RFA-CE-24-013; The CDC's National Center for Injury Prevention and Control (NCIPC)

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

Questions and Answers (Q&A)

1. What behavioral intervention strategies would be considered responsive vs. nonresponsive to this Notice of Funding Opportunity (NOFO)?
    - **Answer:** Please see **Section III. Eligibility Information, Responsiveness** listed on **page 21** of the NOFO to identify more information of what interventions would be considered responsive. We cannot answer any questions about the specific appropriateness of your application's proposed activities or aims. We encourage you to review **Section I. Funding Opportunity Description, 2. Approach section** beginning on **page 9** to determine if your application is responsive to the NOFO.

2. If a program employs various community level interventions to encourage initiation into treatment strategies, would this program be considered responsive?
    - **Answer:** Additional information on the selection of community-based strategies can be found in **Section I. Funding Opportunity Description, 2. Approach** beginning on **page 9** of the NOFO**.** This NOFO is not intended to support applications that solely evaluate strategies in healthcare settings without also connecting to community resources (e.g., an intervention in a primary care or emergency department setting for youth treated for an overdose). The proposed research may include an evaluation of strategies involving a collaboration between healthcare settings and community-based partners (e.g., a brief intervention in a healthcare setting to treat for overdose that then links patients to community programs). Further, research funds are not available to evaluate the effectiveness of medications or a clinical behavioral-based intervention (e.g., contingency management, cognitive behavioral therapy [CBT]). Therefore, a collaboration between healthcare settings and community-based partners would be considered responsive.
    - For this NOFO, an "untested" strategy is theoretically justified but has not been developed or has not been implemented in the participating community or another community. A "new", "innovative", or "under-developed" strategy (i.e., "untested") that has been implemented in the participating community or another community but has not been rigorously evaluated for effectiveness overall or for a specific population, setting, or a primary outcome, and evaluating such a strategy is consistent with the intent of this NOFO. Applicants must demonstrate that the proposed strategy is untested and justify why the proposed research is needed and likely to have substantial implications for addressing the drug overdose epidemic. Applicants are encouraged to rigorously evaluate strategies with the potential for population wide effects. Applicants are expected to examine a range of outcomes from the community-based strategies evaluated, including potential unintended negative effects such as costs or consequences. Applicants should describe how the proposed research is innovative, advances the field of overdose prevention, and adds to the current evidence base.

3. Can CDC better define what an untested community-based strategy is?
    - **Answer:** Additional information on the selection of community-based strategies can be found in **Section I. Funding Opportunity Description, 2. Approach** on **page 9** of the NOFO. An untested community-based strategy is a "new", "innovative" or "under-developed", strategy that has been implemented in the participating community or another community but has not been rigorously evaluated for effectiveness overall or for a specific population, setting, or a primary outcome, and evaluating such a strategy is consistent with the intent of this NOFO. Applicants must demonstrate that the proposed strategy is untested and justify why the proposed research is needed and likely to have substantial implications for addressing the drug overdose epidemic.

4. What are the primary outcomes of interest?
    - **Answer:** Primary outcomes of interest include, but are not limited to, nonfatal and fatal drug overdose, drug use, drug use initiation, substance use disorders (SUDs). Applicants are expected to include at least one primary outcome. Please review **Section I. Funding Opportunity Description, 2. Approach** on **page 10** of the NOFO for more information.

5. Could CDC better define the peer review process? How are peer reviewers selected and are there any similarities between CDC funded NOFOs?
    - **Answer:** Considerations are given to the NOFO's research topics and the application's scientific content and merit. These considerations are used to identify subject matter experts in the respective research area. Through proper recruitment and selection, diverse panel representation is approved and appointed by the CDC Director. Each application is considered individually. Applications submitted by the same institution for different funding opportunities are considered independently of the other. As part of 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, and receive a written critique. The NOFO describes additional information on the Peer review process in **Section V. Application Review Information, 4. Review and Selection process** beginning on **page 40** of the NOFO.

6. How does the scope and responsiveness of RFA-CE-24-013 differ from RFA-CE-24-012?
    - **Answer:** RFA-CE-24-013 is soliciting investigator-initiated research to partner with communities to develop and rigorously evaluate the effectiveness of new, innovative, under -developed, or untested community-based strategies/interventions/programs/practices to reduce overdose. RFA-CE-24-012 is soliciting investigator-initiated research to rigorously evaluate the effectiveness of policies for reducing drug use and overdose as well as the effect of these strategies on disparities in medical care and health outcomes.
    - Each application received is reviewed individually under the NOFO for which it is submitted by the responsiveness and review criteria specific to that NOFO. The NOFO

describes additional information on the Peer review process in **Section V. Application Review Information, 4. Review and Selection process** on **page 40** of the NOFO.

7. Is this funding opportunity unique or will other opportunities like this one be available in the future?
    - **Answer:** We cannot speak to future opportunities. However, if you are interested in staying up to date on Injury Center funding announcements, please consider subscribing to our annual newsletter that is sent in the fall to receive updates on grants as they become available/active annually. To subscribe, search for "Injury Center Funding Announcements" which will be found on **page 7** of the subscription list. Please complete the instructions to subscribe to the newsletter.

8. Would a new intervention being launched with funding from this NOFO be considered less responsive than an existing intervention that has already been implemented but not rigorously evaluated?
    - **Answer:** All applications that meet all the responsiveness criteria listed in **Section III. Eligibility Information, 5. Responsiveness** on **page 21** are equally responsive to the NOFO. Please review **Section V. Criteria** on **page 34** for additional information on the application review criteria and additional information on the review and selection process.

9. We are interested in testing an intervention strategy that has not yet been rigorously evaluated. Will applications that propose to evaluate a strategy that has already been implemented be considered responsive or do applications need to evaluate a new implementation?
    - **Answer:** Please see the NOFO **Section I. Funding Opportunity Description, 2. Approach** on **page 9** for additional information about the selection of a community-based strategy. It is incumbent on the applicant to justify the appropriate methods of their approach and research. An untested community-based strategy is a “new”, “innovative” or “under-developed”, strategy that has been implemented in the participating community or another community but has not been rigorously evaluated for effectiveness overall or for a specific population, setting, or a primary outcome. Evaluating such an untested strategy is consistent with the intent of this NOFO. Applicants must demonstrate that the proposed strategy is untested and justify why the proposed research is needed and likely to have substantial implications for addressing the drug overdose epidemic. Proposed activities must align with the outlined **Intent and Purpose** of the NOFO beginning on **page 9** to ensure responsiveness.

10. The budget has an annual cap. Is it allowable to underbudget in the beginning years of funding in anticipation for increased spending in following budget years that would surpass the yearly awarded amount but not the total awarded amount?
    - **Answer:** The maximum total award project ceiling is $3,750,000 with an annual maximum of $750,000. However, it is incumbent on the applicant to propose an appropriate budget based on the activities being proposed. A budget justification is

required to provide specific costs needs. This funding opportunity allows recipients to carry over unspent funding from award years if applicable.

- The NOFO provides information on **Budget and Period of Support** on **page 39** of the NOFO. The applicant can obtain budget preparation guidance for completing a detailed justified budget on the CDC website (see **CDC Budget Preparation Guidelines)**. Following this guidance will also facilitate the review and approval of the budget request of applications selected for this award.

11. Is there a page limit on the budget narrative?
    - **Answer:** Additional information on page limitations can be found in the NOFO in **Section IV. Application and Submission Information, 7. Page Limitations** on **page 28**. For this specific NOFO, the Research Strategy component of the Research Plan narrative is limited to 12 pages. The budget narrative is not included in the research plan narrative; however, supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 25 pages for all appendices.

12. The funding structure of this NOFO is unsupportive of direct costs and salary needs of a small business. Are there alternative methods or examples for small businesses to apply for grants like this to maintain profits?
    - **Answer:** CDC National Center for Injury Prevention and Control grants must adhere to federal polices and requirements, and additional information on cost principles for grants with For-Profit Organizations, such as small businesses, can be found in the HHS Policy Statement, "Except for grants awarded under the [Small Business Innovation Research/ Small Business Technology Transfer] SBIR/STTR programs, no profit or fee will be provided to a for-profit organization, whether as a recipient or subrecipient. A profit or fee under a grant is not a cost, but is an amount in excess of actual allowable direct and indirect costs. In accordance with normal commercial practice, a profit/fee may be paid to a contractor under an HHS grant providing routine goods or services to the recipient."
    - We advise you to review CDC's Small Business Innovation Research (SBIR) program and NIH SEED to learn more about funding opportunities available to small businesses. Indirect Cost rates are negotiated at the U.S. Department of Health and Human Services Headquarter level (see Indirect Cost Negotiations).

13. In terms of utilizing multiple Project Directors/Principal Investigators (PD/PIs) and key personnel, is it acceptable for a portion of the evaluation team to be located external to the funded applicant institution and target intervention area?
    - **Answer:** As described in the NOFO **Section I. Funding Opportunity Description, 2. Approach, Collaborations and Partnerships** on **page 15,** it is incumbent on the applicant to clearly describe each contribution of each partnership to the proposed research in the Research Strategy and to document the intent and capabilities of each partnership with a signed Data Sharing Agreement, Letter of Support, or Memorandum of Understanding.

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

14. Given that an experimental research design may impact the ethical viability of the study, if the proposed research design is not experimental or quasi experimental, can it still be considered responsive?
    - **Answer:** This funding opportunity is intended to support evaluations that are designed to detect whether any measured changes in outcomes can be attributed to the untested strategy. Applicants are expected to use the most objective and rigorous study designs possible to answer the proposed research questions. For this announcement, rigorous evaluation designs include those that utilize experimental (i.e., randomized controlled trials) or quasi-experimental designs (e.g., comparative interrupted time series design, difference-in-differences, instrumental variable methods, regression discontinuity, regression point displacement, stepped wedge, designs using propensity-score matching, designs involving matched comparison groups). Randomized trials are not feasible for some prevention strategies, and alternative quasi-experimental designs are appropriate and acceptable. Applicants are expected to justify that the proposed design and data analysis plans (including attention to statistical power and baseline measures) are appropriate for evaluating the impacts of the strategy. Please also refer to **Data Collection, Acquisition, and Analysis** on **page 13** of the NOFO for information on relevant data sources.

15. Are evaluation performance measurement plans and translation plans expected to be included in the 12-page Research Strategy or as separate attachments?
    - **Answer:** Please include these and other items related to your research plan in the Research Strategy. Per the NOFO, the research strategy should be organized under 3 headings: Significance, Innovation, and Approach and should describe the proposed research plan, including staffing and timeline. Please see **5. PHS 398 Research Plan Component** on **page 26** for more information. Page limits for this section can be found on **page 3** of the NOFO under **Required Application Instructions.**

16. Will we have access to recordings of the pre application call?
    - **Answer:** This pre application call is being recorded for CDC internal quality and assurance use only. All questions asked will be included in the amended NOFO that can be subscribed to on grants.gov.

17. Does the award ceiling of $750,000 includes both direct and indirect costs?
    - **Answer:** The total award funding includes both direct and indirect funds. Please see **Budget and Project Period** on **page 4** of the NOFO for more information.

18. Where can additional questions be directed to?
    - **Answer:** Please send additional questions to NCIPC_ERPO@cdc.gov.

19. Is the letter of intent binding?
    - **Answer:** The 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. Please review **Letter of Intent Due Date** on **page 2** of the NOFO for more information.

20. What is the required level of effort for the PD/PI for this grant?
    - **Answer:** The NOFO does not require a specific level of effort (%) for the PD/PI for the grant. Please review the section on **Eligible Project Directors/Principal Investigators (PDs/PIs**) beginning on **page 4** to ensure eligibility.

21. Can you provide the link to the data management plan template?
    - **Answer:** Please refer to **Section IV. Application and Submission Information, Part 5. PHS 398 Research Plan Component** on **page 27** of the NOFO for information on what should be included in the data management plan. The CDC NCIPC data management plan template can be found here. Other examples of data management plans include the CDC OMB approved template (e.g., NCCDPHP template https://www.cdc.gov/chronicdisease/pdf/nofo/DMP-Template-508.docx) and USGS (http://www.usgs.gov//products/data-and-tools/data-management/data-management-plans).

22. Can we utilize funding from this opportunity to compensate subcontractors hired to support the principal institution and investigators (e.g., to conduct focus groups)?
    - **Answer:** Paying a contractor to facilitate a focus group is an allowable cost, but all costs must be allowable within the goals and objectives of the NOFO. Per the **Section V. Application Review Information, 3. Additional Review Considerations, Budget and Period of Support** on **page 39** of the NOFO: "Indirect costs could include the cost of collecting, managing, sharing and preserving data." If you plan to use a contractor, please ensure that their work is allowable within the goals and objectives of the NOFO.

23. I do not see specific guidance on whether equipment such as Fournier transformed infrared spectroscopy machine for drug checking would be an allowable expense?
    - **Answer:** We are not able to provide specific guidance on an applicant's proposed budget items. However, we encourage you to review the NOFO, **Section V. Applicant Review Information, 3. Additional Review Considerations, Budget and Period of Support** beginning on **page 39**. For additional budget preparation guidance for

completing a detailed justified budget on the CDC website, please visit here (see **CDC Budget Preparation Guidelines)**.

24. Would you have 15-30 minutes in the coming weeks where I could have a brief call with you to ask about my questions?
    - **Answer:** We are not able to discuss specific strategies or aims of potential applicants and prefer all questions to be emailed to us at NCIPC_ERPO@cdc.gov. It is incumbent on the applicant to justify the proposed research aims and demonstrate how they align with the purpose and intent of the NOFO. We encourage you to review **Section V. Application Review Information** beginning on **page 34** that contains valuable questions that will be considered during the scientific and technical peer review process and can assist you in developing an application that is responsive to this funding opportunity.

25. Does this grant opportunity require Institutional Review Board (IRB) approval?
    - **Answer:** While not required to be considered responsive to the NOFO, research involving human subjects should include IRB approval certification. Per **Protection of Human Subjects and Personally Identifiable information** on **page 13** of the NOFO, if research is conducted with more than one institution, a single IRB to conduct ethical review is required. Please review **Human Subjects** on **page 31** of the NOFO for more information.

26. Are for profit organizations that are small businesses considered eligible to apply?
    - **Answer:** Per the NOFO small business are eligible to apply. Please review **Section III. Eligibility Information, 1. Eligible Applicants** on **page 19** of the NOFO for more information regarding eligibility.

27. Can CDC clarify the definition of the focus population of interest, "people with lived experience with drug use?"
    - **Answer:** We encourage you to review the NOFO for additional information of the target population in **Section I. Funding Opportunity Information, 2. Approach, Target Population** on **page 14** of the NOFO. People with lived experience with drug use is just one example of a focus population of interest. It is incumbent on the applicant to clearly describe how they have identified the target population and how the proposed research will improve health equity among those at greatest risk of overdose or with the least access to care.

28. Does CDC require a specific format for the Letters of Intent?
    - **Answer:** CDC does not have a specific template for Letters of Intent. We encourage you to review the NOFO **Section IV. Application and Submission Information, 3. Letter of Intent,** on **page 25** of the NOFO for more information about what should be included. Please note that Letters of Intent are not required, not binding, and do 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.

29. For submission of our first application, do we need to include, "Introduction to Application?"
    - **Answer:** Per **Section IV. Application and Submission Information, 5.PHS 398 Research Plan Component** beginning on **page 26** of the NOFO, the application should include bolded headers and Introduction to Application for resubmission and revised applications only.

30. Are we required to provide reasoning for the budget?
    - **Answer:** Per **Budget and Period of Support** on **page 39** of the NOFO, reviewers of the applications will consider whether the budget and request period of support are fully justified and reasonable in relation to the proposed research. The applicant can obtain CDC budget preparation guidance for completing a detailed justified budget here (see **CDC Budget Preparation Guidelines)**. It is incumbent on the applicant to adequately justify the budget's direct and indirect cost requirements.

31. Is there a font, and font size for the 12-page narrative document?
    - **Answer:** Per **Section IV. Application and Submission Information, 7. Page Limitations,** on **page 28** of the NOFO, the Research Strategy component of the Research Plan narrative is limited to 12 pages. 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." Please review the application guide for more information regarding font size requirements.

32. Does the timeline need a narrative portion?
    - **Answer:** It is incumbent upon the applicant to include planned milestones and deadlines for the project timeline. The timelines for data acquisition must be specified. Please review **Evaluation/Performance Measurement** on **page 18** of the NOFO for more information.

33. Are letters of support submitted after the application due date acceptable?
    - **Answer:** We are unable to accept supplemental documents relating to an application after the due date of 12/1/2023. All application related materials must be submitted at one time as indicated in the NOFO **Section IV. Application and Submission Information** on **page 24**.

34. Can CDC send an example of a successful proposal that we can use as a model?
    - **Answer:** While we are unable to share previous examples, we encourage you to review **Section I. NOFO Funding Opportunity Description 2. Approach, Section III. Eligibility Information, 5. Responsiveness, and Section V. Application Review Information** on **page 34** to ensure your proposal is responsive to the NOFO. We also encourage you to visit CDC's Injury Prevention and Control's Extramural Research webpage, which includes a section on "What Grantees Need to Know" as they apply for CDC Injury Center-related funding. You may also search inactive grants on NIH Reporter.

35. Has there been consideration to extend the deadline for this NOFO?
    - **Answer:** The deadline has been set, and we are unable to extend it. Please see **Section IV. Application and Submission Information, 9. Submission Dates and Times** beginning on **page 29** of the NOFO for more information.

36. To be considered eligible, do any or all PD/PI's have to be an Early Status Investigator?
    - **Answer:** Please review **Eligible Project Directors/Principal Investigators** on **page 4** of the NOFO for more information on PI eligibility. Applications in which the contact Eligible PD/PI meets NIH Early Stage Investigator (ESI) status, as verified via the NIH Determination of Investigator Status process, *and* whose application has a meritorious peer review score, may be considered for prioritization during the second level of review. PD/PIs are encouraged to verify and/or enter the date of their terminal research degree or the end date of their post-graduate clinical training in their eRA Commons Profile to ensure the correct identification.

37. If part of the proposal includes creating undeveloped content for a primary prevention program that is untested, at the end of the grant cycle, would the applicant own the intellectual property, or would it share it with the funder (CDC)?
    - **Answer:** Please see **Section VI. Award Administration Information, 2. CDC Administrative Requirements** beginning on **page 43** and **3. Additional Policy Requirements** on **page 44** for information on the requirements for awarded projects. CDC requires all award recipients under this NOFO 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. Please also review **Copyright Interests Provision** on **page 45** in the NOFO, which outlines requirements to ensure that the public has access to the results and accomplishments of public health activities funded by CDC.

38. Will there be a "cut off" of applications that are submitted that will not be reviewed? Or will all applications submitted be reviewed?
    - **Answer:** All applications will be evaluated first for eligibility and responsiveness by the CDC Office of Grants Services and NCIPC Extramural Research Program Operations (ERPO), respectively. If accepted, the application will move to scientific and technical merit by an external peer review panel convened by NCIPC. Per the NOFO, "As part of the scientific peer review, all applications:
        i. 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.
        ii. Will receive a written critique."
    - Please review **4. Review and Selection Process** on beginning on **page 40** for information on what reviewers will consider in making funding recommendations.

39. Once applications have been reviewed and the CDC has chosen the proposals to move forward, will there be a public announcement of the agencies receiving funding?
    - **Answer:** Per **Section II. Award Information, Total Period of Performance Length** found on **page 19** of the NOFO, 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.

40. Are committees considered human subjects?
    - **Answer:** We are unable to provide specific guidance or information on the appropriateness of your aims for the NOFO. We encourage you to review Section I. NOFO Funding Opportunity Description **2. Approach**, **Section III. Eligibility Information, 5. Responsiveness**, and **Section V. Application Review Information** beginning on **page 34** to ensure your proposal is responsive to the NOFO. Per the NOFO, this funding opportunity is intended to support evaluations that are designed to detect whether any measured changes in outcomes can be attributed to the untested strategy. Applicants are expected to justify that the proposed design and data analysis plans (including attention to statistical power and baseline measures) are appropriate for evaluating the impacts of the strategy. Also, we encourage you to review the following website for guidance on the Definition of Human Subjects Research.

41. Are there methods that for-profit companies can use or have used in the past to allow for making a profit from their research?
    - **Answer:** NCIPC grants must adhere to federal polices and requirements and additional information on cost principles for grants to For-Profit Organizations can be found in the HHS Policy Statement: "Except for grants awarded under the SBIR/STTR programs, no profit or fee will be provided to a for-profit organization, whether as a recipient or subrecipient. A profit or fee under a grant is not a cost but is an amount more than actual allowable direct and indirect costs. In accordance with normal commercial practice, a profit/fee may be paid to a contractor under an HHS grant providing routine goods or services to the recipient."

42. Can CDC better define the ESI status as it relates to eligible PD/PIs?
    - **Answer:** An Early-Stage Investigator (ESI) is a Program Director/Principal Investigator who has completed their terminal research degree or end of post-graduate clinical training, whichever is later, within the past 10 years and who has not previously competed successfully as a PD/PI for a substantial NIH independent research award. For more information about Early-Stage Investigator policies, please visit Early-Stage Investigator (ESI) Policies at NIH.