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

Technical Assistance Webinar

RFA-OD-22-011

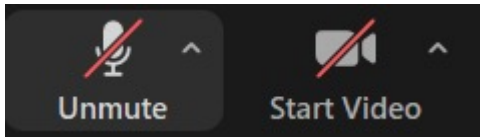
National Institute on Minority Health and Health Disparities

May 2, 2022

National Institute on Minority Health and Health Disparities

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

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I. RFA objectives and expectations

Rapid Acceleration of Diagnostics (RADx): Programs

Signed into law, April 24, 2020

https://www.nih.gov/news-events/news-releases/nih-mobilizes-national-innovation-initiative-covid-19-diagnostics

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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

Program	Description
RADx-Tech	Competitive, rapid three-phase challenge to identify the best candidates for at-home or Point-of-Care COVID-19 tests
RADx-Advanced Technology Platforms (RADx-ATP)	Rapid scale-up of advanced Point-of-Care technologies and laboratories to accelerate, enhance and validate utility of ultra-high throughput machines and facilities
RADx-Radical (RADx-rad)	Develop and advance novel, non-traditional approaches, or new applications of existing testing approaches
RADx-Underserved Populations (RADx-UP)	Interlinked community-engaged projects on implementation strategies to enable and enhance COVID-19 testing in underserved and/or vulnerable populations

RADx | National Institutes of Health (NIH) https://www.nih.gov/research-training/medical-research-initiatives/radx

NIH National Institute on Minority Health and Health Disparities

RADx[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[2]
- **July 30, 2021:** NIH RADx Tribal Data Repository-NIH Tribal Consultation[2]
- **August 31, 2021:** NIH RADx Tribal Data Repository-End of Open Comment Period

[1]Rapid Acceleration of Diagnostics (RADx) Initiative https://www.nih.gov/research-training/medical-research-initiatives/radx
[2]Tribal Consultation for COVID-19 https://dpcpsi.nih.gov/thro/tribal-consultations/covid-19

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)

Data Coordinating Centers

- RADx-UP (Duke University; The University of North Carolina at Chapel Hill)
- RADx-Tech (UMASS)
- RADx-RAD (UCSD; UTHealth The University of Texas Health Science Center at Houston)
- RADx Digital Health

RADx Data Hub (Repository)

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

- Data Management
- Data Curation and Harmonization
- Researcher Auth Service (RAS)

Researcher Analytics Environments

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

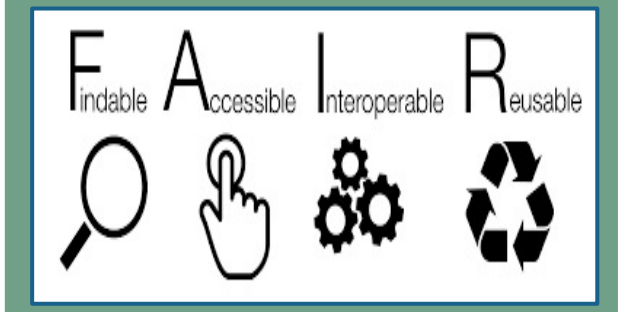
Core Objectives

+ 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)**

Rapid Acceleration of Diagnostics (RADx): Some Points Considered

F.A.I.R[1]



C.A.R.E[2]

NIH TRIBAL HEALTH RESEARCH OFFICE[3]

- 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

[1] F.A.I.R. https://static1.squarespace.com/static/5d3799de845604000199cd24/t/5da9f4479ecab221ce848fb2/1571419335217/CARE+Principles_One+Pagers+FINAL_Oct_17_2019.pd

[2] C.A.R.E https://static1.squarespace.com/static/5d3799de845604000199cd24/t/5da9f4479ecab221ce848fb2/1571419335217/CARE+Principles_One+Pagers+FINAL_Oct_17_2019.pdf

[3] TRIBAL CONSULTATIONS:DATA SHARING https://dpcpsi.nih.gov/thro/tribal-consultations/draft-policy-for-data-management-and-sharing COVID RESEARCH https://dpcpsi.nih.gov/thro/tribal-consultations/covid-19

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.

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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.

https://grants.nih.gov/grants/peer/guidelines_general/scoring_system_and_procedure.pdf

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

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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

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