Emergency Award: Rapid Acceleration of Diagnostics
Tribal Data Repository (RADx TDR) (U24 – Clinical Trial Not Allowed)

Technical Assistance Webinar
RFA-OD-22-011

National Institute on Minority Health and Health Disparities
May 2, 2022
Webinar Tips

• Please remain on mute during presentation.

• The slides and recording of today’s webinar will be available on the NIMHD website: www.nimhd.nih.gov

• Submit questions throughout the presentation via e-mail to vanessa.marshall@nih.gov
RADx—Tribal Data Repository Team

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Agenda

I. RFA objectives and expectations
II. Peer review of applications
III. Timeline for submission, review, and selection of applications
IV. Participant questions

NOTE: Questions about specific aims will not be addressed
I. RFA objectives and expectations
Rapid Acceleration of Diagnostics (RADx): Programs

Supplemental Appropriations Language:

...not less than $1,000,000,000 shall be transferred to the “National Institutes of Health—Office of the Director” to develop, validate, improve, and implement testing and associated technologies; to accelerate research, development, and implementation of point of care and other rapid testing; and for partnerships with governmental and non-governmental entities to research, develop, and implement the activities outlined in this provision...


(Courtesy: (Adapted from T. Schwetz)
## Rapid Acceleration of Diagnostics (RADx): Programs

<table>
<thead>
<tr>
<th>Program</th>
<th>Description</th>
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<tbody>
<tr>
<td>RADx-Tech</td>
<td>Competitive, rapid three-phase challenge to identify the best candidates for at-home or Point-of-Care COVID-19 tests</td>
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<tr>
<td>RADx-Advanced Technology Platforms (RADx-ATP)</td>
<td>Rapid scale-up of advanced Point-of-Care technologies and laboratories to accelerate, enhance and validate utility of ultra-high throughput machines and facilities</td>
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<tr>
<td>RADx-Radical (RADx-rad)</td>
<td>Develop and advance novel, non-traditional approaches, or new applications of existing testing approaches</td>
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<tr>
<td>RADx-Underserved Populations (RADx-UP)</td>
<td>Interlinked community-engaged projects on implementation strategies to enable and enhance COVID-19 testing in underserved and/or vulnerable populations</td>
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RADx | National Institutes of Health (NIH) [https://www.nih.gov/research-training/medical-research-initiatives/radx](https://www.nih.gov/research-training/medical-research-initiatives/radx)
RADx\textsuperscript{1}—Tribal Data Repository Tribal Consultation Process

- **May 2020:** NIH Tribal Consultation for COVID-19 Research

- **July 20, 2021:** NIH RADx Tribal Data Repository-NIH Pre-Tribal Consultation Informational Webinar\textsuperscript{2}

- **July 30, 2021:** NIH RADx Tribal Data Repository-NIH Tribal Consultation\textsuperscript{2}

- **August 31, 2021:** NIH RADx Tribal Data Repository-End of Open Comment Period

\textsuperscript{1}Rapid Acceleration of Diagnostics (RADx) Initiative [https://www.nih.gov/research-training/medical-research-initiatives/radx](https://www.nih.gov/research-training/medical-research-initiatives/radx)

General Goals of TDR:

*Tribal Data Repository will:*

- Support and promote AI/AN researchers and other scientists working with AI/AN communities
- Help contribute toward a better understanding of COVID-19 impact
- Provide data to allow for data informed decisions and policy development in addressing the COVID-19 pandemic and potential future pandemics

*Note:*

- No biospecimens will be stored within the RADx TDR
- Intended to be independent from and not associated with NIH or NIH existing programs, such as the All of US Program or the National COVID Cohort Collaborative (N3C)
RADx-Tribal Data Repository

RFA-OD-22-011  Emergency Award: Rapid Acceleration of Diagnostics Tribal Data Repository (RADx TDR) (U24 Clinical Trial Not Allowed)

Core Objectives

+ Is a central research data repository resource for researchers and their collaborators who are generating or interested in working with Tribal RADx research data.

+ Collaborate with the Coordination and Data Collection Center (CDCC).

Data Coordinating Centers

• RADx-UP
• RADx-Tech
• RADx-RAD
• RADx Digital Health

RADx Data Hub (Repository)

Studies are discoverable in the RADx Data Hub and dbGaP catalogue listings.

Tribal Data Repository

- Tribal sovereignty and governance
- Manage and share Tribal-Indigenous research data
- Coordinate with RADx-UP Data Coordination Center
- Enhance Tribal data science capabilities

Researchers Analytics Environments

• Data Management
• Data Curation and Harmonization
• Researcher Auth Service (RAS)
Rapid Acceleration of Diagnostics (RADx): Some Points Considered

**F.A.I.R.**
- Strengthen Engagement built on Trust Between Researchers and Tribal Nations
- Train Researchers to Responsibly and Respectfully manage and share AI/AN Data
- Ensure Research Practices Align with Laws, Policies, and Community Partners

**C.A.R.E.**
- Findable
- Accessible
- Interoperable
- Reusable
- Collective Benefit
- Authority to Control
- Responsibility
- Ethics

**NIH TRIBAL HEALTH RESEARCH OFFICE**


Initiative Description

- RADx TDR is a **four-year cooperative agreement** to support COVID-19 testing and vaccination hesitancy research activities collected by RADx projects in Tribal communities
  - The TDR will focus on data storage, access and monitored sharing of AI/AN RADx research data
- Overall coordination of data collection, management guidance, and support of RADx AI/AN data
- Negotiate and execute Data Transfer, Ownership, and Use Agreements (DTOUA) with Tribal Nations and communities contributing data
- Determine the process for review and approval for data access
- Provide data outcomes that inform the COVID-19 impact
- Coordinate with the RADx-UP CDCC for community engagement
- Conduct on-going discussions with Tribal Nation leadership and other designated representatives from RADx Program AI/AN communities
Required Elements

• Administrative Operations and Logistics
  • Implementing a governance structure under principles and practices of tribal sovereignty
  • Provide administrative, fiscal, and management oversight
    • data sharing, access provision, regular weekly progress reporting, and evaluation functions
    • synergistic resources, when possible, with the RADx UP Program CDCC
  • prepare and distribute reports to the NIH

• Data Collection, Integration and Data Sharing
  • establish a secure, centralized, user-friendly data repository that can accept individual participant data including unique participant IDs
  • facilitate data standardization, harmonization, integration, and analysis for projects using RADx AI/AN data
  • encourage adherence to federal health data standards
Cooperative Agreement

• Definition: An "assistance" mechanism, in which substantial NIH programmatic involvement with the awardees is anticipated during the performance of the activities provide administrative, fiscal, and management oversight.

• NIH's purpose: To support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role

• Roles and Responsibilities:
  • PD(s)/PI(s) have the primary responsibility
  • NIH staff have substantial programmatic involvement that is above and beyond the normal stewardship role in awards
  • Areas of Joint Responsibility
Responsiveness

Applications which propose studies in *vertebrate animals* and / or *the inclusion of biospecimens* will be considered *non-responsive* to this funding opportunity and will be withdrawn without review.
**Key Definitions**

- **Common Data Elements (CDEs)** are a type of health data standard commonly used and reused to provide a way to standardize data collection.

- **Data Use Agreements (DUAs)** are contractual documents used for the transfer of nonpublic data that is subject to some restriction on its use.

- **Data Transfer Agreements (DTA)** are a legal contract governing the transfer of non-human subject data or completely de-identified human subject data.

- **Artificial Intelligence** is the theory and development of computer systems able to perform tasks that normally require human intelligence.

- **Data Ecosystem** refers to the programming languages, packages, algorithms, cloud-computing services, and general infrastructure an organization uses to collect, store, analyze, and leverage data.

- **Hashing** is taking a variable created for storing data and representing it as a value with a shorter string than the original.
II. Peer Review of Applications
Peer Review RFA-OD-22-011- Clinical Trials Not Allowed

• Applications will be evaluated for completeness and compliance with instructions by CSR and NIMHD Program Staff.

• Program Staff from participating Offices and Institutes (ODSS, THRO, and NIMHD will assess the application for responsiveness to the RFA-OD-22-011.

NIMHD Scientific Review Branch will coordinate and manage the review of the applications.

• A letter of intent to submit is not mandatory and it is not binding however it is helpful to the Review branch

• Applications will be assigned to a special emphasis panel (SEP).
  • Use eRA Commons to access administrative information relating to your application.

• Administrative Review of Applications
  • Based on FOA RFA-OD-22-011 requirements and NIH peer review policy and procedures.

• Scientific Expertise
  • As defined in the FOA: RFA-OD-22-011
  • Collective expertise based on content of the applications
  • At least 3 reviewers will be assigned to each application

• Roster will be posted approximately 30 days before the meeting.
  • Do not contact the members of the review panel (NOT-OD-22-044)

• Post Submission Materials:
  • Applicants are required to follow the instructions for post-submission materials, as described in the policy NOT-OD-22-113.
Application Review Information Section V

- Reviewers will consider the criteria described in Section V of the FOA: RFA-OD-22-011 in the determination of scientific and technical merit.

- Read this section carefully and make sure the questions included in Section V of the FOA are addressed.

- In addition to the standard review questions, make sure that the FOA specific questions are addressed.
Application Review Information (Section V)

Scored Review Criteria:

- Overall Core
  - Significance
  - Investigators
  - Innovation
  - Approach
  - Environment

- FOA Specific Criteria of review
  - Program goals
  - Mechanism specific characteristics
  - Review Criteria: Specific to this FOA queries
Additional Review Criteria

Scored Review Criteria:

• **Study Timeline**
  • Detail description
  • Timeline feasible and justified
  • Efficient and resourceful
  • Discussion of challenges

• **Human subjects**
  • Protection of Human Subjects against research risk
  • Five criteria
  • Ability to protect the identity of both individual study participants as well as Tribal Nation and community identity

• **Inclusion**
  • Women
  • Lifespan
Review Process

The NIH utilizes a 9-point rating scale (1 = exceptional; 9 = poor) for all applications.


Final Impact Score based on average of all voting reviewers x 10
- Scores range from 10 (exceptional) to 90 (poor)

A summary statement for all applications would be available approximately 30 days after the review meeting

Do not contact the members of the review panel!
Peer Review Resources

• The Center for Scientific Review (CSR) has produced a series of webinars and videos to give you an inside look at how scientists from across the country review NIH grant applications for scientific and technical merit: click here.

• Resources for using eRA Commons: click here.

• Problems with submission process: click here.
  • Always contact eRA Service desk
III. Timeline for submission, review, and selection of applications
Key Dates

Posted: April 6, 2022
Letter of Intent: May 1, 2022
Application Due: May 31, 2022
Review Dates: July 2022
Council Dates: August 2022
Earliest Start Dates: September 2022
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IV. Participant Questions