

National Institutes of Health (NIH) Tribal Consultation on COVID-19 Research

May 28, 2020 | 2:00 – 4:00 p.m. ET

This document provides an overview for Tribal leaders and community members to participate in the upcoming *NIH Tribal Consultation on COVID-19 Research* on Thursday, May 28, 2020, 2:00 – 4:00 p.m. ET. This rapid-response Tribal Consultation and Urban Confer session will be held as a web-based meeting.

National Institutes of Health (NIH)

NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.

- [NIH](#) invests nearly \$40.3 billion¹ annually in medical research for the American people.
- More than 80% of NIH's funding is awarded through almost 50,000 competitive [grants](#) to more than 300,000 researchers at more than 2,500 universities, medical schools, and research institutions in every state.
- Located in Bethesda, Maryland, the NIH is a component of the U.S. Department of Health and Human Services and is composed of the Office of the Director and 27 [Institutes and Centers](#), many of which have an organ- or disease-specific focus. The Office of the Director is the central office at NIH and is responsible for setting policy for NIH and for planning, managing, and coordinating the programs and activities of all the NIH components.

Purpose of Consultation

NIH is focused on supporting research and projects that can increase our overall understanding of COVID-19 and its effects on American Indians and Alaska Natives (AI/AN) and their communities. As NIH accelerates its research efforts, it is critical that the agency requests Tribal input on initiatives that are of interest to and address the needs of AI/AN communities. The input heard at the consultation will be used to develop programs to shape funding opportunities, focused on but not limited to the Rapid Acceleration of Diagnostics in Underserved Populations (RADx-UP) and the *All of Us* Serology Study, so that NIH can support research that will provide vital information to combat COVID-19 in Tribal communities.

COVID-19 Research Efforts

Urgent public health measures are needed to control the spread of the novel coronavirus (SARS-CoV-2) and the disease it causes, coronavirus disease 2019, or COVID-19. Scientific research to improve our understanding of the virus and how it causes disease, and to develop strategies to mitigate illness and death, is of paramount importance.

¹ This amount reflects the sum of discretionary budget authority of \$40.3 billion received by NIH in FY 2020 under the "Further Consolidated Appropriations Act, 2020," Public Law (P.L.) 116-94, which includes \$80 million for Superfund Research activities. The total also includes \$1.23 billion derived from PHS Evaluation financing and mandatory budget authority of \$150 million for special type 1 diabetes research. The allocation of \$225 million to NIH per P.L. 116-94 from Nonrecurring Expenses Fund is excluded. [Details regarding appropriations or budget requests are available from the Office of Budget.](#)

Rapid Acceleration of Diagnostics (RADx) Initiative

The [Rapid Acceleration of Diagnostics \(RADx\)](#) initiative challenges science and engineering's most inventive and visionary minds with speeding innovation, development and commercialization, and implementation of COVID-19 testing. As part of the RADx initiative, NIH proposes to develop a series of interlinked community-engaged projects focused on implementation strategies to enhance testing for COVID-19 in underserved, under-resourced, underrepresented, rural, and/or vulnerable communities across the U.S. This initiative, Rapid Acceleration of Diagnostics in Underserved Populations (RADx-UP), aims to develop an infrastructure to assess and expand evidence-based testing interventions and capacity for those populations that are disproportionately affected by, have the highest infection rates of, and/or are most at risk for adverse outcomes from contracting the virus.

***All of Us* Research Program Serology Study**

The *All of Us* Research Program is planning a study to identify COVID-19 antibodies in samples collected by the program between Fall 2019 and March 2020, and potentially return those results to individuals in the future. Since the study will only look at past samples and only at antibodies, this study's results will indicate prior potential exposure to SARS-CoV-2 and does not indicate active infection. Instead, the study aims to better understand when and where the disease arrived in the U.S. and how the disease spread. Aggregate results will be available first. The program hopes to return individual-level results, but this may take time, as the program is still learning about the benefits and risks of such information. To return these results responsibly, more data is needed about the limitations of these novel tests, especially for diverse populations, and about immunity to the virus. Given the disproportionate burden faced by Tribal communities with COVID-19 related outcomes, NIH is seeking input from Tribal leaders on the unique testing-related challenges and needs of Tribal communities to inform the development of the RADx-UP initiative and on whether self-identified AI/AN samples that were collected between Fall 2019 and March 2020 should be included within this *All of Us* COVID-19 serology study.

Discussion

Some potential discussion items are identified below:

- What concerns need to be addressed to enable the participation of Tribal communities in COVID-19 research?
- How should research results be returned to the communities?
- What can the NIH do to assist Tribes in applying for funding or developing research partnerships?
- What are the priorities of Tribal communities with respect to COVID-19 prevention, diagnosis, and treatment?
- Are there ongoing efforts or research programs in Tribal communities that could be leveraged?
- Should *All of Us* include samples from current self-identified AI/AN participants who joined the program between Fall 2019 and March 2020 in the COVID-19 antibody analysis?
- What are some unintended health-related consequences that have resulted in your community from the COVID-19 pandemic?