



NATIONAL CONGRESS OF AMERICAN INDIANS

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Research Policy Update

NIH All of Us Research Program: An Update for Tribal Leaders

Key Points:

- The NIH All of Us Research Program plans to recruit diverse participants, including AI/ANs
- A tribal workgroup is preparing a report for All of Us Research Program leadership
- Tribal consultation is planned, but input and oversight by tribes is critical

Background – *Description of the NIH All of US Program*

The National Institutes of Health (NIH) is an operating division within the U.S. Department of Health and Human Services that supports research to improve health. NIH funds investigators and research studies.

The Precision Medicine Initiative was launched in 2016 as a long-term research effort to understand how genetics, environment, and lifestyle factors can help develop the most effective strategies to treat or prevent disease in individuals. NIH received \$130 million to develop the All of Us Research Program.

The NIH All of Us Research Program was established and funded as a part of the Precision Medicine Initiative to gather research data over many years from one million or more volunteer participants, especially from diverse populations to:

- Gather research data from study participants and their health records to understand genetic, environmental, and lifestyle factors that contribute to health conditions and health disparities; and
- Make the research data available to researchers to conduct research studies to help further advance the science of precision medicine.

Research Study Participants will be recruited and can enroll in the study online or at participating health centers around the country. After informed consent is obtained, the study participants have the option to participate in several study procedures:



- 1) **Personal Surveys** – includes basic sociodemographic information, health history, medications, family history, lifestyle habits, and health care access and utilization;

- 2) **Physical exam** – includes blood pressure, height and weight, hip/waist circumference measurements;
- 3) **Lab testing** – includes blood, urine, and in some cases saliva samples for routine lab tests and genetic testing, with all of these “bio specimens” stored in the All of Us centralized biobank;
- 4) **Electronic health record (EHR) access** – participants will be asked for their consent to allow the program to access their patient records with their health care providers or regular health care facility, including all records, diagnoses of health, mental health, substance abuse disorders, HIV status;
- 5) **Use of personal health technologies/sensors** – in the future, wristbands, watches, and sensors in smartphones or cars are being discussed as tools that could be used to collect data from participants;
- 6) **Geolocation data** – in the future, the program will track the home address of participants to gather data on the local geography, such as weather patterns, U.S. Census data; and
- 7) **Linkage to other existing datasets** – in the future, the All of Us program may link data with various other datasets including Social Security Death Master File, Medicare/Medicaid/insurance claims data.

All the data gathered from participants will be put into a data repository and, in the future, researchers will be allowed to propose studies to analyze the de-identified data and answer various research questions. The All of Us Research Program plans to set up data access policies and procedures to manage this process, including a Resource Access Board. This data will likely be available for decades for numerous research studies.

Tribal Considerations – *Risks and Benefits for Individuals and Tribes*

The benefits of the All of Us Program include the potential for the study data to inform new therapies for the prevention and treatment of disease that can be tailored to individuals. Participants can receive incentives to participate and may enjoy contributing to better healthcare in the future. The study creates a large data repository of information that researchers can use to conduct studies designed to find better interventions for treatment and prevention of diseases, which may lead to important discoveries on a more rapid basis.

The risks for individuals include the usual ones related to research studies, including potential loss of privacy and/or confidentiality, discomfort with the examinations and tests, risks related to accessing electronic health records, the burden of continued contact while in the study, stress over any medical findings during the study, and costs for follow up and treatment (the All of Us Research Program protocol states it is not responsible to pay for medical care for participants for any illnesses discovered during the study). The participants could be followed for as long as 10 years or more.

The risks for tribes are not covered in the All of Us Research Program research study protocol but have been voiced by tribal leaders, researchers, and community members in discussions with NIH and the All of Us Program during initial outreach. Concerns expressed by tribes so far include:

- **Potential negative impacts** of the study, especially concerns about the genetic testing portion, given cultural concerns, respectful handling of specimens, access, storage and use of the data, impact of the research on individuals and tribes, and protection and ownership of the data.

- Potential issues around **recruitment of individual AI/ANs** in urban vs. rural/tribal communities and the role of tribal sovereignty over research conducted with their members;
- **Potential unlimited availability of study data** to many investigators that may not understand possible negative impacts of the research for individual AI/ANs, tribes, their health facilities, their communities, and their histories, cultures and traditions; and
- A lack of **consultation** during the development of the initial protocol, and the need for ongoing consultation that will impact the current and future development of the All of Us Research Program.

NIH Response – *Current Efforts to Work with Tribes*

The NIH All of Us Research Program has conducted several outreach and engagement activities with tribes, including presentations and discussions at the NIH Tribal Advisory Committee meetings, discussions with Tribal representatives and researchers in various forums, and meetings with tribal organizations, including the National Congress of American Indians. The NIH All of Us Research Program developed a national tribal engagement plan to address the specific concerns raised to date and so far includes the following activities:

- **Formation of a Tribal Collaboration Working Group** to provide options on how the All of Us Research Program can collaborate with AI/AN communities in a meaningful and culturally sensitive manner to address any identified risks. The members include tribal leaders, researchers, health care providers, and other community members. The full roster is available at: <https://allofus.nih.gov/tribal-collaboration-working-group-all-us-research-program-advisory-panel>. A report is in development for the All of Us Research Program leadership and is planned to be completed by April 2018;
- **Development of strategies to gather additional input** including presentations at meetings and conferences, as well as plans for tribal consultation in 2018 after completion of the report; and
- **Implementation of feedback and consultation input** received to potentially impact future versions of the research protocol and define future opportunities to partner with tribes, health care providers, and researchers on recruitment and oversight.

Recommendations – *Tribal Input and Consultation is Critical*

The All of Us Research Program’s outreach and engagement work with AI/AN communities is in progress, but the involvement of tribes in these discussions and future consultation is critical, given the potential benefits and risks of individual AI/AN participation in this study. There are also potentially significant risks associated with the plans to make this data available to researchers in the future. AI/AN tribes are all too familiar with the potential negative impacts of research that is not conducted in partnership with tribes, and it is important to ensure that when AI/AN individuals and tribes agree to participate in research they also reap its benefits.

Recommendations for current and future participation of tribes in the NIH All of Us Research Program include:

- **Transparency.** The NIH All of Us Program should ensure that they are transparent about their activities, including posting updates on their website, providing meeting minutes from their Tribal

Collaboration Working Group, releasing the Working Group's report for tribal review and comment, and creating a clear timeline for these activities in relation to the overall timeline for the All of Us program. Any changes that may impact tribes should be made public and widely available.

- **Consultation.** The NIH All of Us Research Program should ensure that tribal consultation is held before the final protocol is developed, before AI/ANs are recruited to join the study, and throughout the study. Consultation must be on a government to government basis with federally recognized tribes, must be well advertised, must allow sufficient time for input, should have clear consultation questions and background information, and should ensure broad input. Information on how tribal consultation eventually impacts or changes the All of Us Research Program should be made public. NIH should also work closely with the NIH Tribal Advisory Committee and provide frequent updates.
- **Oversight.** The NIH All of Us Program should involve tribes in ongoing oversight of the research study, including participation in any advisory or governance councils and in the development, oversight of and access to the data repository. Tribal input must be ongoing and contribute meaningfully to all phases of this program, including recruitment, conduct of the study, analysis, reporting and future data access. Input and oversight from Indian Health Service (IHS), tribal, and urban Indian health programs and providers is also essential.
- **Respect for the sovereignty of tribes.** The NIH All of Us Program must acknowledge through its communications and its actions the sovereign status of AI/AN tribes and their rights to govern their lands, programs, services, culture, traditions and any outside activities that impact their members. Since this program is federally funded, the NIH and its All of Us Program must develop an ongoing and meaningful government to government relationship and partnership with tribes.

References:

The following references were used to develop this policy brief and are resources for tribes as they provide input and participate in consultation activities for the All of Us Program:

- *What is the Precision Medicine Initiative? Genetics Home Reference, U.S. National Library of Medicine, National Institutes of Health. Accessed on January 31, 2018 at: <https://ghr.nlm.nih.gov/primer/precisionmedicine/initiative>.*
- *FACT SHEET: President Obama's Precision Medicine Initiative, Press Release, Office of the Press Secretary, The White House, January 30, 2015. Accessed on January 31, 2018 at: <https://obamawhitehouse.archives.gov/the-press-office/2015/01/30/fact-sheet-president-obama-s-precision-medicine-initiative>.*
- *All of Us Research Program – Core Protocol V1, National Institutes of Health. Accessed on January 31, 2018 at: https://allofus.nih.gov/sites/default/files/allofus-initialprotocol-v1_o.pdf.*
- *Update on the Tribal Collaboration Working Group, Presentation by Daozhong Jin, AI/AN Engagement Team, All of Us Program during NCAI Policy Research Center's Monthly Webinar Series, NIH Update on January 25, 2018. Webinar Recording available at: <http://www.ncai.org/policy-research-center/events/webinars>.*

Websites: National Institutes of Health: <https://www.nih.gov/>; NIH All of Us: <https://allofus.nih.gov/>

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