RFA CE-25-149 Questions and Answers

1. **How can I obtain the full announcement for this NOFO?**

More information about the Notice of Funding Opportunity (NOFO) can be found here on grants.gov under the opportunity number RFA-CE-25-149. The full announcement can be found under section "Related Documents" which provides additional guidance for applying and navigating the application process. Application submissions can be accessed by pressing the red buttons to apply and/or subscribe for updates and research application portal.

2. **Are my aims appropriate for the purpose of this Notice of Funding Opportunity (NOFO)?**

Thank you for your interest in RFA-CE-25-149. Please note that for this NOFO, "research should rigorously evaluate either primary or secondary prevention strategies for reducing rates of nonfatal overdose, fatal overdose, and/or substance use disorders involving federally illegal drugs or misuse of prescription medications, drug use, or initiation of drug use, particularly among youth." (NOFO Summary Page 5). We are not able to provide specific guidance or information on the appropriateness of your aims to this NOFO. It is incumbent on the applicant to demonstrate that the proposal meets the NOFO intent and objectives.

We can, though, point you to sections of the NOFO that can assist in developing your application.

- To get a detailed description of the intent of this NOFO, please especially review **Step I: Review the Opportunity > Program description > Background and purpose** starting on page 11
- We encourage applicants to review **Step I: Review the Opportunity > Eligibility > Other required responsiveness factors** on page 8 and **Step IV: Learn About Review and Award > Application review > Initial review** on page 36 for details on what constitutes a responsive application.
- In addition, please review **Step I: Review the Opportunity > Approach** beginning on page 15 and **Step IV: Learn About Review and Award > Application review > Scientific Merit Criteria** beginning at page 36, these sections describe the expectations for the research and the criteria the Peer Review panel will use to determine the scientific merit of each proposal.

3. **"Law enforcement" is identified as non-responsive - does research with staff in carceral settings or research with OHRP-defined "prisoners" fall under this? And relatedly, this sounds like a targeted NOFO for people residing in the community. Incarcerated individuals are at great risk of OD but are not actively using drugs**.

We are not able to provide specific guidance or information on the appropriateness of your aims/project proposal/idea to the NOFO. The proposed research is expected to expand the evidence base for primary and secondary prevention of drug use outcomes, making it essential that proposed approaches meet the criteria for outcome measures and research designs. It is incumbent on the applicant to demonstrate that the proposal meets the NOFO intent and objectives (see the above

sections listed in ***Question 1*** to assist with the development of your application). We do however have a section in **Step I: Review the Opportunity > Approach> Focus populations** on page 19 that does detail how focus populations will be considered responsive for this NOFO, which may help determine whether your population of focus meets the requirements of this opportunity.

Additionally, it is important to note that "the proposed research must not focus on law enforcement strategies **without inclusion of a strong public health component**, as a primary research aim. Applications that propose to focus on law enforcement strategies without a public health component or focus, as evidenced in the Research Strategy section of the application's research plan, will be considered nonresponsive and will not be forwarded for peer review." Please see **Step I: Review the Opportunity > Eligibility > Other required responsiveness factors** on page 9 for more information.

4. Are indirect costs included in the budget cap for this mechanism?

The budget cap includes both indirect and direct costs. Please see **Step 3: Prepare Your Application > Application contents and format > Budget form** on page 33 more for information on how to develop your budget.

5. Is the budget cap for one year or for the entire performance period?

Both budget caps (Option A: $350,000; Option B: $700,000) are per year (per 12-month budget period). Please see **Step 1: Review the Opportunity > Basic information > Funding details** starting on page 5 of the NOFO for more information.

6. When the NOFO indicates that it will not fund clinical care, does that include any salary support for program staff, particularly those who are not reimbursable by insurance (e.g., peer recovery specialists)?

The primary purpose of this NOFO should rigorously evaluate either primary or secondary prevention strategies for reducing rates of nonfatal overdose, fatal overdose, and/or substance use disorders involving federally illegal drugs or misuse of prescription medications, drug use, or initiation of drug use, particularly among youth. It may be allowable for program staff to be included in the budget with a budget justification. It is incumbent for the applicant to justify how program staff (e.g., peer recovery specialists) will contribute to the NOFO intent and objectives.

7. When logging on to the grant submission platform I am having trouble to apply for said grant

We are sorry to hear that you are encountering technical issues when applying! We do not manage the application submission platforms, and thus if the issue has occurred on eRA Commons ASSIST or grants.gov we encourage you to reach out to the following contacts:

- NIH eRA Service desk at: Toll-free: 1-866-504-9552; Phone: 301-402-7469 | https://www.era.nih.gov/need-help| Hours: Mon-Fri, 7 a.m. to 8 p.m. Eastern Time.
- Grants.gov Contact Center at: Toll-free: 1-800-518-4726 | https://www.grants.gov/support| Email: support@grants.gov

8. Does "implementation" of prevention activities include delivery of intervention activities?

Correct, the implementation of prevention activities includes delivery of intervention activities.

9. In funding option B, it appears that there is a portion of the grant activities that includes "development." Does "development" include creating and/or piloting an intervention?

For Funding option B, development includes creating and piloting an intervention. Also included in Funding option B are implementation and evaluation (pg 6 of the NOFO). Please also see the response to question 10.

10. Is there guidance regarding how extensive development must be to be considered responsive? Is CDC looking for interventions that are developed from scratch or can they also be evidence-based practices that are being refined and adapted to go beyond what the intervention has initially been designed for (e.g., to larger audiences, different drugs, etc.)? Are there parameters in how development is defined?

As a note, development and corresponding additional two years of funding are the features that separate **Funding Option A** (in which strategies need to be in a place that is ready for implementation and rigorous evaluation) and **Funding Option B** (which provides 2 years for the development of prevention activities). Ultimately, development is not defined to allow for nuance on what development looks like in each application and it is up to the applicant to determine the appropriateness of their proposal to the funding options as well as to the objectives and intent of the NOFO. Please see **Step I: Review the Opportunity > Eligibility > Other required responsiveness factors** starting on page 8 and **Step IV: Learn About Review and Award > Application review** starting on page 36 of the NOFO to review what would be considered a responsive application.

11. Can funding Option A be an evaluation of an intervention that has already started being implemented (e.g., including exposure/outcome data collected in the last 2 years) or does it only include prospective data with new implementation of an intervention after the award?

Funding Option A may support implementation and rigorous evaluation of prevention activities. Funding Option B supports **development**, implementation, and rigorous evaluation of prevention activities (See page 6 of the NOFO).

12. Would an application focusing on cannabis be considered responsive?

For this NOFO (pg 16), drug use is defined as use of federally illegal drugs (e.g., heroin, cocaine, methamphetamine, psilocybin, **cannabis**) or misuse of prescription medications (i.e., use in any way not directed by a doctor, including use of someone else's prescription; use in greater amounts, more

often, or longer than recommended; or use in any other way not directed by a doctor). Please see **Step I: Review the Opportunity > Eligibility > Other required responsiveness factors** starting on page 8 and **Step IV: Learn About Review and Award > Application review** starting on page 36 of the NOFO to review what would be considered a responsive application.

13. Would an applicable focusing on screening and service utilization be considered responsive, including drug use and SUD as outcomes, even if it does not include overdose as an outcome?

Drug use and substance use disorder are included in the two required outcomes that the research should rigorously evaluate. Applications should include at least two outcomes from this list (NOFO pg 17):

- Nonfatal overdose
- Fatal overdose
- Substance use disorders involving federally illegal drugs or misuse of prescription medications
- Drug use
- Initiation of drug use, particularly in youth

14. Can you talk a little more about the definition of secondary prevention that you are using for this NOFO? For example, would evaluation of a strategy to improve retention in treatment for someone who has been identified as having an SUD fall within the category of secondary prevention?

As stated in **Step I: Review the Opportunity > Approach > Strategy focus: Primary or secondary prevention** on page 16, "for this NOFO, secondary prevention strategies should include linkage to and retention in care for ***people already engaged in drug use*** who are experiencing disproportionate burden of drug overdose or who are at greater risk of experiencing adverse drug use outcomes related to social determinants of health, like people who experience nonfatal overdoses and do not receive care at an emergency department, persons leaving incarceration, persons who inject drugs, parents who may fear child removal, pregnant persons, people with co-occurring mental health conditions and substance use disorders involving federally illegal drugs or misuse of prescription medications, and people experiencing homelessness on reducing rates of at least two required outcomes (also see **Objectives and Outcomes** on page 17). Ultimately, it is incumbent upon the applicant to determine whether their proposal would meet the definition of secondary prevention strategies as defined in the NOFO.

15. Are there any types of interventions not allowed?

Please see **Step I: Review the Opportunity > Eligibility > Other required responsiveness factors** starting on page 8 for more information on measures that are not allowed. Here the NOFO states, "the proposed research should not focus on measures of alcohol use disorder only, alcohol use only, tobacco use disorder only, or tobacco use only. The proposed research must also not focus on law

enforcement strategies without inclusion of a strong public health component, as a primary research aim."

16. **Would you consider a PI with a relevant PhD and documented work in this area if that work did not include a publication?**

Please see **Step I: Review the Opportunity > Eligibility > Other required responsiveness factors** starting on page 9 for more information. Specifically, the following documentation is needed for PD or PI/Co-PIs:

- at least one first-authored, peer-reviewed publication as defined by the NIH National Library of Medicine in the relevant area of substance use, substance use disorders, or overdose, **OR**
- by serving as a PD, PI, or co-PI on a research grant in substance use, substance use disorders, or overdose

As a reminder, "experience requirements may be demonstrated through the combined experiences of a PI and Co-PI (if applicable). The citation of the relevant publication(s) or research experience must be clearly identified (by bold text or highlight) in the appropriate SF 424 Biographical Sketch. Applications that do not include documentation to meet this PI/co-PI requirement will be considered nonresponsive and will not be forwarded for peer review." (NOFO pg 10).

17. **Are multiple PIs are allowed?**

Yes, please see **Step III: Prepare Your Application > Application contents and format > Other research plan section** for more information on how to format a multiple PI/PD leadership plan.

18. **Would you have time to meet with us to discuss this grant opportunity further?**

We unfortunately are unable to meet with potential applicants but will happily assist you with any questions you would like to send via email to NCIPC_ERPO@cdc.gov.

19. **This CDC funding mechanism is new to me. Do you have any sense of historically, how many entities typically apply for these?**

CDC is unable to disclose this information.

20. **Can you clarify whether this NOFO can fund any program/service delivery costs or if the entire award must be dedicated to researching/evaluating a program that is fully-supported by some other funding source?**

The primary purpose of this NOFO should rigorously evaluate either primary or secondary prevention strategies for reducing rates of nonfatal overdose, fatal overdose, and/or substance use disorders involving federally illegal drugs or misuse of prescription medications, drug use, or initiation of drug use, particularly among youth. It may be allowable for program/service delivery costs to be included in the budget with a budget justification. It is incumbent for the applicant to

justify how program/service delivery costs will contribute to the NOFO intent and objectives (See NOFO page 17).

21. **Per opportunity guidelines: "Your organization cannot serve as a "pass through" to fund another entity to conduct the majority of the research or provide the scientific or technical leadership necessary to complete the proposed research project." Please let us know if we are allowed to include subawards. If so, how do you define "majority of the research"? Is there a basis for determining what is considered majority of the research to be performed by the applicant or subawards?**

Subawards are allowable for this NOFO. Please include the R&R Subaward Budget Attachments Form for each subaward. The NOFO does not define specific limits regarding percentage of research performed by the applicant or subawards. However, it is incumbent upon the applicant to demonstrate the applicant organization and contact PD/PI will provide the scientific and technical leadership necessary to conduct the proposed research throughout the entire period of performance (See period of performance for Funding Option A or B on pg 6 of the NOFO).