

# Intervention Research to Improve Native American Health (IRINAH) *Informational Webinar*

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The webinar is being recorded.

Please put questions in the Q & A box

For more information about  
**IRINAH**, visit:

[https://cancercontrol.cancer.gov/  
native-american-intervention](https://cancercontrol.cancer.gov/native-american-intervention)

*short URL:*

<https://go.nih.gov/HfHkj46>



# Overview

- Welcome
- IRINAH Program
- IRINAH Notices of Funding Opportunity
- Working with NIH Staff
- Q&A

# IRINAH Program Overview and Objectives

*Shobha Srinivasan, National Cancer Institute*

## Included Populations

For the purposes of the IRINAH NOFOs, **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.

## Objectives of IRINAH

To support research on interventions to improve health in Native American populations. This includes:

1. **etiologic research** that will directly inform intervention development or adaptations
2. research that **develops, adapts, or tests interventions** for health promotion, prevention, treatment, or recovery
3. research on **dissemination and implementation** that develops and tests strategies to overcome barriers to the adoption, integration, scale-up, and sustainability of effective interventions



# IRINAH Notices of Funding Opportunity (NOFOs)

# What are the IRINAH NOFOs?

1. **PAR-23-298 (R01)** -  
<https://grants.nih.gov/grants/guide/pa-files/par-23-298.html>
2. **PAR-23-299 (R21)** -  
<https://grants.nih.gov/grants/guide/pa-files/PAR-23-299.html>
3. **PAR-23-285 (R34)** -  
<https://grants.nih.gov/grants/guide/pa-files/PAR-23-285.html>

## What's **New** with the IRINAH NOFOs?

1. Deadline: **October 21** (in 2024, 2025, and 2026)
2. Addition of **R34** mechanism
3. **Non-responsiveness** criteria
4. Participating **Institutes/Centers** (ICs)



# Differences between R01, R21, and R34

	R01 <u>PAR-23-298</u>	R21 <u>PAR-23-299</u>	R34 <u>PAR-23-285</u>
<b>Purpose of the Award</b>	<ul style="list-style-type: none"> <li>Supports research on a discrete, specified, circumscribed project</li> </ul>	<ul style="list-style-type: none"> <li>Exploratory/development grant that supports investigation of novel scientific ideas or technologies</li> </ul>	<ul style="list-style-type: none"> <li>Supports the initial development of a clinical trial or research project</li> </ul>
<b>Budget (direct costs)</b>	<ul style="list-style-type: none"> <li>Budget is not limited, but prior approval required for budgets over \$500,000</li> </ul>	<ul style="list-style-type: none"> <li>Maximum of \$275,000 over total project period</li> <li>Maximum of \$200,000 in any one year</li> </ul>	<ul style="list-style-type: none"> <li>Maximum of \$450,000 over total project period</li> <li>Maximum of \$225,000 in any one year</li> </ul>
<b>Duration</b>	<ul style="list-style-type: none"> <li>Up to 5 years</li> </ul>	<ul style="list-style-type: none"> <li>Up to 2 years</li> </ul>	<ul style="list-style-type: none"> <li>Up to 3 years</li> </ul>
<b>Details</b>	<ul style="list-style-type: none"> <li>12-page Research Strategy</li> <li>Preliminary data are <u>not</u> required for IRINAH R01, though may be included if available</li> </ul>	<ul style="list-style-type: none"> <li>6-page Research Strategy</li> <li>Preliminary data <u>not</u> required; however, they may be included if available</li> <li>Extensive background material or preliminary information also not required</li> <li>Emphasis on conceptual framework, level of innovation</li> </ul>	<ul style="list-style-type: none"> <li>12-page Research Strategy</li> <li>Preliminary data <u>not</u> required</li> <li>Supports planning studies to strengthen partnerships, develop/adapt interventions, collect feasibility &amp; acceptability data, and/or address CT study design</li> <li>Must include “<b>Milestones and Study Targets</b>”</li> <li><b>Will <u>not</u> support research testing intervention efficacy/effectiveness</b></li> </ul>

## R34 Milestones and Study Targets *(see Part 2. Section IV of NOFOs)*

- Describes the **decision points** that would justify moving to a full trial
- Discuss in the context of the **goal of future trial**
- Include specific ways that reaching the targets will indicate **readiness for a future trial of the intervention**
- **Examples:**
  - Agreements reached with community and tribal partners
  - Metrics for measurement validation
  - Success metrics for recruitment strategies
  - Thresholds for measures of intervention and/or protocol acceptability and feasibility

# IRINAH Non-Responsiveness Criteria

*Applications with the following attributes will be deemed **non-responsive** and will **not** be reviewed (See **Part 2. Section I** of NOFOs):*

## ■ R01 and R21

- 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**

## ■ R34

- R01 and R21 criteria PLUS...
- 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**

# Participating Institutes/Centers (ICs)

*Not all ICs participate in all three grant mechanisms. See **Part 2. Section I** of NOFOs 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](#)) ● ●

The following NIH Offices may co-fund applications assigned to those Institutes/Centers:

- Office of Disease Prevention ([ODP](#))
- Office of Behavioral and Social Sciences Research ([OBSSR](#))
- Office of Research on Women's Health ([ORWH](#))

● R01

● R21

● R34

# Community Engagement



- Research must be conducted in a **community-engaged** manner
  - The community has an **equal voice** as a research partner
  - The research should be consistent with and informed by community desires
- Partnerships and collaborations must be thoroughly documented in the Research Strategy (*see Part 2. Section IV of NOFOs*)
  - Describe the community's involvement in the overall project and history of the partners collaborating on prior research projects or activities
  - Describe the scientific, logistic, and organizational responsibilities of each collaborator
- Letters of Support: each Native American organization that participates in the project should submit a letter of support (*see Part 2. Section IV of NOFOs*)
  - **Note:** 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** (this flexibility is **NOT** extended to letters from Key Personnel and consultants affiliated with academic/research organizations)

# Additional Application Requirements

See **Part 2. Section IV** of *NOFOs for Application and Submission Information*

- **R&R or Modular Budget**
  - Budgets should include domestic travel funds for one or more study team members to attend the annual IRINAH investigators meeting
- **Data Management and Sharing Policy**
  - All R01, R21, and R34 applications (among others) are now required to include a **Data Management and Sharing Plan**
    - Plan is submitted as an “Other Plan” attachment
    - The policy seeks to maximize data sharing while including justifiable reasons not to share (<https://sharing.nih.gov/faqs#/data-management-and-sharing-policy.htm?anchor=56549>)
    - [sharing.nih.gov](https://sharing.nih.gov) has many resources, including sample plans
      - Please review [Considerations for Researchers Working with AI/AN Communities](#) and [NOT-OD-22-214](#)

# IRINAH Network

- Current co-chairs: Michelle Johnson-Jennings and Elizabeth Rink
- Network meetings
  - Annual in-person: focus of meeting selected by network
  - Quarterly teleconferences
- Past network activities
  - Special issue: Prevention Science
  - Working on publications
- Website: <https://cancercontrol.cancer.gov/native-american-intervention>



# IRINAH Review Criteria



# IRINAH Study Section



Center for  
Scientific Review

- recurring **Special Emphasis Panel**
  - review applications on special topics
  - include only temporary members, recruited based on expertise needed for each meeting

# Review Criteria

See **Part 2. Section V** of *NOFOs for Application Review Information*

- Only the review criteria described in **Section V** of the NOFOs will be considered in the review process
- ***American Indian and Alaska Native Research in the Health Sciences: Critical Considerations for the Review of Research Applications***
  - Provides critical considerations for NIH reviewers assessing applications focused on AI/AN populations
  - Provides context for applicants' AI/AN-focused research to help reviewers interpret and understand the information being presented



[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)

# Standard Review Criteria

## Overall Impact

Will it have a sustained and powerful impact in the field?

## Criterion Scores

### ***Significance***

How important is the science that is proposed?

How strong is the empirical foundation (rigor of prior research)?

### ***Investigator***

How well suited are the PI and research team to the project?

Consider their training and accomplishments in the context of their career stage.

### ***Innovation***

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?

### ***Approach***

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?

### ***Environment***

Will the scientific environment in which the work will be done contribute to the probability of success?

# Review Criteria Specific to the NOFOs

## ■ 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?
- To what extent will the project, if completed successfully, improve the health of one or more Native American communities?

# Review Criteria Specific to the NOFOs

## ■ Investigators

- 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 for examples, including those for community members serving as an investigator)?

### **From Section IV (partial)**

- efforts to build relationships and trust with communities
- knowledge of community systems and settings, and leadership roles in the community
- productivity of community-based investigators may rely on a description of their proficiency in working within the community

# Review Criteria Specific to the NOFOs

## ■ 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 (see Section IV for further examples)?

### From Section IV (partial)

- the use of Indigenous Knowledge
- research capacity development
- novel approaches to community engagement and/or participant recruitment
- determination of culturally/clinically meaningful effect sizes

# Review Criteria Specific to the NOFOs

## ■ 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?
- If there are activities proposed for intervention or measure development or adaptation, to what extent are the intervention or measurement development/adaptation activities **scientifically justified, adequately described, and appropriate to the population?**
- If intervention research is proposed, to what extent does the application address the **future sustainability and/or implications for implementing and/or disseminating the intervention**, if successful, to other Native American communities/tribes?
- If etiology research is proposed, to what extent **will the findings inform** prevention, treatment, or recovery interventions?

# Review Criteria Specific to the NOFOs

- **Environment**

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



# Working with NIH Staff

# Getting to Know NIH Staff



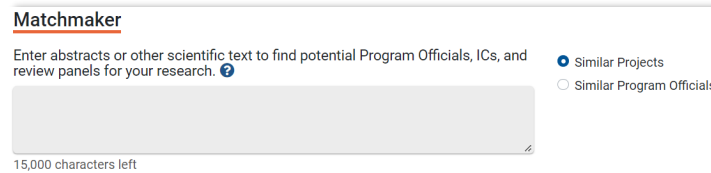
- **Program Official:** extramural staff scientist responsible for developing research initiative, and for the programmatic, scientific, and/or technical aspects of assigned applications and grants
- Often referred to as Program Director or Program Officer

- **Scientific Review Officer:** an extramural staff scientist and the federal official responsible for ensuring that applications receive an objective and fair initial peer review



# Who to Reach Out to?

- Read Notices of Funding Opportunities (NOFOs) thoroughly beforehand
  - RFA, PA, PAR, NOSI - Make **sure** the Institute is participating
- The Scientific/Research Contact(s) listed on the NOFO (*see **Part 2. Section VII** for a list of Program Officials*)
  - **Reach out early**: Email with a brief summary of your area of work and suggest a time for a call
- Utilize NIH Matchmaker tool: <https://reporter.nih.gov/matchmaker>
  - Enter abstracts or other scientific text and Matchmaker will return lists of similar projects from RePORTER or program officials associated with those projects



The screenshot shows the NIH Matchmaker tool interface. At the top, the title "Matchmaker" is underlined. Below it, a descriptive sentence reads: "Enter abstracts or other scientific text to find potential Program Officials, ICs, and review panels for your research." To the right of this text are two radio button options: "Similar Projects" (which is selected) and "Similar Program Officials". Below the text is a large, empty text input field. At the bottom left of the input field, it says "15,000 characters left".

# How to Contact Program Officers?



Identify Program Officer from FOA lists



Send them one-pager (Specific Aims page)



Highlight questions



Ask for 30-minute call



Don't be shy to email reminders (weekly, not daily)



## Contact to obtain information on:

- Program priorities and areas of interest
  - whether your proposed topics align with the Center/Institute's research objectives
- Type and requirements for funding mechanisms
- Institute-specific policies & procedures
- Grant Process (including Review)
- Post Review
  - discuss Summary Statement – even if “not discussed”

# NIH PO Office Hours

<b>Thursday February 29 2-3 pm ET</b>	<b>Wednesday March 6 1:30-2:30 pm ET</b>	<b>Thursday March 7 3-4 pm ET</b>
NIAID	NIAAA	NICHD
NIDCR	NIAMS	NIDA
NICCH	NIDCD	NIMHD
NIEHS	NHLBI	ODP
NIMH	NINR	ORWH

***Stay tuned for registration details and final IC schedule!***

For more information about  
**IRINAH**, visit:

<https://cancercontrol.cancer.gov/native-american-intervention>

*short URL:* <https://go.nih.gov/HfHkj46>



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**Questions?**



# What does the ‘Clinical Trial Optional’ Mean on the NOFOs?

- The R01, R21 and R34 NOFOs are ‘Clinical Trial Optional’
  - This means that you can propose clinical trial and 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>)
  - Please review the **Clinical Trial FAQ**: <https://grants.nih.gov/policy/clinical-trials/faqs.htm> especially the sections on “Health-related biomedical/behavioral outcome” and “Intervention”
  - Applications that do not include all required documentation for clinical trials for review, but are determined to be clinical trials, may not be considered for funding