

Native American Research Centers for Health (NARCH) (S06) PAR-23-166

Pre-Application Webinar

January 17, 2024 2:30 – 4:00 pm EST

NIGMS Staff Participation

Michele McGuirl Acting Director, Division for Research Capacity Building

Krishan Arora Chief, Networks and Development Programs Branch and NARCH Program Lead

Kyungsook Gartrell Program Officer, Research Advancement Programs Branch **Christy Leake** Team Lead, Grants Administration Branch

Q&A via Chat Window, moderated by Michele

Slides and Webinar Recording will be posted on the NARCH website.

If you think of questions after the webinar, send an email to arorak@nigms.nih.gov



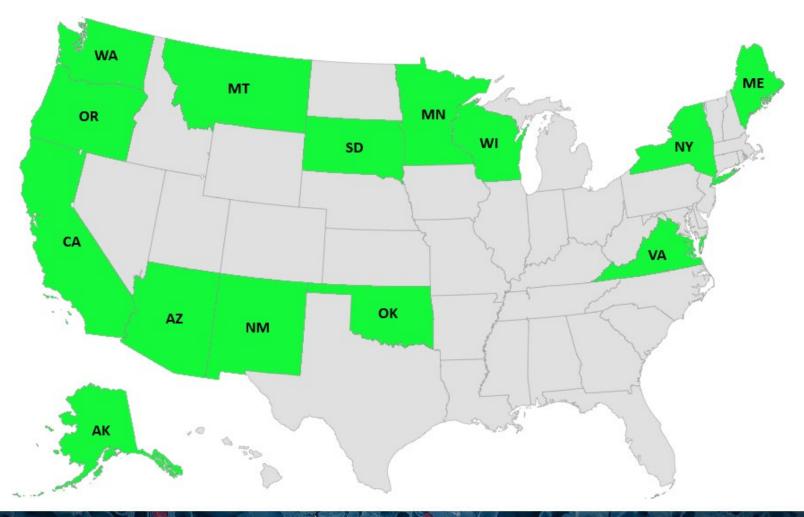
Native American Research Centers for Health (NARCH) Program

- Support federally recognized American Indian/Alaska Native (AI/AN) Tribes and organizations to build their capacity for doing health-related research.
- NARCH program began in 2001 in collaboration with Indian Health Service (IHS).
- Program management was moved from IHS to NIGMS, NIH in FY2017.
- NARCH is a trans-NIH program; each participating NIH ICO can support projects from different grant applications in their mission areas.

NARCH Program

NARCH Dashboard by States:

28 NARCH active awards to 19 Tribal entities in 14 states



NARCH Evaluation and Tribal Consultation

- Purpose: To improve the efficacy of the program in meeting the health research needs of Al/AN communities.
- Tribal Consultations report and feedback at MIGMS Evaluations
- Report presented to <u>National Advisory General Medical Sciences Council in Sep 2021</u>.

A summary of inputs from Tribal leaders

- Ensure that research and capacity building are primarily conducted by Tribal Nations and communities.
- Expand applicant pool through reducing the complexity of applications and supporting the development of new applicants.
- Ensure application review follow culturally-appropriate guidelines.
- Support AI/AN trainees earlier (starting in high school) and strengthen support to AI/AN institutions of higher learning.
- Increase overall program funding.



NARCH Program PAR-23-166

Based on the recommendations from the Tribal Consultation, the NARCH S06 program was revamped.

The new Notice of Funding Opportunity (NOFO) was issued with the purpose to:

- Support health-related research
- Research career enhancement
- Research infrastructure enhancement

NARCH Program PAR-23-166 Continued

Significant Changes:

- Ensure that the majority of NARCH funds remain with the Tribal entities rather than non-Al/AN partner organizations.
- Streamline the process for applicants.
- Career development at all stages including HS students.
- Incorporate culturally appropriate language into review guidelines.
- Increase the budget.
- Make it a 5-year award.
- Have annual application due dates.

Application Due Dates

FY	Due Date	Review	Council	Earliest Start Date
<mark>2024</mark>	July 08, 2024	November 2024	January 2025	April 2025
2025	July 08, 2025	November 2025	January 2026	April 2026
2026	July 08, 2026	November 2026	January 2027	April 2027

Letter of Intent should be sent to: Crystal Richards, Ph.D. (crystal.richards@nih.gov)

- Descriptive title of proposed activity
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
- Names of other key personnel
- Participating organizations(s)
- Number and title of this funding opportunity

Tribal Entities

- The applicant organization <u>must</u> meet one of the following criteria:
 - A federally 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 requirement

Organizational Eligibility

- An applicant organization must be an eligible Tribal entity and must be committed to supporting a NARCH S06 award and its goals.
- The applicant organizations should also have the research administrative infrastructure to manage the multiple-component grant.
- May partner with other eligible Tribal entities as well as additional non-Al/AN organizations.
- The application must be from, and the award must be made to a Tribal entity.

PD/PI Eligibility (Applies to All PD/PIs if MPI)

- 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 S06 awardees, other Tribal entities, or non-Tribal entities.

Budget and Application Types

- Maximum budget \$1.3 million/yr Direct Costs for up to 5 years.
- At least 60% or more of the budget must remain with the Tribal entity, the applicant organization.
- For applications that include partner organizations that are not Tribal entities, the direct costs of subcontracts to these organizations, combined, must be 40% or less of the application's overall direct cost budget.
- New and Resubmission applications are allowed.
 - If an S06 application is unsuccessful the 1st time, resubmission is allowed.

Number of Applications

- Up to two applications for the same due date, provided there is no overlap.*
- If a Tribal entity has <u>one active NARCH S06 award</u>, they can submit one more application, provided there is <u>no</u> overlap.*
- If a Tribal entity has <u>two active NARCH S06 awards</u>, they <u>cannot</u> receive a new NARCH award. If they submit applications in anticipation of expiration of one or both of its current NARCH S06 awards, a new award can only be made <u>after</u> a current NARCH S06 award has ended.*
- Active awards include those in No Cost Extension.
- * Discuss with the NIGMS Scientific/Research Contact listed in Section VII. Agency Contacts.

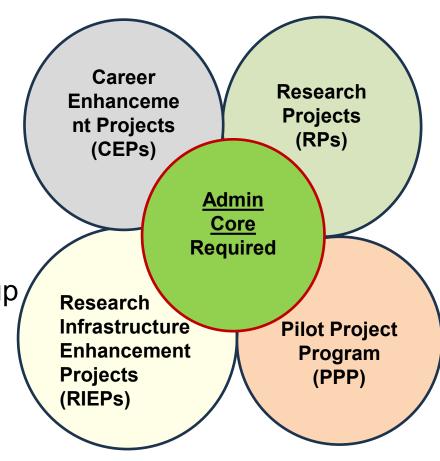
NARCH: Program Description

An Application <u>must</u> include:

- Overall
- Administrative Core

Applications <u>must</u> also include <u>one or more</u> components:

- Research Projects (up to 3)
- Pilot Project Program(1)
- Career Enhancement Projects (up to 2)
- Research Infrastructure Enhancement Projects (up to 2)
- *No overarching scientific theme is required for the application
 - Rather, the research projects should focus on the health research needs of the Al/AN community.



NARCH Application: Overall Component (Required, 6 pages)

- Overall vision, roles of lead/partner organizations.
- Current state of the health-related research enterprise at the applicant organization and, if applicable, partner organizations that are eligible Tribal entities.
- Organizational structure, grants administration infrastructure, and plans to address areas of weakness.
- If partner organizations are included, describe past collaborations and accomplishments with the partner organizations, and how the partner organizations will contribute to the proposed Center.
- Plans for ensuring that the research, career development and capacity building agendas are set by the Tribe(s) involved.

Overall Component (continued)

Letters of Support are required from each lead/partner organization*

- Tribal Resolutions or Tribal Letters of Support for the application and any specific components.
- All projects proposed in the application should have the approval of the Tribal governments with jurisdiction over each Tribal entity involved in the Center.
- If an application includes partner organizations, include a letter (or resolution)
 of support from each.
- The roles and commitments of the partner organization should be clearly described in the letter/resolution.
 - * Each letter should include the proposed Center's name, grant application title, and the title of any relevant component or project.
 - * Attach all Letters of Support in the Overall component

Overall: Data Management Sharing Plan

- The DMS Plan (1-2 pages) must be included in the Overall component in the "Other Plans" attachment if RPs or a PPP are proposed in the NARCH application.
- One DMS Plan per application. The plan covers the scientific data expected to be generated from all components. Use language like, "the data we expect to generate from the proposed research projects are in the following categories" and then describe the plans to share the data. Do not organize the DMS Plan by Research Project number or RP Leader name.
- NIH <u>Scientific Data Sharing webpage</u> has descriptions of the elements to be included and a template.
- Good to describe foreseeable limitations on data sharing, for example, for projects involving AI/AN participant data and/or engagement with AI/AN tribes, including any necessary Tribal approvals, Tribal sovereignty and privacy considerations, or Tribal community review. See supplemental Notice regarding the DMS Plan for AI/AN populations, NOT-OD-22-214.

Administrative Core (AC) (Required, 6 pages)

- Manages the administration of the NARCH Center.
- Manages any partner organizations, advisors, or consultants.
- Handles budget, prepares and submits program and financial reports, ensures all activities are compliant with federal regulations.
- Organizes and coordinates Center-wide activities such as seminars and workshops for research and career development.
- Coordinates activities of the proposed components by working with the leads.
- Coordinates evaluation of the Center.
- AC budget may not exceed \$100,000 DC/yr.

Research Projects (RPs) (Optional, 6 pages each)

May support up to 3 RPs

- Maximum budget \$200,000 DC/yr per project, for maximum of 5 years.
- Could be more for clinical trials but only if well justified.

Focus on issues related to Al/AN health, such as

- Factors contributing to and conditions that impact AI/AN health.
- Mechanisms underlying diseases or conditions prevalent in AI/AN communities.
- Development, implementation, and evaluation of interventions addressing health challenges.
- A research plan on general strategies, approaches, timelines, and milestones, instead of specific experimental procedures or protocols. Incorporate culturally appropriate approaches and methodologies. If CTs, include study design, methods, and interventions.
- If human subjects are involved, provide a plan to address any gap in the leader's scientific and regulatory knowledge base relevant to the study.

RP Leader:

- Should have expertise in the subject area.
- May not receive funding for another RP or PP under the Center.



Pilot Project Program (PPP) (Optional, 6 pages)

- PPP develops and manages an internal funding mechanism to support exploratory and/or preparatory research as pilot projects (PPs).
 - PPs may address any question in health-related research.
 - Plans for solicitation, review, and selection of PP applications, and mentoring.
 - Do Not include PPs in the application.

PP Leader:

- Should be <u>Early Stage Investigators</u> (ESIs)/<u>New Investigators</u> as defined by NIH.
- May not simultaneously lead more than one PP nor a RP supported by NARCH award.
- **PPP Director**: Is not eligible to receive a PP from the NARCH.
 - Should have experience in mentoring, health-related research, and knowledge in culturally appropriate research approaches.

PPP budget:

- Maximum budget: \$200,000 DC/yr for all activities and pilots.
- Up to \$65,000 DC/yr, may be renewed once; a total of two years support for a PP.



Career Enhancement Projects (Optional, 6 pages)

- May support up to 2 CEPs
- Enhance knowledge and research skills of participating health researchers.
 - For early career investigators, post-doctoral fellows, graduate students, undergraduate students, and/or high school students.

Research Plan

- Eligibility criteria of participants and a plan for the recruitment, selection, and support of participants.
- Design of the program, its target participants, curriculum/program, approaches, timeline and anticipated outcomes; Incorporate development of participants' quantitative and computational skills as part of the planned activities.
- CEP Leader:
 - An investigator with experience in mentoring, career development, research, and knowledge of culturally appropriate research and educational approaches.
- CEP budget: Maximum budget \$200,000 DC/yr per project.



Research Infrastructure Enhancement Projects (Optional, 6 pages)

- May support up to 2 RIEPs
- Address a specific research infrastructure need of the NARCH, such as:
 - Support technical or methodological cores to develop/strengthen technical capacity needed for health-related research.
 - Research resources such as a bio- or data- repository.
 - Research administration infrastructure such as Tribal Institutional Review Boards.
- Research Plan: Needs, design, timeline and management plan, coordination with other programs.
- RIEP Leader:
 - Should have expertise in the appropriate areas of scientific capacity building.
- RIEP budget: Maximum budget \$200,000 DC/yr per project.

Summary of Components

Required:

- Overall: Include Letters of Support for <u>all components</u> in this section as an attachment; One DMS Plan, if RPs or a PPP proposed.
- Administrative Core

Optional: At least one of the following components is required; if more than one, any combination is allowed:

- Research Projects (up to 3)
- Pilot Project Program (1), if included, <u>do not</u> describe individual PPs in the application
- Career Enhancement Projects (up to 2)
- Research Infrastructure Enhancement Projects (up to 2)

Include:

- Data Management Sharing Plan: if research is proposed (RPs or PPP)
- Human Subjects and Clinical Trials Information: if proposed in the RPs
- Vertebrate Animals Information: if proposed in the RPs
- Authentication of Key Biological and/or Chemical Resources: if the proposed RPs will use
- Select Agent Research: if the proposed RPs will use
- Resource Sharing Plan: if the proposed components will develop any resources

Review Process: Step 1 – Administrative Review

- All applications go through Administrative Review by NIGMS POs and CSR.
- All applications deemed non-compliant/non-responsive/ineligible are withdrawn. To avoid this:
 - Read and follow the <u>NOFO (PAR-23-166)</u> instructions.
 - Make sure all PIs are eligible.
 - Make sure the submitting organization(s) are eligible.
 - Apply a few days prior to the deadline, check your application, and make corrections if needed.

Review Process: Step 2 – Scientific Review

- Applications are divided among Special Emphasis Panels (SEPs).
- Reviewer Orientation Meetings: Same material is given to all reviewers, includes guidance about reviewing Tribal research.
- Reviewer Assignments: At least two reviewers are assigned to each component of the application.

Process

- Assigned reviewers present comments on each component, then the panel discusses it.
- All panel members vote individually on every component of the application and provide individual impact scores.
- Each component gets overall impact score.

Advice to Applicants

- Read the entire NOFO carefully.
- Complete all the required registrations for the submitting organization.
- Pay attention to Section V review criteria (<u>Section V</u>) reviewers' critique templates contain these criteria/questions.
- **DO NOT duplicate letters of support.** Avoid including letters of support that do not add substance it can limit the pool of reviewers and usually annoys reviewers.
- 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).

Post Award Program & Reporting Requirements

- Prior Approval of Pilot Projects
 - If a Pilot Project Program is proposed, prior approval by NIGMS is required before a new Pilot Project can begin. See details in Section VI.
- Annual <u>Research Performance Progress Report (RPPR)</u> and financial statements as required in the <u>NIH Grants Policy Statement</u>.

