms and behaviors surrounding prescription opioid misuse, illicit drug use, overdose, and related health and behavioral outcomes? What are norms and behaviors among people experiencing a disproportionate burden of substance use disorders and overdose and/or groups that are at greater risk of experiencing adverse outcomes related to substance use due to social determinants of health? What are the best strategies to

tailor communication about risk such that messages related to these outcomes resonate with all members of the public, particularly those disproportionately affected by overdose?

Research Outcomes

Applications must provide, in the Research Strategy (Significance), a description of the research intent and the expected research outcomes. Applications must assess key risk or protective factors related to at least one outcome including drug use/overdose (e.g., opioids including fentanyl and stimulants, etc.), SUD, and stigma (e.g., how do certain factors impact stigma). NCIPC is specifically interested in funding applications focused on identifying risk and protective factors among certain populations, such as those that have been disproportionately impacted by overdose (including but not limited to those experiencing reduced economic stability; people experiencing homelessness, a mental health condition, chronic pain, incarceration or recent release from incarceration, limited educational attainment, access or quality, limited healthcare access or quality, limited access to substance use treatment or limited health literacy; people with disabilities; people from non-English speaking populations, tribal populations, rural communities and other geographically underserved areas, racial/ethnic minority groups, sexual and gender minority groups) and/or experienced adverse childhood experiences, suicidal ideation or suicide attempts, chronic pain, or pain for which individuals received treatment with prescription opioid medications, as these factors may increase risk for drug use.

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 three-year project period. Applications should clearly describe and justify the proposed sampling methods, sample size, power estimates, and data collection methods for the primary outcome(s) 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 prior to or in the context of the evaluation are potential sources. Appropriate data sources will vary by the proposed research approach and outcome measures. The outcome(s) should be measured at the level consistent with the research focus (e.g., federal, state, local, or organizational), the population of interest and the data sources available or collected for the purposes of this project (e.g., administrative, survey, surveillance, hospital or emergency departments, detention facilities, etc.).

Research Products

The impact of a research investment can be measured by the research products. Examples include publications, reports, conference proceedings, databases, tools, methods, guidelines, recommendations, training and education materials, and investigator career development. The research products represent the impact of the research on goals envisioned for the project. The products can include identification of risk and protective factors or evidence for a new prevention strategy. Applications are encouraged to develop a translation plan for the development and dissemination of research products developed as a result funding under this

NOFO.

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

Target Population
Populations of interest include those that have been disproportionately impacted by overdose (including but not limited to those experiencing reduced economic stability; people experiencing homelessness, a mental health condition, chronic pain, incarceration or recent release from incarceration, limited educational attainment, access or quality, limited healthcare access or quality, limited access to substance use treatment or limited health literacy; people with disabilities; people from non-English speaking populations, tribal populations, rural communities and other geographically underserved areas, racial/ethnic minority groups, sexual and gender minority groups) and/or experienced adverse childhood experiences, suicidal ideation or suicide attempts, chronic pain, or pain for which individuals received treatment with prescription opioid medications, as these factors may increase risk for drug use and overdose.

Collaboration/Partnerships
It is required that, for all applications, the majority (60% or greater) of the proposed research work plan, as evidenced by the application's SF-424 Research and Related Budget, will be directly carried out by the applicant organization 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.

It is required that, for all applications, the contact PD/PI commit a minimum of 60% of full-time professional effort (i.e., a minimum of 7.3 person-months/year) to their research project and career development throughout the entirety of the project period. **Applications that do not demonstrate contact PD/PI commitment to a minimum of 60% of full-time professional effort to their research project and career development throughout the entirety of the project period, as evidenced by the application's SF-424 Research and Related Budget effort of at least 7.3 person-months/year for the contact PD/PI, will be considered nonresponsive and will not be forwarded for peer review.**

Partnerships with state and local Departments of Public Health, health systems, hospitals, law enforcement, municipalities or any other entities are encouraged to support the conduct of the proposed research. Partnerships with entities that hold the existing data or data sources necessary to answer any proposed questions of interest should be demonstrated by letters of agreement or memorandums of understanding. The role of the partners, and their level of involvement and commitment to provide the data, support, etc., required for the study should be clearly specified. The letters documenting any partnerships required for the conduct of the study should be included in the Letters of Support section of the grant application.

Applications will be evaluated during peer review on the extent to which Letters of Support, Memoranda of Understanding, and Data Sharing Agreements, as applicable to the application's research plan, demonstrate the necessary collaborations and commitment from research partners. Therefore, 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.

Evaluation/Performance Measurement

Applicants must evaluate performance during each stage of the research process, including data extraction, retention, and data analysis. Successful applicants will be expected to conduct periodic performance monitoring to ensure that each stage is progressing appropriately and in a timely manner, and that research activities are of high scientific quality.

The application is expected to include a clear description of relevant performance measures for each stage of the research project. Comparison of actual progress to the performance measures is expected to document whether research is progressing appropriately and in a timely manner, and whether the research activities are of high scientific quality.

Translation Plan

Investigators are expected to develop a data dissemination plan for the research findings. The plan should describe how the results will be disseminated to achieve the greatest impact. Presentation and publication of findings in peer-reviewed journals is encouraged.

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

3. Funding Strategy

N/A

Section II. Award Information

Funding Instrument Type:

G (Grant)

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

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

Estimated Total Funding:
$1,350,000
NCIPC intends to fund up to three (3) awards. The estimated total funding (direct and indirect costs) for the first budget period for three (3) awards is $450,000. The estimated total funding (direct and indirect costs), for three (3) awards, for the 3-year project period is $1,350,000. Indirect costs 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.

Anticipated Number of Awards:
3
Awards issued under this NOFO are contingent on the availability of funds and submission of a sufficient number of meritorious applications.

Award Ceiling:
$150,000
Per Budget Period

Award Floor:
$0
Per Budget Period

Total Period of Performance Length:
3 year(s)

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

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

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:
00 (State governments)

01 (County governments)

02 (City or township governments)

04 (Special district governments)

05 (Independent school districts)

06 (Public and State controlled institutions of higher education)

07 (Native American tribal governments (Federally recognized))

08 (Public housing authorities/Indian housing authorities)

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

12 (Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education)

13 (Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education)

20 (Private institutions of higher education)

22 (For profit organizations other than small businesses)

23 (Small businesses)

25 (Others (see text field entitled "Additional Information on Eligibility" for clarification))

99 (Unrestricted (i.e., open to any type of entity above), subject to any clarification in text field entitled "Additional Information on Eligibility")

Additional Eligibility Category:

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

Hispanic-serving Institutions

Historically Black Colleges and Universities (HBCUs)

Tribally Controlled Colleges and Universities (TCCUs)

Alaska Native and Native Hawaiian Serving Institutions

Nonprofits (Other than Institutions of Higher Education):

Nonprofits (Other than Institutions of Higher Education)

Other:

Faith-based or Community-based Organizations

Regional Organizations

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

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. The proposed total costs for the first 12-month budget period does not exceed $150,000 in total costs (direct and indirect).
    a. The proposed total costs for the first 12-month budget period cannot exceed $150,000 in total costs (direct and indirect). **Applications whose proposed total costs for the first 12-month budget period exceed $150,000 in total costs, as evidenced by SF424 (R&R) Budget Period 1 Section K, Total Costs and Fee, will be considered nonresponsive and will not be forwarded for peer review.**

2. The proposed research proposes to address at least one aspect of one of the key overdose prevention research priority questions.
    a. **Applications that do not clearly propose to address at least one aspect of one key overdose prevention research priority question in the Specific Aims section of the application will be considered nonresponsive and will not be forwarded for peer review.**

3. Application demonstrates that the contact PD/PI has a qualifying (relevant to the field of study) research or health- professional doctoral or medical degree (such as PhD, ScD, DO, DrPH, MD, DVM, PharmD, DDS, DMD, PsyD, DPT) from an accredited institution of higher learning.
    a. The SF-424 Biographical Sketch must demonstrate that the contact PD/PI has a qualifying (relevant to the field of study) research or health- professional doctoral or medical degree (such as PhD, ScD, DO, DrPH, MD, DVM, PharmD, DDS, DMD, PsyD, DPT from an accredited institution of higher learning, at the time of the NOFO application due date. **Applications that do not demonstrate that the contact PD/PI has a qualifying (relevant to the field of study) research or health- professional doctoral or medical degree (**such as PhD, ScD, DO, DrPH, MD, DVM, PharmD, DDS, DMD, PsyD, DPT)) **from an accredited institution of higher learning, as evidenced by their SF-424 Biographical Sketch, will be considered nonresponsive and will not be forwarded for peer review.**

4. Application demonstrates that the contact PD/PI has less than five years of post-graduate experience as a researcher in the substance use and overdose prevention field.
    a. The SF-424 Biographical Sketch must demonstrate that, at the time of the NOFO application due date, the contact PD/PI has less than five years of post-graduate experience as a researcher in the substance use and overdose prevention field. The Positions and Employment section of SF-424 Biographical Sketch must clearly document all of the contact PD/PI's relevant research experience. **Applications that do not demonstrate that the contact PD/PI has less than five years of post-graduate experience as a researcher in the substance use and overdose prevention field, as evidenced by their SF-424 Biographical Sketch, will be considered nonresponsive and will not be forwarded for peer review.**

5. Application documents the contact PD/PI has relevant post-graduate research experience in substance use and overdose prevention (including breaks in employment or research in other areas).
    a. Time periods for significant breaks in post-graduate employment or employment in areas unrelated to substance use and overdose prevention should be clearly documented. Only the years where any substance use and overdose prevention research was conducted after the completion of the qualifying degree will count towards the limit of five years of research experience. Research conducted during undergraduate or pre-graduate training does not count towards the five-year research time. **Applications from contact PD/PIs who do not clearly document their relevant post-graduate research experience in substance use and overdose prevention (including breaks in employment or research in other areas), as evidenced by their SF-424 Biographical Sketch, will be considered nonresponsive and will not be forwarded for peer review.**

6. Contact PD/PI's eRA Commons Grant History profile demonstrates no current or former funding as a contact PD/PI on an excluded independent research mechanism.
    a. The contact PD/PI's NIH eRA Commons Grant History profile must demonstrate no current or former funding as a contact PD/PI on an excluded independent research mechanism: a CDC or NIH research project (R01 or U01), program project (P01), center grant (R49, P50), sub-project of program project (P01), sub-

project of center grant (R49, P50), or other major individual career development award (e.g., K01, K07, K08, K22, K23, K25, K76, K99/R00). **Applications with a contact PD/PI eRA Commons Grant History profile that reflects a current or former award in any of the above named excluded independent research mechanisms will be considered nonresponsive and will not be forwarded for peer review.**

7. Application demonstrates contact PD/PI's commitment to a minimum of 60% of full-time professional effort to their research project and career development throughout the entirety of the project period.
    a. The budget, budget justification, and PHS 308 Career Development Award sections of the application must clearly describe the contact PD/PI's commitment to dedicating at least 7.3 person-months/year (60% effort) to the proposed research and career development and training activities throughout the entirety of the project period. **Applications that do not demonstrate contact PD/PI commitment to a minimum of 60% of full-time professional effort to their research project and career development throughout the entirety of the project period, as evidenced by the application's SF-424 Research and Related Budget effort of at least 7.3 person-months/year for the contact PD/PI, will be considered nonresponsive and will not be forwarded for peer review.**

8. Application includes a Letter of Support from the primary mentor in which the primary mentor commits to supporting the contact PD/PI throughout the entirety of the project period.
    a. The primary and each co-mentor must provide a distinct Letter of Support in the Plans and Statements of Mentor and Co-Mentor(s) section of the application. **Applications that do not include a Letter of Support from the primary mentor in which the primary mentor commits to supporting the contact PD/PI throughout the entirety of the project period will be considered nonresponsive and will not be forwarded for peer review.**

9. Application includes a Candidate Eligibility Statement that: (1) explicitly verifies the contact PD/PI's full time employment status and (2) is signed by the applicant institution's Authorized Representative.
    a. At the time of the NOFO application due date, the contact PD/PI must have a full-time position at the eligible applicant institution. The application must include a Candidate Eligibility Statement (e.g., an institutional letter of attestation) that is signed by the eligible applicant institution's Authorized Representative that explicitly verifies the contact PD/PI's full time employment status. This should be included in the Institutional Commitment to Candidate's Research Career Development section of the application. **Applications that do not include a Candidate Eligibility Statement that: (1) explicitly verifies the contact PD/PI's full time employment status and (2) is signed by the applicant institution's Authorized Representative will be considered nonresponsive and will not be forwarded for peer review.**

6. Required Registrations

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

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

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

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

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

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

All applicant organizations **must obtain** a Unique Entity Identifier (UEI) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The UEI number is a twelve-digit number assigned by SAM.gov. An AOR should be consulted to determine the appropriate number. If the organization does not have a UEI number, an AOR

should register through SAM.gov. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a UEI number.

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

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

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

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

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/institutions may submit more than one application, provided that each application is scientifically distinct. However, applicant institutions can submit only one grant application with the same contact PD/PI in response to this NOFO. Additionally, applicant institutions can submit only one grant application with the same individual designated in a Mentor project role in the application in response to this NOFO. Only one application per contact PD/PI will be reviewed or funded under this announcement; only one application per Mentor will be reviewed or funded under this announcement. If two or more applications from the same contact PD/PI are received, the only application that will be submitted for review will be the last

application received based on the document's time and date stamp in Grants.gov (http://www.grants.gov). If two or more applications identifying same Mentor are received, the only application that will be submitted for review will be the last application received based on the document's time and date stamp in Grants.gov (http://www.grants.gov). The contact PD/PI and primary Mentor may be employed by the applicant institution or be employed at different institutions.

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.

Contact PD/PIs submitting applications to this NOFO and any other CDC/ATSDR NOFO will not be funded under more than one NOFO.

Section IV. Application and Submission Information

1. Address to Request Application Package

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

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

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

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

2. Content and Form of Application Submission

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

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

It is critical that applicants follow the instructions in the SF-424 (R&R) Application Guide How to Apply - Application Guide except where instructed in this Notice of Funding Opportunity to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review. The package associated with this NOFO includes all applicable mandatory and optional forms. Please note that some forms marked optional in the application package are required for submission of applications for this NOFO. Follow the instructions in the SF-424 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 assists NCIPC staff in planning for the scientific and technical merit peer review. By the date listed in *Part 1. Overview Information*, eligible applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed research
- Description (one-two paragraphs) of the proposed research including a description of the proposed research objectives
- Name, address, and telephone number of the contact PD/PI
- Name, address, and telephone number of the Primary Mentor
- Name(s) of all other Senior/Key Personnel
- Name(s) of participating institutions
- Number and title of this funding opportunity

The letter of intent should be sent electronically to:
Aisha L. Wilkes, MPH
Scientific Review Official
National Center for Injury Prevention and Control (NCIPC)
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.

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 5 appendices of supporting materials for the Research Plan narrative described below in "7. Page Limitations" will also count towards the 10 PDF documents allowed in the appendix and the page limit allowed in the appendix. The appendix may not exceed 25 pages.

For this NOFO, the page limit for Candidate Information and Goals for Career Development and Research Strategy components (within the PHS 398 Career Development Award Supplemental Form) is 12 pages total for both attachments.

For all other components of the applications to this NOFO follow the page limitations specified in the General Instructions for NIH and Other PHS Agencies, SF424 (R&R) Application Packages (https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf) for the Career Development (K01) applications.

7. Page Limitations

All page limitations described in this individual NOFO must be followed. For this specific NOFO, the Research Strategy component of the Research Plan narrative is limited to 12 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 5 PDF files with a maximum of 25 pages for all appendices. Pages that exceed page limits described in this NOFO will be removed and not forwarded for peer review, potentially affecting an application's score.

8. Format for Attachments

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

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

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.

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 personal identifiable information from loss and/or misuse. The application is expected to identify each performance site that will be conducting human subjects research and include the FWA number for the applicant institution and each performance site. Research conducted with more than one institution will be expected to use a single Institutional Review Board (sIRB) to conduct the ethical review required by HHS regulations.

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 access/management plan that meets the requirements of AR-25 using their own template. Applicants funded under this NOFO will be required to use NCIPC's Data Management Plan Template, OMB NO: 0920-1301 to make revisions to the DMP as required during the award's project period.

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."

The budget included with the application must take into account the following funding restrictions associated with this NOFO:

- Grant funds will not be made available to support the provision of direct care.
- Grant funds will not be made available for mentor or research assistance support.
- Eligible applicants may enter into contracts, including consortia agreements, as necessary to meet the requirements of this program and strengthen the overall application.
- Allowable costs include partial salary and tuition support for the applicant contact PD/PI; direct research project expenses such as trainee stipends, interviewer costs, data processing, participant incentives, statistical consultation services, and supplies. Travel to one scientific meeting, if adequately justified, is allowable.
- Funds for tuition support are limited to no more than 20% of the overall award and their use must be generally related to the content and methods of the proposed research.
- Applicants should include travel costs for one, two-day trip to CDC in Atlanta per budget year to present research findings.
- Indirect costs for this trainee-related grant are limited to eight (8) percent of the Modified Total Direct Cost.
- 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.

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?

This NOFO is for a K01 Training Grant; the review criteria for the applications submitted to this NOFO are described under the following scored criteria headings: **Contact PD/PI (i.e. Candidate)**, **Career Development Plan/Career Goals and Objectives**, **Research Plan, Mentor(s)**, **Co-Mentor(s), Consultant(s), Collaborator(s)**, and **Environment and Institutional Commitment to Contact PD/PI**. Please review the guidance under these sections described below for complete details on the criteria to be used to evaluate all applications submitted to this NOFO.

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?

This NOFO is for a K01 Training Grant; the review criteria for the applications submitted to this NOFO are described under the following scored criteria headings: **Contact PD/PI (i.e. Candidate)**, **Career Development Plan/Career Goals and Objectives**, **Research Plan, Mentor(s)**, **Co-Mentor(s), Consultant(s), Collaborator(s)**, and **Environment and Institutional Commitment to Contact PD/PI**. Please review the guidance under these sections described below for complete details on the criteria to be used to evaluate all applications submitted to this NOFO.

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?

This NOFO is for a K01 Training Grant; the review criteria for the applications submitted to this NOFO are described under the following scored criteria headings: **Contact PD/PI (i.e. Candidate)**, **Career Development Plan/Career Goals and Objectives**, **Research Plan, Mentor(s)**, **Co-Mentor(s), Consultant(s), Collaborator(s)**, and **Environment and Institutional Commitment to Contact PD/PI**. Please review the guidance under these sections described below for complete details on the criteria to be used to evaluate all applications submitted to this NOFO.

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?

This NOFO is for a K01 Training Grant; the review criteria for the applications submitted to this NOFO are described under the following scored criteria headings: **Contact PD/PI (i.e. Candidate)**, **Career Development Plan/Career Goals and Objectives**, **Research Plan, Mentor(s)**, **Co-Mentor(s), Consultant(s), Collaborator(s)**, and **Environment and Institutional Commitment to Contact PD/PI**. Please review the guidance under these sections described below for complete details on the criteria to be used to evaluate all applications submitted to this NOFO.

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?

This NOFO is for a K01 Training Grant; the review criteria for the applications submitted to this NOFO are described under the following scored criteria headings: **Contact PD/PI (i.e. Candidate)**, **Career Development Plan/Career Goals and Objectives**, **Research Plan, Mentor(s)**, **Co-Mentor(s), Consultant(s), Collaborator(s)**, and **Environment and Institutional Commitment to Contact PD/PI**. Please review the guidance under these sections described below for complete details on the criteria to be used to evaluate all applications submitted to this NOFO.

Contact PD/PI (i.e. Candidate

- To what extent is the PD/PI well suited to both lead the proposed research and complete the proposed career development activities?
- To what extent has the PD/PI demonstrated the appropriate experience, training, skills, leadership, and management abilities to successfully conduct the proposed research?
- To what extent are the research and career development plans appropriate to the PD/PI's stage of research development and appropriate as a vehicle for developing the research skills described in the career development plan?

Career Development Plan/Career Goals and Objectives

- If successfully implemented, to what extent would the combined program of career development and research experience lead to significant growth and development of the PD/PI's research skill and leadership as an independent scientific investigator?
- To what extent are the content, scope, phasing, and duration of the career development plan appropriate when considered in the context of prior training/research experience and the stated training and research objectives for achieving research independence?
- To what extent is the description of the quality and extent of the mentor's proposed role in providing guidance and advice to the PD/PI adequate?
- Is there an adequate description of the elements of the research career development activities?

Research Plan

- To what extent is the research likely to impact the field of overdose prevention?
- To what extent is the research likely to contribute to improvements in populations who may be at elevated risk for drug use and overdose (e.g., those experiencing reduced economic stability; people experiencing homelessness, a mental health condition, chronic pain, incarceration or recent release from incarceration, limited educational attainment, access or quality, limited healthcare access or quality, limited access to substance use treatment or limited health literacy; people with disabilities; people from non-English speaking populations, tribal populations, rural communities and other geographically underserved areas, racial/ethnic minority groups, sexual and gender minority groups).
- To what extent does the application propose a sound research design?
- Is the conceptual framework, design, methods, sample size and analyses adequately developed, well- integrated, and appropriate to the Specific Aims of the project?
- To what extent is the proposal likely to be completed within the 3-year project period? Is the workplan and timeline appropriate to meet the Specific Aims of the project?

Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s)

- To what extent does the mentor have the appropriate experience, qualifications, and background to provide scientific and technical guidance on the development, conduct, and analysis of the proposed research?
- Is there an adequate description of the quality and extent of each mentors' proposed role in providing guidance and advice to the PD/PI?
- Are there adequate plans for monitoring and evaluating the career development candidate's progress toward independence?

Environment and Institutional Commitment to Contact PD/PI

- To what extent does the application demonstrate that the institution intends to support the PD/PI's development as an independent investigator?
- To what extent does the application demonstrate sufficient institutional support for both the career development and research plans?
- To what extent do the Letters of Support, Memoranda of Understanding, and Data Sharing Agreements, as applicable to the application's research plan, demonstrate the necessary collaborations and commitment from research partners?

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.

Applications that meet scientific and technical merit as determined by scientific peer review may also undergo consideration at the second level of review for:

- Relevance to NCIPC Research Priorities.
- The significance of the proposed activities in relation to the priorities and objectives stated in *Section I. Funding Opportunity Description 1. Background and Purpose Healthy People 2030 and other National Strategic Priorities,* as evidenced by the Research Strategy section of the application's research plan.
- Consideration for applications proposing research focused on identifying risk and protective factors among underserved populations that have been disproportionately impacted by overdose, as evidenced by the Research Strategy section of the application's research plan, to broaden 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 the Research Strategy of their application.
- Consideration for applications in which the contact eligible PD/PI is from an underrepresented population, for instance, as defined by the NIH Diversity Statement, or has a demonstrated record of, or commitment to, serving underrepresented populations,

and as verified by the applicant institution, to broaden distribution of awards in order to support career development in overdose prevention research for PD/PIs. If the applicant institution wishes to be considered for this secondary review consideration, the applicant institution can include a Candidate Eligibility Statement which attests to the considerations discussed above and which is signed by the Authorized Representative named on the SF-424 (R&R) application e-submission Face Page. The Candidate Eligibility Statement should be included as part of the application page in the appendix. An applicant institution is not required to submit a Candidate Eligibility Statement in order to be considered for funding under this announcement.

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-17: Peer and Technical Reviews of Final Reports of Health Studies – ATSDR
AR-21: Small, Minority, And Women-owned Business
AR-22: Research Integrity
AR-24: Health Insurance Portability and Accountability Act Requirements
AR-25: Data Management and Access
AR-26: National Historic Preservation Act of 1966
AR-28: Inclusion of Persons Under the Age of 21 in Research
AR-29: Compliance with EO13513, "Federal Leadership on Reducing Text Messaging while Driving", October 1, 2009
AR-30: Information Letter 10-006, - Compliance with Section 508 of the Rehabilitation Act of 1973
AR-31: Research Definition
AR-32: Appropriations Act, General Provisions
AR-33: United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern
AR-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

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.

Should you successfully compete for an award, recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy).This includes taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/civil-rights/forindividuals/nondiscrimination/index.html.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting your legal obligation to take reasonable

steps to ensure meaningful access to your programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheetguidance/index.html and https://www.lep.gov/.

- For information on your specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and taking appropriate steps to provide effective communication, see https://www.hhs.gov/civil-rights/for-individuals/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment, see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html.
- For guidance on administering your project in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

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 SF-424 Research Plan at the time of application.

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

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

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

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.

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:

Annual Report Requirements

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

- A description of the completion status of each Specific Aim and/or research objective or milestone for the budget period.
- A complete list of the publications planned or completed to date - including status (e.g., published, 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 Data Management Plan 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

Joyce Dieterly, MPH
National Center for Injury Prevention and Control (NCIPC)
Telephone: 404-718-5301
Email: ncipc_erpo@cdc.gov

Peer Review Contact

Aisha Wilkes, MPH
National Center for Injury Prevention and Control (NCIPC)
Email: awilkes@cdc.gov

Financial/Grant Management Contact(s)

Angie Willard
Grants Management Specialist
CDC Office of Grants Services
Email: awillard@cdc.gov

Manal Ali
Grants Management Specialist
CDC Office of Grants Services
Email: mali@cdc.gov

Section VIII. Other Information

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

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

Authority and Regulations

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

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

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

Application Submission Process

Applications must be successfully submitted and complete all validation actions prior to 11:59PM ET of the application due date for this NOFO. Applicants are encouraged to submit the application in ASSIST three (3) business days before the stated due date to provide sufficient time to correct any errors. If post-submission errors are identified during the validation process, the errors must be corrected and the application must be re-submitted in ASSIST prior to 11:59PM ET of the application due date. HHS/CDC grant submission procedures do not provide a grace period beyond the grant application due date time to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems.

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

General Information

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

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

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