Intervention Research to Improve Native American Health (IRINAH)
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1. **What is the purpose of the Intervention Research to Improve Native American Health (IRINAH)?**
   IRINAH aims to support research on interventions, including: (a) **etiologic research** that will directly inform intervention development or adaptations, (b) research that **develops, adapts, or tests interventions** for health promotion, prevention, treatment, or recovery, and (c) research on **dissemination and implementation** that develops and tests strategies to overcome barriers to the adoption, integration, scale-up, and sustainability of effective interventions.

   Through this initiative, intervention and related research is sought to build upon community knowledge, resources, and resilience to identify and rigorously test culturally appropriate solutions to reduce morbidity and mortality. Interventions should be designed with a consideration for sustainability within the communities where they are tested, and have the flexibility to be readily adapted, disseminated, and scaled up to other communities where culturally appropriate.

2. **What Native American populations are included in IRINAH?**
   For the purposes of IRINAH, **Native Americans include the following populations**: Alaska Natives, American Indians (whose ancestral lands fall at least partially within the U.S. mainland border), and Native Hawaiians. The term 'Native Hawaiian' means any individual any of whose ancestors were natives, prior to 1778, of the area which now comprises the State of Hawaii.

3. What are the current Notices of Funding Opportunity (NOFOs) for IRINAH?
IRINAH NOFOs were reissued in 2023 for both **R01 (PAR-23-298)** and **R21 (PAR-23-299)** applications, and included a funding opportunity for **R34 (PAR-23-285)** applications.

R01 - https://grants.nih.gov/grants/guide/pa-files/par-23-298.html

R21 - https://grants.nih.gov/grants/guide/pa-files/PAR-23-299.html

R34 - https://grants.nih.gov/grants/guide/pa-files/PAR-23-285.html

4. When are applications due?
The **application deadline** for the reissued NOFOs is **October 21** in 2024, 2025, and 2026.

5. Which Institutes/Centers (ICs) are participating in the IRINAH program?
The following ICs are participating in the IRINAH program. However, **not all ICs listed participate in all three of the NOFOs.** Please see Part 2. **Section I** of each NOFO for a list of participating ICs.

National Institute on Drug Abuse (NIDA)
National Institute on Alcohol Abuse and Alcoholism (NIAAA)
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
National Institute of Dental and Craniofacial Research (NIDCR)
National Institute of Environmental Health Sciences (NIEHS)
National Institute of Mental Health (NIMH)
National Institute of Nursing Research (NINR)
National Institute on Minority Health and Health Disparities (NIMHD)
National Library of Medicine (NLM)
National Center for Complementary and Integrative Health (NCCIH)
National Cancer Institute (NCI)
National Institute of Child Health and Human Development (NICHD)
National Heart, Lung, and Blood Institute (NHLBI)
National Insitute on Deafness and Other Communication Disorders (NIDCD)

All applications to this funding opportunity announcement should fall within the mission of the Institutes/Centers. The following NIH Offices may co-fund applications assigned to those Institutes/Centers.

Division of Program Coordination, Planning and Strategic Initiatives, Office of Disease Prevention (ODP)
Office of Behavioral and Social Sciences Research (OBSSR)
Office of Research on Women's Health (ORWH)

6. How do I find out if my proposed topic fits the mission of participating ICs?
Please review Part 2. **Section I** of the NOFOs for a **list of participating ICs' research objectives**. It is best to **contact a Program Official** to discuss whether your proposed topics align with their Center/Institute's missions. It is fine to contact Program Officials from multiple ICs if you need help deciding where your proposed research would best fit. Note that not all Institutes/Centers (ICs) participate in all three NOFOs. For a **list of Program Official contacts**, see Part 2. **Section VII o**f the NOFOs.

7. **Which grant mechanism is best suited for my proposed project?**
    We encourage you to **contact a Program Official** to discuss which mechanism may be best suited for your project. Note that not all Institutes/Centers (ICs) participate in all three NOFOs. For a **list of Program Official contacts**, see Part 2. **Section VII** of the NOFOs.

    The **R01 research project grant** supports a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing his or her specific interest and competencies. For additional information, see: https://grants.nih.gov/grants/funding/r01.htm.

    The **R21 exploratory/developmental grant** supports investigation of novel scientific ideas or new model systems, tools, or technologies that have the potential for significant impact on biomedical or biobehavioral research. An R21 grant application need not have extensive background material or preliminary information. Emphasis is given on the conceptual framework, the level of innovation, and the potential to significantly advance knowledge or understanding of the field of study. Appropriate justification for the proposed work can be provided through literature citations, data from other sources, or, when available, from investigator-generated data. Preliminary data are not required for R21 applications; however, they may be included if available. For additional information, see: https://grants.nih.gov/grants/funding/r21.htm.

    The **R34 planning grant** supports the initial development of a clinical trial or research project, including the establishment of the research team; the development of tools for data management and oversight of the research; the development of a trial design or experimental research designs and other essential elements of the study or project, such as the protocol, recruitment strategies, procedure manuals and collection of feasibility data. For additional information, see: https://grants.nih.gov/grants/funding/r34.htm.

    This R34 NOFO will not support research testing intervention efficacy or effectiveness. Efficacy or effectiveness research could be submitted to the companion IRINAH NOFOs (PAR-23-298 and PAR-23-299).

8. **What are Milestones and Study Targets?**
    An **R34 application** (see PAR-23-285) must include a section on "Milestones and Study Targets," which describes the **decision points that would justify moving to a full trial**. These milestones and study targets must be discussed in the context of the goal of a future trial and include specific ways that reaching the targets will indicate readiness for a future trial. Some examples of milestones and study targets include: agreements reached with community and tribal partners, metrics for measurement validation, success metrics for recruitment strategies, and thresholds for measures of intervention and/or protocol acceptability and feasibility.

    Milestones and Study Targets are not required for R01 and R21 applications.

9. **What applications are considered "non-responsive" to the NOFOs?**
    For the current **NOFOs (R01, R21, and R34)**, applications with the following attributes will be deemed **non-responsive** and **will not be reviewed**:

    ▪ Applications that propose research objectives that are not aligned with the mission of any of the participating ICs
    ▪ Applications that do not propose community-engaged projects

- Applications that do not propose research with Native Americans

For the **R34 NOFO**, applications with the following attributes will be deemed **non-responsive** and **will not be reviewed**:

- Applications that include exclusively mechanistic or etiological research, include only analysis of existing data and/or do not include an intervention or proposal to develop an intervention.
- Applications that do not include a "Milestones and study targets" section within the Research Strategy
- Applications that propose efficacy or effectiveness testing of an intervention
- Applications that only propose to write a protocol or manual

10. Who reviews the IRINAH applications?

IRINAH applications are reviewed at the NIH Center for Scientific Review (CSR) by a recurring Special Emphasis Panel (SEP) consisting of temporary members recruited based on their expertise with Native American research and communities.

11. How are applications evaluated?

Only the **review criteria described in** Part2. **Section V** of the NOFOs will be considered in the review process. Applications submitted to the NIH in support of the NIH mission (https://www.nih.gov/about-nih/what-we-do/mission-goals) are evaluated for **scientific and technical merit** through the NIH peer review system (https://grants.nih.gov/grants/peer-review.htm).

In addition to the standard review criteria described in Part 2. **Section V** of the NOFOs, https://grants.nih.gov/grants/peer-review.htm note that the current NOFOs have **additional and specific review criteria**, including but are not limited to:

Significance
- To what extent will the project address research questions that are relevant to and prioritized by the Native American community partners for the study?

Investigator
- To what extent does the application provide evidence of the PD(s)/PI(s)'s proficiency to conduct the proposed research, including proficiency for working with Native American partners and communities (see Section IV of the NOFOs for examples, including those for community members serving as an investigator)?

Innovation
- To what extent does the project innovate in its approach to Native American health, by incorporating Indigenous Knowledge, addressing the cultural appropriateness of new or standard measures, developing or adapting interventions, or in other ways as appropriate?

Approach
- To what extent does the application provide evidence of the community-research organization partnership and mutual understanding of the responsibilities of each of the collaborators for the proposed project?

Environment

- To what extent does the application provide evidence of Native American community/tribal support?

12. **Who makes funding decisions for IRINAH applications?**
Applications are assigned to a specific IC who makes the funding decision based on its research objectives and funding processes.

13. **We are not able to obtain a letter of support from the tribes or tribal government in time for the application submission deadline. Is there flexibility in submitting a letter of support as part of the application package?**
Tribal resolutions and **letters of support from community collaborators** may be submitted as post-submission material up to 30 days before the study section meeting. Note that this **flexibility is <u>not</u> extended to letters of support from Key Personnel and consultants with academic or research organization affiliations**.

14. **Do community partners need a PhD in order to be a co-Investigator or an MPI on an application?**
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.

15. **Can submissions be from multiple investigators (MPIs/MPDs)?**
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 SF424 (R&R) Application Guide.

16. **Can I be an investigator on more than one application at a time?**
Yes.

17. **Can institutions submit more than one application at a time to IRINAH?**
Yes. 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 NIH Grants Policy Statement Section 2.3.7.4 Submission of Resubmission Application. 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 NIH Grants Policy Statement 2.3.9.4 Similar, Essentially Identical, or Identical Applications)

18. **Do we have to include a Data Management and Sharing Plan in our application?**

    Yes, all applications with due dates on or after January 25, 2023 require a **Data Management and Sharing Plan**. For more information, please see:

    Supplemental Information to the NIH Policy for Data Management and Sharing: Responsible Management and Sharing of American Indian/Alaska Native Participant Data: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-214.html

    2023 Data Management & Sharing Policy FAQs: https://sharing.nih.gov/faqs#/data-management-and-sharing-policy.htm

    Considerations for Researchers Working with AI/AN Communities: https://sharing.nih.gov/data-management-and-sharing-policy/protecting-participant-privacy-when-sharing-scientific-data/considerations-for-researchers-working-with-aian-communities

19. **I still have questions. Who do I contact?**

    We encourage you to **contact a Program Official** to discuss additional questions about the IRINAH NOFOs. For a **list of Program Official contacts**, see **Section VII of the NOFOs**.