# Intervention Research to Improve Native American Health (IRINAH) Frequently Asked Questions (FAQs)

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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 this NOFO, **Native Americans** are defined as people who are members of Indigenous Tribes and communities, irrespective of where they live or reside, that have been recognized as having a special political and trust relationship with the United States, including those Tribes, bands or groups terminated since 1940 and those recognized now or in the future by the State in which they reside. This includes members or up to second generation descendants of **federally recognized American Indian and Alaska Native Tribes** (U.S. Constitution, Article I, Section 8, Clause 3; Cherokee Nation v. Georgia, 30 U.S. 1 (1831); Worcester v. Georgia, 31 U.S. 515 (1832); 25 U.S.C. 5301(a)), and **state recognized tribes** and **Urban Indians** as described in the Indian Health Care Improvement Act (Public Law 94-437, 25 U.S.C. 1601 et seq., as amended by Public Law 117-58, November 21, 2021)). Also included for purposes of this NOFO are **Native Hawaiian communities** as described in the Native Hawaiian Health Care Improvement Act (42 U.S.C. 11701 et seq.).

3. **What are the current Notices of Funding Opportunity (NOFOs) for IRINAH?**
   R01 - https://grants.nih.gov/grants/guide/pa-files/PAR-25-379.html

   R34 - https://grants.nih.gov/grants/guide/pa-files/PAR-25-378.html

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

   The application deadline for AIDS/HIV-related research proposals is **January 7** in 2025, 2026, and 2027.

5. **When are renewal, resubmission, and revised applications due?**
   Renewal, Resubmission, and Revised (as allowed) applications have the **same due date** as new applications—**October 21** for non-AIDS/HIV research proposals and **January 7** for AIDS/HIV research proposals.

6. **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 both R01 and R34 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 Allergy and Infectious Diseases (NIAID)
- National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
- National Institute of Biomedical Imaging and Bioengineering (NIBIB)
- National Institute of Dental and Craniofacial Research (NIDCR)
- Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
- National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
- 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 Cancer Institute (NCI)
- National Center for Complementary and Integrative Health (NCCIH)
- National Heart, Lung, and Blood Institute (NHLBI)
- National Institute on Deafness and Other Communication Disorders (NIDCD)
- National Institute on Aging (NIA)

*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)
- Tribal Health Research Office (THRO)

7. **How do I find out if my proposed topic fits the mission of participating ICs?**
   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.

8. **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 **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 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**. R34 applications proposing efficacy or effectiveness testing as part of the project may be withdrawn prior to review. Efficacy or effectiveness research could be submitted to the R01 NOFO.

9.  **The R34 NOFO requires a section called "Milestones and Study Targets" within the Research Strategy section of the application. What are "Milestones and Study Targets?"**
    An **R34 application** (see https://grants.nih.gov/grants/guide/pa-files/PAR-25-378.html) 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 applications**.

10. **What applications are considered "non-responsive" to the NOFOs?**
    For both **R01 and R34 NOFOs**, 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

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

    ▪ Applications that do not include an intervention or proposal to develop an intervention within the award period
    ▪ Applications that propose efficacy or effectiveness testing of an intervention
    ▪ Applications that only propose to write a protocol or manual

11. **Are preliminary data required for IRINAH applications?**
    No. Preliminary or pilot data are not required for any of the IRINAH grant mechanisms, including the R01.

12. **What does the "Clinical Trial Optional" mean on the NOFOs?**
    The R01 and R34 NOFOs are "Clinical Trial Optional." This means that you can propose clinical trial and/or non-clinical trial (e.g., etiologic) research under these mechanisms.

    **Investigators are strongly encouraged to review the NIH Clinical Trials definitions and policies:**

    ▪ https://grants.nih.gov/policy/clinical-trials.htm (please also see the decision tool https://grants.nih.gov/ct-decision/index.htm)

Applications that do not include all required documentation for clinical trials for review, but are determined to be clinical trials, may <u>not</u> be considered for review or funding. It is best to contact a Program Official to discuss whether your project meets the **NIH definition** of clinical trial prior to submission. For a **list of Program Official contacts**, see Part 2. **Section VII o**f the NOFOs.

13. **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.

14. **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](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](https://grants.nih.gov/grants/peer-review.htm)).

    In addition to the standard review criteria described in Part 2. **Section V** of the NOFOs (also see: [https://grants.nih.gov/grants/peer-review.htm)](https://grants.nih.gov/grants/peer-review.htm), note that the current NOFOs have **additional and specific review criteria.** Please see the section, **"Specific to this NOFO"** within Section V for Factor 1: Importance of Research, Factor 2: Rigor and Feasibility, and Factor 3: Expertise and Resources.

    We also encourage applicants to review the **American Indian and Alaska Native Research in the Health Sciences: Critical Considerations for the Review of Research Applications** ([https://dpcpsi.nih.gov/sites/default/files/Critical_Considerations_for_Reviewing_AIAN_Research_508.pdf](https://dpcpsi.nih.gov/sites/default/files/Critical_Considerations_for_Reviewing_AIAN_Research_508.pdf)), which provides context for American Indian/Alaska Native-focused research to help reviewers interpret and understand the information being presented.

15. **Who makes funding decisions for IRINAH applications?**
    Applications are assigned to a specific NIH Institute or Center that makes the funding decision based on its research objectives and funding processes.

16. **How many awards will be given each year? Will there be a set payline for these NOFOs?**
    IRINAH funding decisions are based on the research objective and funding process for the specific Institute or Center to which the application is assigned.  Thus, there is no specific number of awards given each year and there is no set payline for the IRINAH NOFOs.

17. **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**.

18. **Do community partners need a PhD 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.

19. **Can submissions be from multiple principal 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.

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

21. **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)

22. **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

23. **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**.