

American Indian and Alaska Native (AI/AN) Involvement in the NIH RADx for Underserved Populations (RADx-UP) COVID-19 Initiative

Key Points

- More information on RADx-UP is now available at the new [RADx website](#) and through several [pre-application webinars](#).
- Due to the urgent nature of the COVID-19 response, Phase I of RADx-UP will primarily expand on existing NIH grants. NIH looks forward to receiving applications from our currently funded awardees associated with Tribal nations for additional funding through RADx-UP. New partnerships with other applicants are also encouraged in Phase I. Phase II is expected this fall and will offer opportunities for new awards.
- RADx-UP awardees will only be using diagnostic tests that are FDA-approved or have received an emergency use authorization (EUA) from the FDA. There will be an opportunity to be among the first to access newly developed, but EUA cleared, technologies resulting from the other RADx efforts (e.g., RADx-tech). This way, it will provide an opportunity to make the latest technologies available to populations who may need their unique capabilities most.
- RADx-UP applicants are expected to demonstrate knowledge of, and to comply with, Tribal requirements on testing, reporting, and surveillance policies in study protocols. When required, Tribal resolutions should be included with the application, if possible, but before funds are awarded in all cases.

Background

RADx Program: In late April 2020, Congress passed the Paycheck Protection Program and Health Care Enhancement Act which appropriated \$1,000,000,000 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.

In response, the NIH has launched the Rapid Acceleration of Diagnostics (RADx) program to accelerate innovation, development, commercialization, and implementation of COVID-19 testing. The program will accomplish this by funding early innovative diagnostic technologies, advancing late-stage diagnostic technologies to expand testing infrastructure, and identifying effective testing implementation strategies in underserved populations, all while working closely with other government agencies.

RADx-UP Initiative: One important initiative of RADx is Rapid Acceleration of Diagnostics for Underserved Populations (RADx-UP). This initiative is being planned to support a consortium of interlinked community-engaged projects to enhance testing, including implementation strategies,

among underserved, under-resourced, underrepresented, rural, and/or vulnerable populations across the U.S. RADx-UP will build and expand collaborations between program sites and their communities—Tribal health centers, houses of worship, homeless shelters, and prison systems—to identify and address their unique needs. RADx-UP will initially consist of three initiatives:

- Testing research sites that will increase reach, access, uptake, and impact for COVID-19 testing in underserved and/or vulnerable populations by creating strategies to widely disseminate up-to-date FDA-authorized/approved testing technology. These sites will range from well-established, large-scale centers to individual research projects, and will tackle a variety of questions around testing to understand the factors associated with disparities in COVID-19 morbidity and mortality and to lay the foundation to reduce disparities for underserved and vulnerable populations.
- Social, ethical, and behavioral implications research that assesses how ethical, historical, healthcare, social, economic, and contextual factors surrounding COVID-19 testing, as well as cultural beliefs and attitudes, expectations, and preferences for testing and test results, influence underserved or vulnerable populations' ability and willingness to get tested.
- A coordination and data collection center which will provide overarching support to the RADx-UP network related to operations and logistics; COVID-19 testing technologies; community engagement; and data collection, integration, and sharing.

TRIBAL CONSULTATION: For NIH to proactively and responsibly involve tribes in the time-sensitive response to the COVID-19 pandemic, a rapid-response Tribal Consultation was held on Thursday, May 28, 2020 to discuss two distinct issues that affect Tribes: 1) the development of and plans for the RADx-UP initiative to solicit research on COVID-19 diagnostic testing in underserved and/or vulnerable populations, and 2) the *All of Us* COVID-19 Serology Study to test participants for the seroprevalence of SARS-CoV-2 serum antibodies. Input was collected during the video conference and through written feedback submitted by Friday, June 5, 2020.

Issues Presented for Consideration During Consultation

The following questions were presented by NIH for consideration during consultation, in order to understand the needs, challenges, and concerns for Tribes regarding COVID-19 testing.

- What are some of the most challenging issues your communities are dealing with?
- What research questions, including around COVID-19 testing, are most important to your respective communities during the current COVID-19 pandemic?
- What special considerations for Tribes should be in place as we are developing funding opportunities?
- How can we better encourage and facilitate research partnerships to respond to the current pandemic and prepare for future public health emergencies?

Input Received Through Consultation

During the consultation, NIH received comments concerning the implications of RADx-UP for Tribal nations and the proposed RADx-UP initiative. Tribes noted potential issues related to the level of detail available on RADx-UP and short timeline for launching the initiative. Tribes noted the need for attention to:

- quality and implementation of COVID-19 testing, including the essential need for accurate, validated tests
- importance of returning results to Tribes, respecting Tribal laws, engaging Tribal IRBs, and careful examination of reporting to prevent stigmatization
- ensuring researchers are respectful of Tribal sovereignty, Tribal laws, and the unique needs of Tribal nations
- opportunities for Tribes to be included in RADx-UP research activities

NIH has discussed these concerns and is aiming to address them as comprehensively as possible through the decisions detailed below.

Results

While developing the three Notices of Special Interest (NOSIs) and one Request for Applications (RFA) that were recently released for RADx-UP, we considered the feedback we received from consultation in order to be as responsive as possible. These funding announcements, in addition to the new RADx website (<https://www.nih.gov/radx>) and applicant webinars (<https://www.nih.gov/research-training/medical-research-initiatives/radx/events>), should provide additional detail and clarity on the initiative. We also look forward to discussing specific questions about RADx-UP at the upcoming July meeting with the Tribal Advisory Committee, which has representatives from 12 Indian Health Service (IHS) regions nominated by Tribes.

We structured RADx-UP to enable community-engaged projects to address the scarcity of COVID-19 testing and resources available in underserved and/or vulnerable populations on a short timeline to enhance rapid response to the pandemic. As such, we anticipate that most applications from this first phase of RADx-UP will be from current NIH awardees that already have existing relationships with underserved and/or vulnerable populations. As NIH currently funds awardees who are Tribes, Tribal organizations, or partnering with Tribal nations, we look forward to receiving applications from those awardees for additional funding through RADx-UP. The next phase of RADx-UP, beginning with the issuance of funding solicitations planned for this Fall, will provide the opportunity to fund new NIH awardees. In addition, other applicants are encouraged to include community partners (where possible) as investigators. In this scenario, community partners would have a role in the oversight of their project and the overall consortium. We specifically encourage applicants to collaborate with awardees funded by other federal agencies, including IHS, the Department of the Interior, and the Bureau of Indian Affairs. In all scenarios involving Tribal nations, we want to ensure that applications promote respectful research partnerships. To facilitate this, we have stated in the funding opportunities that applicants are expected to demonstrate knowledge of, and to comply with, Tribal requirements on testing, reporting, and surveillance policies in study protocols. When required, Tribal resolutions should be included with the application, if possible, but before funds are awarded in all cases.

It should be noted that we are not establishing set-asides for any population within RADx-UP. However, our application review and decision processes will ensure that our resulting awards serve a diverse set of underserved and/or vulnerable populations. Our review process will primarily involve federal employees who are familiar with research involving vulnerable and underserved populations; however, we will provide them with copies of *American Indian and Alaska Native Research in the Health Sciences: Critical Considerations for the Review of Research Applications* and discuss the primary concepts prior to the review meeting.

It should also be noted that we will not be assessing the efficacy of *experimental* diagnostic tests through RADx-UP. In fact, awardees will only be using diagnostic tests that are FDA-approved or have received an emergency use authorization (EUA) from the FDA. We have developed a process to pilot newly developed, but EUA cleared, technologies resulting from the other RADx efforts (e.g., RADx-Tech). This way, it will provide an opportunity to make the latest technologies available to populations who may need their unique capabilities most. All testing participants will receive information on the type of test they are receiving, the results of the test, as well as information on how to interpret a test result.

While data sharing and management is critical for the success of RADx-UP, we also understand the concerns raised by the Tribal nations during consultation. It is expected that awardees will rapidly disseminate data, results, and analyses to the broader scientific community, using existing public repositories whenever possible, when not prohibited by Tribal laws, data sharing policies, and IRB decisions. In addition, a Data Safety Management Board (DSMB) will be established and managed by the RADx-UP Coordination and Data Collection Center to review the study data for participant safety and study conduct and progress. We will ensure the DSMB contains experts on any vulnerable or underserved populations that are engaging with the various RADx-UP projects.