

American Indian and Alaska Native (AI/AN) Inclusion in the *All of Us* Research Program COVID-19 Serology Study

Key Points

- The NIH *All of Us* Research Program consulted with Tribal leaders about including existing AI/AN participant samples in a COVID-19 Serology Study looking for SARS-CoV-2 antibodies.
- Responding to Tribal concerns, *All of Us* has decided not to include these samples and will continue focusing on finalizing consultation about the main program.

Background

COVID-19 ANTIBODY TEST: The *All of Us* Research Program (*All of Us*) has proposed the *All of Us* COVID-19 Serology Study to test participant samples for the seroprevalence of SARS-CoV-2 serum antibodies. This study will look for the presence of antibodies that will help us understand when and where the virus may have entered the U.S.

RETURN OF RESULTS: *All of Us* plans to initially release aggregate-level results from the study. The program is very motivated to return individual-level results to participants that wish to receive them once the sensitivity, specificity, and positive predictive value of the tests, as well as their scientific significance and utility are better understood.

TRIBAL CONSULTATION: *All of Us* consulted with Tribes about the entire program in 2019 and has completed a draft report of those consultations. The draft is currently under review by the NIH Tribal Advisory Committee (TAC) and the program hopes to share the report with Tribal leaders for input in late summer. That series of consultations did not include any discussion of rapid-response projects (such as the COVID-19 Serology Study) or anything outside the planned program protocol.

For NIH to proactively and responsibly involve Tribes in the time-sensitive response to the COVID-19 pandemic, a rapid-response consultation was held on Thursday, May 28, 2020 to discuss two distinct issues with Tribes: 1) the plans to publish four Funding Opportunity Announcements (FOAs) as part of the Rapid Acceleration of Diagnostics for Underserved Populations (RADx-UP) initiative to solicit research on COVID-19 diagnostic testing in underserved and 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.

AI/AN DATA AND SAMPLE HOLD: Currently, no data or samples from AI/AN participants are being shared with researchers or the public until the full program consultation is completed. Once the final consultation report has been made available, *All of Us* has proposed a time period in which participants could read the report and decide about their continued participation. An IRB-approved message has been sent to AI/AN participants letting them know that *All of Us* is still consulting with Tribes and that their data and samples are not yet being shared.

Issues Presented for Consideration During Consultation

AI/AN COVID-19 STUDY EXCLUSION AND CONSULTATION: In the current IRB submission for the COVID-19 study, it states, “Samples from self-identified American Indians and Alaska Natives [AI/AN] will be excluded from testing at this time and until Tribal Consultation is complete and the Program has finalized the policies in response.” While this action was intended to respect the current period of Tribal Consultation, it risked excluding AI/AN participants from receiving individual-level results and excluding a population that has been both highly impacted by COVID-19 and known to experience higher rates of health disparities that increase co-morbidity.

DATA SHARING AND SAMPLE PROCESSING: In order to include self-identified AI/AN participants in the COVID-19 Serology Study, data and samples from those participants would be made available to researchers before the main consultation report had been shared with Tribes. That data would have included information provided by the participant through surveys and electronic health records, but it would not have included Tribal affiliation or genomic data. In addition, samples from AI/AN participants would have been processed as part of the serological testing. These requirements would have contradicted the statements made by the program during consultation and previous messaging sent to AI/AN participants. Data sharing and the potential for stigmatization or community harm was an issue raised in consultation and was discussed with Tribes as it applies to this study.

ADDITIONAL CONSIDERATIONS

- This scenario had not previously been raised to Tribes through consultation.
- *All of Us* has not recruited on Tribal lands, so this information was likely to be of benefit primarily to individuals who are living off Tribal lands, not to the benefit of Tribes for public health.
- If AI/AN participants were not included in the aggregate study, it was unclear if their samples would be available to be tested and have results returned later, or if that will have the same benefit.
- The AI/AN samples currently excluded from the study included any participant who self-identified as AI/AN. Some of these may not be federally-recognized Tribal members, such as Central and South American Indians, participants from First Nations, state-recognized Tribal members, etc.

Input Received Through Consultation

Tribal leaders were generally positive about the serology study and that *All of Us* had raised this issue for discussion through consultation. However, there were concerns raised about how results could be perceived by individuals and about the potential for stigmatization or misrepresentation of AI/AN people based on results for a small number of participants.

NIH also heard that if *All of Us* were to include self-identified AI/AN participants in the serology study, researchers should not have access to AI/AN race data for use in analyses and results should not be disaggregated by AI/AN race. Overall, it was suggested the potential harms would be greater than the benefits.

Decisions

NIH weighed carefully the decision to include or exclude AI/AN individuals from this study in light of the obligations to both the nation-to-nation relationship between Tribes and the federal government and to individual participants in the *All of Us* Research Program. The study has the potential to provide important public health information and individual benefits, in keeping with the values of the program. However, the program also has a responsibility to prevent stigmatization and group harm, and to respect Tribal sovereignty. With the valuable, deliberative input from the rapid-response Tribal Consultation, the NIH has made the following decision:

ALL OF US WILL NOT INCLUDE AI/AN SAMPLES OR DATA IN THE COVID-19 SEROLOGY STUDY. After hearing from Tribal leaders during a rapid-response consultation on May 28, the program has decided that the antibody study will not include samples or data from self-identified American Indians and Alaska Natives at this time. The message conveyed by Tribal leaders through consultation was both that the risks outweighed the benefits and that *All of Us* could be confusing or damaging the trust with participants if AI/AN participants were included in this study before the main consultation was completed. NIH takes this input seriously, and so the most appropriate response is to continue the main consultation activities and focus on sending the information from the consultation report out to Tribes and participants.