Rapid Acceleration of Diagnostics (RADx) Initiative

RADx Tech – $908M*
Highly competitive, rapid three-phase challenge to identify the best candidates for at-home or point-of-care tests for COVID-19

RADx Underserved Populations (RADx-UP) – $533M
Interlinked community-engaged research projects focused on implementation strategies to enable and enhance testing of COVID-19 in vulnerable populations

RADx Radical (RADx-rad) – $187M
Develop and advance novel, non-traditional approaches or new applications of existing approaches for testing

RADx Advanced Testing Program (RADx-ATP) – $192M
Rapid scale-up of advanced technologies to increase rapidity and enhance and validate throughput — create ultra-high throughput laboratories and “mega labs”

Data Management Support – $70M
Build an infrastructure for and support coordination of the various data management needs of many of the COVID-19 efforts

At-Home Diagnostic Testing – $20M
Evaluate the effectiveness of existing diagnostic technologies and platforms in at-home environments

* Includes $185M in BARDA funds for development of RADx tests (funds were not transferred to NIH)
RADx-Underserved Populations (RADx-UP)

Overarching Goals

- Enhance COVID-19 testing among **underserved and vulnerable populations** across the US
- Develop/create a **consortium of community-engaged research projects** designed to rapidly implement testing interventions
- **Strengthen the available data** on disparities in infection rates, disease progression and outcomes, and **identify strategies to reduce these disparities** in COVID-19 diagnostics

<table>
<thead>
<tr>
<th>September – November 2020</th>
<th>2021</th>
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<tbody>
<tr>
<td>Phase I</td>
<td>Phase II</td>
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<tr>
<td><strong>Build infrastructure</strong></td>
<td><strong>Integrate new advances</strong></td>
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<tr>
<td><strong>Rapidly implement testing, other capabilities</strong></td>
<td><strong>Expand studies/populations</strong></td>
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RADx- UP Components

Testing

- Increase testing access and uptake of COVID-19 diagnostic testing
- Understand and address disparities associated with COVID-19 diagnostic testing

Social, Ethical and Behavioral Implications (SEBI)

- Assess ethical, historical, healthcare, social, economic, and contextual factors around COVID-19 testing
- Investigate influence of cultural beliefs and attitudes, perceived expectations, and preferences

Return to School

- Implement specific, targeted diagnostic testing approaches in education settings for underserved or vulnerable children and their families
- Identify scalable, and sustainable testing implementation strategies
Communities served by RADx-UP projects

Self-reported data reflects RADx-UP Phase I and II projects as of 8/1/2021
RADx-UP CDCC - Guiding Principles

**Communities** are at the center of our work.

**Data sovereignty** protections and sharing with communities and participants are essential in building trust and being trustworthy.

**Intentional support** of study teams is critical to streamline results and troubleshoot.

**Broad dissemination** of program activities, data, and best practices are key.

**Strategic partnerships** will augment community benefits from the program.

**Impact** will be broad and will inform national guidance, strategy, and response to COVID-19.
RADx-UP Awarded Projects

American Indian or Alaskan Native Populations and Residents of Tribal Lands or Reservations (10 total)

The awarded projects include the RADx-UP Phase I and Return to School Program awarded projects. This map shows projects that either focus on or include AI/AN populations.

Note: Four projects have studies across multiple states; the total number of participant study sites does not add up to the total number of projects represented.
### Project Information - Primarily focused on AI/AN Populations and Residents of Tribal Lands or Reservations

The chart below highlights the RADx-UP projects focusing on American Indian and Alaska Native populations.

<table>
<thead>
<tr>
<th>Contact PI</th>
<th>Project Summary</th>
<th>Institution</th>
<th>Study Locations</th>
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<tbody>
<tr>
<td>MARSIGLIA, FLAVIO</td>
<td>This study will perform targeted SARS-CoV-2 testing within defined testing deserts in Arizona and will compare a subset of affected individuals who undergo the proposed testing and educational protocol with those who receive the same testing through standard systems available in the state.</td>
<td>ARIZONA STATE UNIVERSITY-TEMPE CAMPUS</td>
<td>Arizona</td>
</tr>
<tr>
<td>KHAN, SOHAIL</td>
<td>This study will enhance understanding of COVID-19 within the significantly and disproportionately impacted residents of Cherokee Nation. The researchers will perform rapid point-of-care testing, antibody testing, and contact tracing, and will develop educational materials for the community. Rapid data analysis will be used to nimbly move testing sites to areas of need.</td>
<td>CHEROKEE NATION</td>
<td>Cherokee Nation (NE Oklahoma)</td>
</tr>
<tr>
<td>CWIK, MARY</td>
<td>This study will address high rates of morbidity and mortality due to COVID19 among American Indian (AI) and Navajo Nation (NN) communities in the US. The goal of this study is to increase and speed up the testing among those with symptoms and improve adherence to recommended strategies.</td>
<td>JOHNS HOPKINS UNIVERSITY</td>
<td>East Central Arizona and Western New Mexico</td>
</tr>
<tr>
<td>ARMSTRONG, KATRINA</td>
<td>This research will perform a phased study of three Lakota tribes in South Dakota to address attitudes and access to testing.</td>
<td>MASSACHUSETTS GENERAL HOSPITAL</td>
<td>Lakota Tribes of the Western Plains, Western South Dakota</td>
</tr>
<tr>
<td>ADAMS, ALEXANDRA K</td>
<td>This study will use pragmatic randomized testing to evaluate home based testing through comparing community health workers with mail in at-home testing and their related feasibilities.</td>
<td>MONTANA STATE UNIVERSITY- BOZEMAN</td>
<td>Flathead Reservation in MT and Yakima Valley in WA</td>
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# Project Information - Primarily focused on AI/AN Populations and Residents of Tribal Lands or Reservations

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<tr>
<td>KUMAR, DEEPAK</td>
<td>This study will evaluate the impact of work to increase testing uptake for American Indians in North Carolina.</td>
<td>NORTH CAROLINA CENTRAL UNIVERSITY</td>
<td>Lumbee Tribe of North Carolina, In Robenson, Scotland, Hoke and Cumberland</td>
</tr>
<tr>
<td>MALDONADO, YVONNE A</td>
<td>This study will upgrade and sustain local capacity at the Native BioData Consortium (NBDC) with training and development of Personal Protective Equipment (PPE) and Lab Protocols to improve COVID-19 testing and outcomes for Tribal populations by creating an improved diagnostics lab/local data resource and by testing the use of wearables on early diseases detection.</td>
<td>STANFORD UNIVERSITY</td>
<td>Great Plains Tribes, South Dakota</td>
</tr>
<tr>
<td>BUCHWALD, DEDRA</td>
<td>This study focuses on satellite centers that partner with six geographically contiguous Urban Indian Health Programs (UIHPs) across the United States to launch studies under Community Organizations for Natives: COVID-19 Epidemiology, Research, Testing, and Services (CONCERTS). Satellite Centers and partners include: Alaska Satellite Center &amp; Southcentral Foundation, Pacific Northwest Satellite Center and Denver Indian Health and Family Services, Rocky Mountain Satellite Center and Indian Health board of Minneapolis, Southwest Satellite Center and First Nations Community Health source, and Southern Plains Satellite Center and Hunter Health Clinic.</td>
<td>WASHINGTON STATE UNIVERSITY</td>
<td>National sample of urban Indians</td>
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<tr>
<td>JAMES, JUDITH A</td>
<td>The Oklahoma Shared Clinical and Translational Resources (OSCTR) proposes to implement a multi-faceted, culturally-responsive, and versatile testing program that will compare the effectiveness and acceptability of two different testing schemes designed to increase diagnostic testing in minority and rural underserved communities and to better understand specific testing challenges in vulnerable populations.</td>
<td>UNIVERSITY OF OKLAHOMA HEALTH SCIENCES CENTER</td>
<td>Southern Plains Tribal Health Board, Chickasaw Nation</td>
</tr>
<tr>
<td>BARLOW, ALISON</td>
<td>The proposed study will utilize a community-based participatory research process to understand implementation barriers to in-person school instruction and various testing strategies (e.g., students vs. teachers; screening vs. surveillance; at-home vs at-school) in schools that serve Native American students ages 3-16 years.</td>
<td>JOHNS HOPKINS UNIVERSITY</td>
<td>Arizona, New Mexico</td>
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Project Information - Primarily focused on AI/AN Populations and Residents of Tribal Lands or Reservations

All RADx-UP projects focused on conducting research with American Indian and Alaska Native Communities included letters of support from appropriate Tribal leaders and Tribal Health Boards with whom they are collaborating.

Tribal Advisory Committee discussion in June 2020 at the start of the RADx-UP Initiative has informed NIH efforts in the past 16 months.
Key Takeaways

- Testing is acceptable
- Cases enter school, but in-school spread is rare
- Rates in school aged children parallel rates in the community indicating school is not a significant driver of COVID-19 spread, particularly when mitigation measures are followed
Example Communications Materials- Barlow Project

- Website and toolkit to provide a resource for schools serving Native communities, with a specific playbook to help schools implement testing programs
- [https://caih.jhu.edu/schoolresources/](https://caih.jhu.edu/schoolresources/) also includes other communication materials related to school safety
Project Level Lessons Learned- Barlow Project

Implementation Support
- Implementing testing is acceptable and feasible in schools
- Greater success achieved with implementation support from partners and organizations knowledgeable about the culture and community

Multi-Test Approach
- Data to date suggest that surveillance + rapid follow-up testing helps communities feel safer about in-person learning

Spread in Schools
- Re-opening schools does not seem to be a significant driver of SARS-CoV-2 spread

 Returning to School
- Roughly 60% of families returning to in-person learning – we are exploring more about this through our qualitative work.

Mental Health
- Additional mental health support is needed; school resources stretched thin and child mental health is a concern is elevated.
What can be done?- Barlow Project

Increase Support to schools for implementation of COVID-19 Testing

- Needs to be with people who are familiar with the community
- Layered mitigation is key
- Consider additional support for athletics as these are higher risk

More resources needed to increase access to culturally competent care for individuals in need

- Family/community navigators to help support families and returning to school
- Support engagement with protective activities/programs including those that draw on cultural teachings and traditions
RADx-Tribal Data Repository: A Stand-Alone Independent Entity

*The Tribal Data Repository will be governed by Tribal Nations*

**Data Coordinating Centers**

- RADx-UP
- RADx-Tech
- RADx-RAD
- Digital Health
- NCI@Frederick SeroNet*

**NIH RADx Data Hub**

- Support Common Data Elements
- Metadata & Data Repository
- Data Management & Data Access
- Data Curation & Harmonization

**Tribal Data Repository (TDR)**

- Facilitation, management, and sharing of de-identified AI/AN research data
- Tribal sovereignty and governance
- Enable current & future basic/applied research
- Enhance Tribal data science capabilities
- Coordinate with RADx-UP Data Coordination Center

**Core Objectives**

- Act as 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)
Cumulative RADx-UP AI/AN Participants and Testing Data

CUMULATIVE ENROLLMENT AND TESTING DATA (SELF-REPORTED)

Participants Enrolled
- Anticipated
- Actual

Participants Tested
- Anticipated
- Actual

Tests Conducted (Participants)
- Total
- Positive

Tests Conducted (EHR)
- Total
- Positive

% Positive
RADx-UP CDCC Lessons Learned- Working with Tribal Nations

- Tribal Nation IRB approval is very intentional and specific about the benefits of research for their populations.

- Relationships/partnerships are paramount and have taken years to build, and research can often pose a strain on these relationships.

- Tribal Nation IRB and data sovereignty timelines often do not align with CDCC.

- If the direct benefits cannot be expressed effectively, then it creates challenges on the approval status beyond sharing aggregate data.