

National Institutes of Health Tribal Consultation and Listening Sessions on the *All of Us* Research Program

This document was prepared to aid Tribal leaders and community participants in the upcoming 2019 National Institutes of Health (NIH) Tribal Consultations on the *All of Us* Research Program:

- HHS Regional Consultation on June 18 from 2:30-5:00 pm in Sacramento, California
- NCAI Mid Year Conference and Marketplace on June 24 at 1:30-5:00 pm in Sparks, Nevada
- HHS Regional Consultation on July 16 from 2:30-5:00 pm in Washington, DC
- HHS Regional Consultation on August 21 from 2:30-5:00 pm in Denver, Colorado

On June 3 from 3:00-4:00 pm ET, NCAI is hosting a Webinar in conjunction with *All of Us* to provide Tribal leaders and members with background on the program and on the Tribal Collaboration Working Group report that informs this process (registration link may be found through a Bit.ly link at: <https://t.co/QStEuRv0J3>). In addition, listening sessions are being scheduled at events across the country; the most up-to-date list of events may be found at: <https://allofus.nih.gov/tribalengagement>.

National Institutes of Health

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

- The NIH invests nearly \$37.3 billion¹ annually in medical research for the American people.
- More than 80% of the 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 other research institutions in every state around the world.
- The NIH main campus is located in Bethesda, Maryland.
- The NIH is composed of 27 [Institutes and Centers](#) of which many have an organ- or disease-specific focus, and the Office of the Director, which is responsible for setting policy and planning, managing, and coordinating NIH programs and activities.

***All of Us* Research Program**

Precision medicine is an emerging approach for disease treatment and prevention that considers variability in lifestyle, environment, and biological makeup. This represents a radical shift in health care.

¹ This amount reflects the sum of discretionary budget authority of \$36,238 million received by NIH in FY 2018 under The Consolidated Appropriations Act of 2018, Public Law (P.L.) 115-141, \$923 million derived from PHS Evaluation financing, and mandatory budget authority of \$150 million for special type 1 diabetes research authorized per P.L. 115-123 and P.L. 114-10. [Details regarding current appropriations are available from the Office of Budget.](#)

The *All of Us* Research Program is led by the NIH and is a key element of the Precision Medicine Initiative. **The mission of the *All of Us* Research Program is to accelerate health research and medical breakthroughs, enabling individualized prevention, treatment, and care for all of us.**

The program will do this by **partnering with one million or more people across the United States to build the most diverse biomedical data resource in history.** *All of Us* is planning for the first decade, but hopes this will become a lifelong study, much like the classic Framingham Heart Study, so researchers can understand the changes in health at individual and cohort levels across life stages and health events.

The greatest opportunities of *All of Us*, and the greatest challenges, are to reflect the rich diversity of the U.S. and to integrate a broad set of data types. By doing so, researchers will be able to gain better insights into the lifestyle, environmental, and biological factors that—separately and combined—influence health and disease for all communities, including diverse racial and ethnic groups. ***All of Us* will make the data collected available to researchers and citizen scientists, though with robust safeguards in place to provide the participants’ privacy and the security of their data.**

The *All of Us* Research Program launched nationally in May 2018. However, the *All of Us* leadership is committed to taking the time to thoughtfully engage in consultations with Tribal Nations and has promised **the program will not actively recruit Tribal participants until consultation is completed** and the program has a chance to review the input.

- *For more information about All of Us, please visit: <https://allofus.nih.gov/>*
- *For a copy of the full operational protocol, as well as a lay-friendly summary, describing the data being collected, please visit: <https://allofus.nih.gov/about/all-us-research-program-protocol>*

Background Work for Tribal Consultation

In preparation for engaging American Indian and Alaska Native (AI/AN) peoples in the *All of Us* Research Program, staff conducted an informal literature review to understand the issues related to research involving AI/AN individuals. Program staff also spoke with Tribal leaders and researchers to gather input and feedback and to build relationships, attended and spoke at the NIH Tribal Advisory Committee (TAC) meetings, and presented at events organized by Tribal organizations. The *All of Us* team also conferred with U.S. Department of Health and Human Services (HHS) and NIH colleagues who are experienced in engaging with Tribal Nations. The University of Arizona, an *All of Us* Research Program consortium health care provider organization, organized a conference to engage with Tribal Nations in their region, which was attended by program leadership.

Many of the individuals and organizations the team engaged with recommended for the program to form an advisory group to give thorough input on the inclusion of AI/AN individuals in *All of Us*, which led the program to establish the Tribal Collaboration Working Group (TCWG) of the *All of Us* Research Program’s Advisory Panel. With input from a team of NIH and external advisors, the program identified Tribal leaders, providers, researchers, and other community members to invite to serve on the working group. The program was careful to seek a diverse group in terms of geographic representation, size of tribes, area of expertise, etc.

In October 2017, *All of Us* Research Program director Eric Dishman charged this working group with providing guidance to *All of Us* senior leadership and specifically to describe:

- Strategies for collaborating with Tribal Nations, clinics, and organizations to enable AI/AN participation in the program.
- Unique considerations, such as Tribal sovereignty, cultural beliefs and traditions, and historical trauma, that the program should be aware of as they seek to engage Tribal populations.
- Potential modifications that could be made to current *All of Us* Research Program protocol to facilitate AI/AN participation in the program.
- Ethical, legal, and social issues that should be considered prior to enrollment of AI/AN individuals.
- Major research questions which might be of interest or return value to Tribal Nations and AI/AN individuals.

The TCWG completed their report in April 2018. The report was published to the *All of Us* Research Program's website and is intended to serve as a resource for this Tribal consultation.

- *For information on the TCWG's charge and membership, please visit:*
<https://allofus.nih.gov/about/who-we-are/tribal-collaboration-working-group-all-us-research-program-advisory-panel>
- *For a copy of the TCWG Report, please visit:*
https://allofus.nih.gov/sites/default/files/tribal_collab_work_group_rept.pdf

Consultation and Listening Sessions Goals and Suggested Questions

During this consultation, the NIH seeks to understand how the *All of Us* Research Program can develop meaningful, culturally sensitive collaborations with Tribal Nations and communities. The information presented at the consultation will be used by the NIH and *All of Us* senior leadership to identify priorities and opportunities around the inclusion of AI/AN populations in the research program.

Suggested Questions

- The *All of Us* Research Program recognizes there are many unique considerations when partnering with Tribal Nations, including Tribal sovereignty, cultural beliefs and traditions, and historical trauma. What are the associated challenges and best practices for biomedical research initiatives?
- The TCWG report outlines many points for the *All of Us* Research Program to consider around collaboration with Tribal Nations and communities. Are there specific points in the report that you strongly support or that you disagree with?
- How should *All of Us* collaborate with Tribal Nations, clinics, and organizations to receive permission to recruit members of their communities into the *All of Us* Research Program? What initial pilot partnerships should the program consider?
- What guidance do Tribal Nations have for *All of Us* to deal with individuals that enroll independently and who self-identify as AI/AN?
- What are the major research questions that are of most interest to your nation or community?
- How may *All of Us* help advance research conducted by members of Tribal Nations?