

NIH HEAL Initiative: Preventing Opioid Misuse and Co-Occurring Conditions by Intervening on Social Determinants ([RFA-DA-22-036](#))

Frequently Asked Questions

Application Details

Letter of Intent Due Date: February 2, 2022

Application Due Date: March 2, 2022

General Questions

1. How are you defining “social determinants of health”? Social determinants of health are defined as the conditions in environments where people are born, live, learn, work, play, worship, and age that affect health, functioning, and quality-of-life outcomes. Additional sources of information on social determinants of health can be found at the Department of Health and Human Services, [Office of Disease Prevention and Health Promotion](#) website.

2. What makes an intervention a “multi-level” intervention? For the purposes of this RFA, a multi-level intervention is a strategy to intervene on two or more ecological levels of influence, as identified by the National Institute of Minority Health and Health Disparities Research Framework; specifically, individual, interpersonal, community, and societal levels. To be responsive, projects should not focus solely on tests of individual-level interventions.

3. Are additional (non-NIH) funds required to fund the intervention? Applicants are not required to support interventions with non-NIH funds. However, interventions should have identified funding streams to support future implementation, so there is strong potential for adoption and sustainability.

4. How can I tell if the type of multi-level intervention I am proposing is the type of intervention that is intended under this RFA? Applicants should discuss any questions about the appropriateness of the proposed intervention with the relevant program official listed in Section VII. of the funding opportunity announcement.

5. Is there a requirement to focus on a specific population subgroup? Applications must seek to reduce health inequities in a U.S. population or population subgroup affected by the opioid crisis. Applicants should clearly define the population for whom selected outcomes will be studied and provide a justification for focusing on the population group or subgroup. The population can be defined by geography, sociodemographic characteristics, or other identifying characteristics (e.g., youth aging out of foster care, individuals who do not complete high school, juvenile justice-involved

youth, homeless women, workers experiencing a recent job loss, racial/ethnic minority youth residing in neighborhoods affected by crime and illicit drug markets).

6. Do you expect that the project's primary outcomes will be prevention oriented? Is it acceptable to focus on harm reduction and treatment outcomes? Through this initiative, NIH seeks projects designed to reduce the risk for opioid misuse and co-occurring conditions. Each study submitted in response to this RFA must include an opioid misuse-related prevention outcome as the primary outcome. Harm reduction and treatment outcomes are not the primary focus of this initiative. Applicants should discuss any questions or concerns about acceptable prevention outcomes with a program official listed in Section VII. of the funding opportunity announcement.

7. Is the expectation that a single application would address all 5 areas of SDOH? Applicants must address one or more domains of the social determinants of health in the application. It is not expected that applicants will address all domains.

8. Will there be specific requirements of awardees because projects will be funded by the NIH HEAL Initiative? The NIH HEAL Initiative requires coordination and sharing between investigators. Funded principal investigators will adhere to the HEAL [data-sharing requirements](#) and will participate in Program Director/Principal Investigator (PD/PI) meetings, including an annual HEAL Investigators Meeting. The terms of award will specify the expectations of awardees as NIH HEAL Initiative Awardees.

9. Is data/resource sharing required for projects under \$500K in direct costs? Yes. Applicants should be certain to include a Data and Resource Sharing Plan and should be prepared to contribute to the [HEAL Data Ecosystem](#).

10. Are clinical trials required? RFA-DA-22-036 is a "clinical trials optional" announcement. While clinical trials are not required (e.g., when leveraging a natural experiment), it is expected that many, if not most, applications will meet the [definition of a NIH Clinical Trial](#). If an application can be classified by NIH as a clinical trial, all application materials required for clinical trials must be included (e.g., Protocol Synopsis, Data and Safety Monitoring Plan, Clinical Trials Dissemination Plan).

11. Are Foreign Applications allowed? Applications from foreign institutions and applications that include foreign components are not allowed.

12. Will late applications be considered? Late applications will not be considered for this funding opportunity announcement.

13. When will the scientific merit review take place? When will funding decisions be made? The scientific merit review will take place in June 2022. Investigators should

be notified of priority scores through the NIH eRA Commons shortly after the review meeting. Funding decisions will be made by September 30, 2022. If you have questions about the status of your submission, contact the program official associated with your application.

Application Review Questions

14. Where will applications be reviewed. All applications will be reviewed by a Special Emphasis Panel convened by the National Institute on Drug Abuse.

15. Are there special considerations that all applicants must address for this RFA? Yes. Applications must include elements listed in Section I of RFA-DA-22-036 under “Special Considerations.” Failure to meet these requirements will result in applications being withdrawn from review.

16. Are there specific review criteria for the RFA? Yes. Applicants should carefully read the review criteria for applications submitted under this announcement (see Section V. of RFA-DA-22-036).

General NIH Application Notes/Reminders

17. Are Letters of Intent required? No, but applicants are encouraged to provide them. Letters of intent are non-binding.

18. Are appendix materials allowed? NIH restricts the use of appendices to limited types of materials. Do not include appendices unless you have carefully reviewed the NIH requirements (see [NOT-OD-18-126](#)).

19. Can additional materials be provided to supplement the submitted application after the application receipt date? NIH allows limited types of documents to be submitted after the receipt date and before the review of an application. Post-submission materials are not intended to correct oversights or errors discovered after submission of the application, but to allow applicants the opportunity to respond to unforeseen events. Post submission materials require the concurrence of the Authorized Organization Representative and must be received by the Scientific Review Officer (SRO) no later than 30 calendar days prior to the peer review meeting. For more information, see [NOT-OD-19-083](#).
