

FREQUENTLY ASKED QUESTIONS (FAQS) FOR RFA-NR-24-005

Strategies to Improve Health Outcomes and Advance Health Equity in Rural Populations (R01 Clinical Trial Optional)

GENERAL INFORMATION

What is the purpose of this NOFO?

The purpose of this initiative is to support research to improve health and promote health equity in rural populations. Applications responding to this Notice of Funding Opportunity (NOFO) should develop, adapt, or implement intervention strategies addressing social determinants of health (SDOH) to improve health and promote health equity in rural populations.

ELIGIBILTY

Who is eligible to apply?

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with their organization to develop an application for support. Individuals from diverse backgrounds, including underrepresented racial and ethnic groups, individuals with disabilities, and women are always encouraged to apply for NIH support. See, Reminder: Notice of NIH's Encouragement of Applications Supporting Individuals from Underrepresented Ethnic and Racial Groups as well as Individuals with Disabilities, NOT-OD-22-019.

Are foreign institutions/organizations eligible to apply?

Non-domestic (non-U.S.) entities (Foreign Institutions) are not eligible to apply. Non-domestic (non-U.S.) components of U.S. Organizations are not eligible to apply. Applications to study populations or regions outside the United States will be considered non-responsive.

APPLICATION AND SUBMISSION

When are applications due?

Applications are due on May 17th by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.



May I submit a late application?

No late applications will be accepted for this Notice of Funding Opportunity (NOFO).

Am I required to submit a letter of intent?

A letter of intent is not required, is not binding, and does not enter into the review of a subsequent application. The information that it contains allows staff to estimate the potential review workload and plan review. If a letter of intent is submitted, it is due April 17th, 2024 and should be sent to:

Weiqun Li, MD Chief, Office of Scientific Review National Institute of Nursing Research (NINR)

Telephone: 301-594-5966 Email: wli@mail.nih.gov

Does the application have a page limit?

All page limitations described in the <u>How to Apply – Application Guide</u> and the <u>Table of Page</u> <u>Limits</u> must be followed. For this application, the page limit for the Specific Aims is 1 and the page limit for the Research Strategy is 12.

How should I submit my application?

All applications must be submitted electronically. Applicants should follow instructions in the <u>How to Apply – Application Guide</u> and should be used for preparing an application to this NOFO.

Can I submit this as a Multiple Principal Investigators (MPI) application?

Yes. For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the How to Apply - Application Guide.

Can an organization submit more than one application?

Applicant organizations may submit more than one application, provided that each application is scientifically distinct. The NIH will not accept duplicate or highly overlapping applications under review at the same time, per <u>2.3.7.4 Submission of Resubmission Application</u>. This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see 2.3.9.4 Similar, Essentially Identical, or Identical Applications).



Will awardees under this funding opportunity retain their ESI status?

These awards will be R01 studies. According to the <u>NIH ESI policy</u>, investigators will not retain their ESI status if awarded R01 equivalents.

May an applicant submit multiple applications to this NOFO simultaneously?

Applicants can submit more than one application; however, attention must be given to the <u>NIH</u> <u>Submissions Policy</u> on overlapping applications. Applications must not overlap in scope and content.

May an applicant submit an application to this NOFO and other applications to other NOFOs at the same time?

Applicants can submit more than one application; however, attention must be given to the <u>NIH</u> Submissions Policy on overlapping applications. Applications must not overlap in scope and content.

How is it decided where applications are sent once they are submitted?

All applications will initially be assigned to NINR and the review will take place through NINR. You can request an Institute or Center (IC) assignment through the assignment request form in your application. Applications will be distributed to other ICs after the review.

Where in my application should I include annual milestones?

Annual milestones can be included in the Research Strategy, Timeline, and/or Plan for Enhancing Diverse Perspectives (PEDP).

RESEARCH OBJECTIVES AND SCOPE

How can I determine whether my research topic is a good fit for RFA-NR-24-005?

Applicants are encouraged to contact Scientific/Research Contacts at NINR or other ICs that are named in the RFA to ensure that proposed aims of the project are consistent with the NINR mission and priorities or the mission and priorities of the other ICs.

This RFA states that clinical trials are optional. How is clinical trial status determined?

Applications that propose a clinical trial and applications that do not propose a clinical trial will be accepted for this funding opportunity. Investigators who propose to conduct a clinical trial should review the NIH Definition of a Clinical Trial: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. A decision tool (https://grants.nih.gov/ct-decision/index.htm) is also available to assist in making the determination about whether the study is a clinical trial. It is important to properly designate whether the study is a clinical trial at the time of application. *Applications that propose an NIH-defined clinical trial but are labeled as a non-clinical trial will be withdrawn without review*.



This RFA is "clinical trial optional" and requires applications to include an intervention. How could intervention studies be non-clinical trials?

Applications may propose intervention studies such natural experiments that would not be considered clinical trials. If you have a question about whether a project includes an intervention, please consult with the Scientific/Research Contacts at NINR or other ICs that are named in the RFA prior to submitting an application.

How do I determine if my study population is a rural population?

For the purposes of this NOFO, rural population is defined as: individuals living or working in a rural area, or communities or systems located in a rural area. Rural areas are defined according to the <u>Health Resources & Services Administration (HRSA) definition</u>. Additionally, the <u>HRSA Rural Health Grants Eligibility Analyzer</u> can be used to determine which counties and locations are rural areas.

REVIEW AND SELECTION

Where will my application be reviewed?

Applications will be evaluated for scientific and technical merit by an appropriate Scientific Review Group convened by the National Institute of Nursing Research (NINR), in accordance with NIH peer review policy and procedures, using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

What factors determine what study panel will review my application?

All applications to this RFA will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by the National Institute of Nursing Research (NINR), in accordance with NIH peer review policy and procedures, using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons. The review criteria stated in Section V. of the RFA will be considered.

On what basis are applications selected for funding?

NINR will consider the scientific and technical merit of an application as determined by scientific peer review, alignment with strategic priorities, advancement of diverse perspectives, and availability of funds in making funding decisions. NINR will give additional consideration to applications from <u>early-stage investigator</u> as defined by the NIH.

What is the anticipated number of awards funded under RFA-NR-24-005?

NINR intends to commit an estimated total of \$3,000,000 in FY 2024 to fund 3-4 awards, depending on receipt of meritorious applications and availability of funds. Additional awards may be made by other participating ICs.



Is there a budget cap for applications?

Application budgets are limited to less than \$500,000 direct costs in any year and need to reflect the actual needs of the proposed project.

What will happen if my application is considered non-responsive?

Applications that are deemed non-responsive will not be reviewed. This includes:

- Applications that do not include a Plan for Enhancing Diverse Perspectives
- Applications to study populations or regions outside the United States
- Research projects that do not include a U.S. rural population. For the purposes of this NOFO, rural population is defined as: individuals living or working in a rural area, or communities or systems located in a rural area. Rural areas are defined according to the Health Resources & Services Administration (HRSA) definition: All non-metro counties, as defined by the Office of Management and Budget; all metro census tracts with Rural-Urban Commuting Area (RUCA) codes 4-10; and large area metro census tracts of at least 400 square miles in an area with population density of 35 or less per square mile with RUCA codes 2-3; and outlying metro counties without a UA. For more detail on the addition of outlying metro counties, read the Federal Register Notice, Revised Geographic Eligibility for Federal Office of Rural Health Policy Grants. The HRSA Rural Health Grants Eligibility Analyzer can be used to determine which counties and locations are rural areas. HRSA also provides data files to identify rural areas by county, census tract, and those using a zip code approximation. Remote areas, defined by USDA Frontier and Remote (FAR) Area Code 4, are considered both rural and remote; therefore, the definition of rural above will be used for eligibility. The USDA provides data files and maps using the FAR codes. Rural and remote areas may include American Indian and/or Alaska Native Tribal populations.
- Research projects that do not include a health outcome as the primary outcome
- Research projects that do not address social determinants of health as <u>conceptualized by the</u> NIH
- Applications that do not include a conceptual framework that identifies hypothesized pathways between the intervention and outcome(s)
- Construction and major renovations costs are unallowable through this RFA. Applications that
 propose to use grant funds to support construction or major alteration and renovation projects
 will be considered non-responsive.

RESEARCH IC/OFFICES-SPECIFIC QUESTIONS

For questions that are specific in nature, potential applicants are encouraged to reach out and consult with the Scientific/Research Contacts at NINR or other ICs that are named in the RFA prior to submitting an application. Discussions with the Scientific/Research Contacts about potential research aims can be very helpful in determining project fit and alignment with the IC programmatic research priorities.