



October 25, 2021

Dear Tribal Leader and Urban Indian Organization Leader:

We are writing to follow-up on the Tribal Consultation held July 30, 2021

<https://dpcpsi.nih.gov/sites/default/files/TRIBAL-DATA-REPOSITORY-07302021-TRIBAL-CONSULTATION-FINAL-508.pdf>. At that time, we sought your input on key issues critical to the creation of the RADx Initiative's Tribal Data Repository (TDR). Over the 30-day comment period we received many comments and useful suggestions. This letter is a follow-up of the process that began with the Dear Tribal Leader Letter <https://dpcpsi.nih.gov/sites/default/files/TRIBAL-DATA-REPOSITORY-TRIBAL-CONSULTATION-LEADER-LETTER-FINAL-signed.pdf> and Framing Letter <https://dpcpsi.nih.gov/sites/default/files/TRIBAL-DATA-REPOSITORY-FRAMING-LETTER-FINAL-508.pdf> that described the TDR for the Pre-Consultation Informational Webinar on July 20, 2021. The TDR is a close collaboration with the Office of Data Science Strategy (ODSS) and the National Institute on Minority Health and Health Disparities (NIMHD).

American Indian and Alaska Native (AI/AN) communities across the nation have been among the hardest hit by the COVID-19 pandemic. To address the disparities recognized in these communities, the NIH has focused on supporting research projects that can increase our overall understanding of COVID-19 and its effects on AI/AN people and their communities. In response to the Tribal Consultation for COVID-19 Research¹ held in May 2020, NIH incorporated Tribal input into the design of the **Rapid Acceleration of Diagnostics (RADx) Initiative**² envisioned to accelerate the development, commercialization, and implementation of COVID-19 testing. Specifically, the **RADx-Underserved Populations (RADx-UP)**³ program focused on understanding of COVID-19's effect on health disparities and supporting approaches to improve health outcomes and reduce disparities for populations who are disproportionately affected by the pandemic. Although the NIH has created the RADx Data Hub to make RADx data available to the research community, the NIH believes that it does not meet the cultural, governance, and sovereignty needs, or expectations to support and share de-identified AI/AN RADx research data.

The Tribal Data Repository (TDR) is intended to be a tribally directed research data repository designed to implement sovereignty-based governance for data sharing that will provide responsible data sharing and data access to researchers and their collaborators who are generating or interested in working with RADx AI/AN research data⁴. The TDR would

¹ Tribal Consultation for COVID-19 <https://dpcpsi.nih.gov/thro/tribal-consultations/covid-19>

² Rapid Acceleration of Diagnostics (RADx) Initiative <https://www.nih.gov/research-training/medical-research-initiatives/radx>

³ Rapid Acceleration of Diagnostics Underserved Populations (RADx-UP) Program <https://radx-up.org>

⁴ The RADx initiative and the RADx Tribal Data Repository is independent from and not associated with other NIH projects such as All of Us Program or the National COVID Cohort Collaborative (N3C)

collaborate with the RADx-UP Coordination and Data Collection Center (RADx-UP CDCC) [<https://radx-up.org>]. As an independent, tribally directed and tribally governed research data repository resource, the TDR would:

- be responsible and accountable for ensuring, incorporating, and sustaining Tribal sovereignty and sovereignty-based governance for each proposed analytic project;
- negotiate and execute Data Transfer, Ownership, and Use Agreements with Tribal Nations contributing data to the TDR;
- support and enable current and future research analyses of data;
- support data collected by RADx projects conducted in Tribal and Urban Indian communities;
- facilitate, manage, and oversee responsible data access and sharing of de-identified AI/AN research data;
- build Tribal capacity for 'big data' research by supporting pre- and post-doctoral mentored fellowships for AI/AN students with NIH funding;
- provide better understanding of the impact of COVID-19 to Tribal Health Boards;
- inform and support policies to address current and future pandemics;
- promote and support AI/AN biomedical researchers; and,
- be expected to have ongoing consultation and involvement with Tribal nations contributing data to the Tribal Data Repository.

From Tribal Leaders and their Designees, we heard your support for establishing the TDR and your important emphases of Tribal sovereignty, tribally directed governance, and ongoing Tribal consultations and contact.

NIH acknowledges your support of the TDR and the importance of Tribal sovereignty and governance. Importantly, the TDR awardee will be responsible and accountable for ensuring and sustaining Tribal sovereignty and governance, negotiate and execute Data Transfer, Ownership, and Use Agreements, and sustain ongoing Tribal consultations and contact with Tribal nations contributing data to the TDR.

In addition to questions of sustainability and technical issues of defining data and data harmonization, Tribal Serving Organizations and researchers raised similar critical points of tribal sovereignty in the governance, protection, and stewardship of Tribal data; Data Transfer, Ownership, and Use Agreements, and continual Tribal consultations.

The NIH is very motivated to sustain the TDR. The TDR is a partnership program between ODSS and NIMHD; ODSS and RADx program will be providing the initial funding for the TDR while its' management will be primarily through NIMHD. A sustainability plan will be developed by ODSS and NIMHD for future funding (pending congressional budgets and appropriations) before the

RADx program is completed. In terms of data and data harmonization, the RADx programs collect data but do not collect or store biospecimens. Additionally, the RADx-UP CDCC will assist researchers with data harmonization prior to the data being deposited into the TDR.

The creation of the RADx Tribal Data Repository is intended to be responsive to the historic experiences and harms related to data oversight and data sharing of AI/AN research data and the devastating impacts of COVID-19 on underserved populations. Importantly, the TDR reflects our commitment to partner with Tribal Nations for responsible data sharing. The NIH remains committed to continuing its efforts to improve relations with Tribal Nations, and to partnering with Tribal Nations to use the power of biomedical research to support healthier AI/AN communities. Thank you for your continued partnership as we work together during this public health emergency to improve the health of American Indians and Alaska Natives.

Sincerely,

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