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Tribal Institutional Review Board Establishment and Enhancement (TIRBEE)

PAR-24-260

Pre-Application Webinar

NIGMS Staff Participation

Mercedes Rubio– Director, Division for Research Capacity Building

Erin Iturriaga – Chief, Health Research and Development Programs Branch

Crystal Richards – Program Officer, Health Research and Development Programs Branch, NARCH program lead

Robert Altieri – Team Lead, Grants Administration Branch

Q&A via Chat Window, moderated by Erin Iturriaga

Slides and Webinar Recording will be posted on the NARCH website.
If you think of questions after the webinar, send an email to
crystal.richards@nih.gov

TIRBEE (R24) - Purpose

The purpose of the TIRBEE award is to support federally recognized Tribes, Tribal colleges and universities, Tribal health programs, or Tribal organizations (collectively, eligible Tribal entities) to:

1. Establish Tribal Institutional Review Boards (IRBs) or
2. Enhance the capacity of existing Tribal IRBs.

TIRBEE (R24) Application Due Dates

FY	Due Date	Review	Council	Earliest Start Date
2026	January 27, 2026	July 2026	October 2026	December 2026
2027	January 27, 2027	July 2027	October 2027	December 2027

TIRBEE (R24) Eligible Organizations

The applicant organization must meet one of the following criteria:

- A federally (or other) recognized **Tribe**.

- A **Tribal college or university, a Tribal health program, or a Tribal organization or government**.

- A consortium of two or more **Tribal entities is allowed as long as all meet eligibility requirements.**

TIRBEE (R24) Eligible Individuals

- PD/PI must have a primary appointment with the applicant organization.

- PDs/PIs with special employment arrangements, such as interorganizational personnel agreements among federally recognized AI/AN Tribes, are allowable.

- Multi PI applications are allowed – all MPIs must be from eligible Tribal entities.

- Non-contact PD/PI must also have a primary appointment at an eligible Tribal entity.

- Partners who are not PIs are allowed: can be NARCH awardees, other Tribal entities, or non-Tribal entities.

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TIRBEE (R24) Award Budget

- Maximum $350,000/yr Direct Costs for up to 5 years.

• For applications that include partner organizations that are not Tribal entities, the direct costs of subcontracts to these organizations, combined, must be 25% or less of the application's overall direct cost budget.

• A TIRBEE Grant is not renewable. If a TIRBEE application is unsuccessful the 1st time, resubmission is allowed.

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TIRBEE (R24) - Supported Activities

Supported activities may include but are not limited to:

- Recruiting staff, including consultants and mentors as needed.

- Establishing policies and procedures for day-to-day IRB operations.

- Developing communication and information systems.

- Providing equipment and software that are needed to implement protocol review and track ongoing IRB-related activities.

- Establishing best practices for providing IRB oversight and support.

- Providing or supporting competency-based training, coursework, conference attendance, and related activities.

Application Requirements

- The submitting organization must complete **required registrations** in advance:

- SAM

- eRa Commons

- Grants.gov

- Letter of Support (required) from the applicant organization that is signed by an authorized senior organizational official from the applicant Tribal entity such as a Tribal council leader or president of a Tribal college/university.

- Data Management and Sharing Plan is **not required** for this NOFO.

TIRBEE Application Requirements

- Page limits as described in the [SF424 application guide](#)

  - Project Summary/Abstract – 30 lines of text
  - Project Narrative – 3 sentences
  - Specific Aims – 1 page
  - Research Strategy – 12 pages

Research Strategy – Overall Goal

Outline the objectives and approaches for IRB workforce and infrastructure development.

Use the following headings in the Research Strategy:

- Program Description
- Regulatory Competencies Plan
- IRB development Plan
- Sustainability Plan

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Research Strategy Elements - I

Program Description - Describe the goals of the application (IRB establishment or enhancement) in the context of currently available IRB-related resources and participation in existing IRBs.

In this section, please describe the following:

- The organization's current IRB capability and any existing partnerships or collaborations with other organizations.

- Overview of plans to build IRB capacity and accomplish the Specific Aims.

- The relationship of the proposed IRB activities to the administrative structure of the applicant organization(s) and Tribal community(ies) it serves.

- The roles and contributions of members of a Tribal consortium (if proposed) and any additional partners that will be involved in building IRB capacity.

- Provide a plan for regular evaluation of IRB-related activities.

Research Strategy Elements - II

Regulatory Competencies Plan - Describe plans for providing culturally appropriate and federally required education and training to individuals administering and coordinating an IRB and/or those who will participate in IRB review.

In this section, please describe the following:

- Plans for recruiting Tribal members interested in serving as IRB members.

- Proposed IRB courses to train IRB staff.

- Activities to enhance and maintain IRB member and staff knowledge of federal, institutional, and Tribal human subjects research regulatory policies.

- Plans for training and formally onboarding trained Tribal members into a newly established or enhanced Tribal IRB.

- Plans to track the progress of individuals for completing training and certifications as well as participation in IRB reviews.

Research Strategy Elements - III

IRB development Plan - Describe the overall development strategy, operational plan, and organizational structure of the IRB.

In this section, please describe the following:

- Proposed IRB structure and its workflows.

- Currently available and proposed development of resources to support electronic information handling and secure management of data.

- Recruitment of IRB leadership and members with appropriate skills and knowledge.

- If establishing a new IRB, include plans for registering with the NIH Office of Human Research Protections and documenting IRB user Federal Wide Assurances.

- Overall feasibility for establishing or enhancing the Tribal IRB during the planning, implementation, and sustainability phases.

Research Strategy Elements - IV

Sustainability Plan - A primary goal of the TIRBEE Program is to develop and support sustainable IRB research infrastructure.

In this section, please describe the following:

- Address the need for continued competency training for IRB members and staff.

- Strategies for providing longer-term support for IRB activities.

- A contingency plan in the event key personnel cannot continue in their roles.

- A plan for filling IRB member and administrative staff vacancies.

- Contingencies to meet anticipated future IRB needs due to growth of human subjects research.

- Describe plans to maintain improvements to IRB capacity beyond TIRBEE funding.

Review Process: Step 1 – Administrative and Scientific Review

- **All applications go through Administrative Review by NIGMS Program Officers and Scientific Review by the NIGMS Scientific Review Branch.**

- **All applications deemed non-compliant, non-responsive, or ineligible will be withdrawn.**

- **To avoid this**:

  o Read and follow the NOFO [PAR-24-260](PAR-24-260) instructions.

  o Make sure all PIs are eligible.

  o Make sure the submitting organization(s) are eligible.

  o Apply a few days **prior** to the deadline, check your application, and make corrections if needed.

Review Process: Step 2 – Scientific Review

- Assigned reviewers provide **preliminary scores** (1 – 9) before the meeting starts (1 = best possible score, 9 = worst possible score).

- At the meeting, reviewers describe **strengths** and **weaknesses** of the application and **provide written critiques** according to the review criteria.

- All reviewers then **discuss** the application.

- All panel members **vote** on the application and provide their individual impact scores.

- Those scores are averaged and multiplied by 10 to give the **Final Overall Impact/Priority score,** which is available within **a few days** of the review meeting.

- **Summary Statements** are available **~30 days** later.

Advice to Applicants

- **Read the entire NOFO carefully.**

- **Pay attention to Section V - review criteria (<u>Section V</u>):** reviewers' critique templates contain these criteria/questions.

- **Optional: Use the PHS Assignment form** to indicate expertise needed, but **DO NOT** suggest reviewer names. You may provide names of those who **SHOULD NOT** review your application.

- **Who to contact and when:**

  - Before submission and after the Summary Statement is released: Program Officer (PO).

  - After submission and before the Review Meeting: Scientific Review Officer (SRO).

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Q&A

Thank you very much
Please type your questions into the Chat box