

An Update on the *All of Us* Research Program

All of Us
RESEARCH PROGRAM

Alaska Native Collaborative Hub for Research on Resilience
(ANCHRR) & NIH TAC Joint Meeting



National Institutes
of Health

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[All of Us.nih.gov/TribalEngagement](https://allofus.nih.gov/TribalEngagement)

#JoinAll of Us

Agenda for today...

- ◎ **AOU updates (~30 minutes)**
 - Upcoming AOU Launches
 - Recent & Upcoming AI/AN Activities
 - Overview of Key Themes & Issues Heard
 - Specific Advice Requested from TAC

- ◎ **Discussion and Feedback (~30 minutes)**

Thank you for time on the agenda & continued feedback and ideas on how to do AOU right!

Upcoming AOU Activities

Overview: *All of Us* Research Program at NIH

- **AOU committed to 1 million or more volunteers, reflecting the broad diversity of the U.S.**
 - Funded for and focused on first ten years
 - Goal is lifelong study to understand health changes over different stages of life
- **A research resource to generate studies:**
 - Researchers apply to access the data (eventually samples & cohort) with specific studies approved by their local IRB
 - Data stays in NIH protected enclave: not permitted to leave the enclave; never sold
 - All studies proposed must be made public
- **Launched nationally May 6, 2018**
 - 290k+ participants have started the process
 - 184k+ completed all steps of initial protocol
 - >51% are racial/ethnic minorities
 - >81% are underrepresented in biomed research
 - No current recruitment of AI/AN members--plans will emerge out of Consultation & collaborations
 - No current recruitment of people under 18—plans underway for 50-state compliance



Coming Soon: Beta Launch of Researcher Workbench w/ 1st AOU Data Release

- Researcher Workbench is a tool to view & analyze first tier of “Registered” data
- Researchers must apply, take ethics & data use training, agree to code of conduct, share their name and description of study
- Will not include any Tribal affiliation or AI/AN data until initial Tribal Consultations are complete this fall and summary paper & response are released
- Initial research access only available through ERA Commons- not citizen scientists or general public
- Exact release dates are dependent on continuous security & usability testing

AVAILABLE NOW

Beta of Public Data Browser

- Open to the public now, since May
- Provides summary statistics about the AOU dataset at very high levels
- Does not include any information about AI/AN data

WINTER 2019/2020

Beta of Researcher Workbench

- Opens to registered researchers in winter
- First de-identified dataset, including EHR, survey, & physical measures
- Does not include any information about AI/AN participants

****Note: All of Us currently does not have any genotype or sequence data. Pilots of collection start this winter.***

Coming Soon: Winter Launch of Pilot for Return of Genomics Information

- AOU has not collected any genetic information up to this point, but will begin piloting this over the winter
- Initial pilot of 25,000 diverse participants will teach us responsible & effective ways to return information, IF a participant chooses!
- We will soon announce awardee for Genetic Counseling Resource that will be freely available to help AOU participants make sense of their info
- Over time, we will offer multiple options to receive:
 - Ancestry results
 - ACMG/health relevant findings
 - Drug-gene interactions (pharmacogenomics)
- Exact timing of pilot launch depends upon:
 - Genetic counseling resource in place & tested
 - Security, usability & sample quality testing
 - FDA & IRB approval of AOU process
- Genomic data will not be made available to researchers for quite some time due to curation & privacy process



Recent and Upcoming AOU AI/AN Activities

Changes AOU Has Made As Part of AI/AN “Reset”

- AOU Director/Deputy Director & NIH Principal Deputy Director/Associate Deputy Director more directly & regularly engaged
- Dedicated team in place for full time AI/AN work
 - Announcement soon of additional team members
 - Will grow staff as needed depending on final plans
- Reconvened TCWG to help summarize and give guidance on implementation of feedback
- Weekly meetings between AOU and THRO teams
- AI/AN members invited to AOU’s Resource Access Board & Advisory Panel
- Launched [AllofUs.nih.gov/TribalEngagement](https://allofus.nih.gov/TribalEngagement) as central resource
- Removed sorting by AI/AN from AOU Public Data Browser for good



AOU/NIH leadership committed to using AOU to innovative new & better AI/AN collaborations!

A Reminder of Our Engagement Process

TCWG

- Formed a Tribal Collaboration Working Group to provide input on collaborating with the AI/AN community.

Consultation & Listening Sessions

- Planning formal Tribal Consultation sessions in several IHS regions during summer and fall 2019 (ongoing after that as needed).
- Consultations are supplemented by additional listening sessions.

Implement Feedback

- *All of Us* will review input and potentially make changes to the protocol that will apply to Tribal participants and their data.
- The program will explore Tribal partnership opportunities.

Tribal Consultation & Listening Session Activities

- ◎ **Goal:** Understand how the *All of Us* Research Program can **develop meaningful, culturally sensitive collaborations with Tribal Nations and communities.**

- ◎ **Informed by prior Tribal engagement:**
 - Learned & heard advice from Tribal leaders, researchers, and others through a variety of meetings & conversations
 - Formed the ***All of Us* Research Program Tribal Collaboration Working Group (TCWG)** to provide initial input

- ◎ **Recent and upcoming events:**
 - ✓ May 2: California Rural Indian Health Board Listening Session
 - ✓ June 18: United South & Eastern Tribes Listening Session
 - ✓ June 20: HHS Regional Consultation in Sacramento, CA
 - ✓ June 24: Preceding the National Congress of American Indians' 2019 Mid Year Conference and Marketplace
 - ✓ July 11: HHS Regional Consultation in Spokane, WA
 - ~~✓ July 17: HHS Regional Consultation in Washington, DC — event canceled by organizers~~
 - ✓ August 7: Alaska Native Health Board Mega Meeting Listening Session
 - ✓ August 21: HHS Regional Consultation in Denver, CO
 - **August 22: ANCHRR & NIH TAC Joint Meeting in Fairbanks, AK**
 - October 22: Oklahoma City Listening Session
 - Additional sessions being planned

Continue to look for opportunities through the fall, then will pause to summarize feedback & draft initial plans with TCWG for TAC feedback.

Proposed Plan for “Summary, Response & Implementation Paper”

- ⦿ AOU team already preparing thematic analysis after each event
- ⦿ **August 2:** Reconvened AOU TCWG
- ⦿ **End of August:** Release RFI to invite more feedback from across the nation
- ⦿ **September 16:** Meet w/ TCWG to think through process & early outline
- ⦿ **October 22:** Finish planned Consultation and listening sessions
- ⦿ **November/December:** AOU and TCWG prepare first draft of summary, response & implementation paper
- ⦿ **Early 2020:** Gather feedback from TAC
- ⦿ **Q1 2020:** Publish and distribute of summary, response & implementation paper, explore specific collaborations, plan for additional engagements as needed on specific topics

- ⦿ Advice on length and style of this paper?
- ⦿ Advice on best ways to frame that AI/AN engagement continues after the paper?

Overview of Key Issues & Themes Heard

Highlights of Concerns and Feedback Heard (1 of 2)

Cultural respect, understanding, and trust

- Importance of acknowledging past harm and trauma from previous unethical/stigmatizing research
- Differing beliefs and viewpoints from different Tribes will impact participation in research
- Native American Research Centers can be powerful partners for engagement strategies
- Anticipate and accommodate limited computer access, limited English proficiency in some communities; ensure simplified language and terminology
- Importance of respecting Tribal sovereignty and partnering with Tribal leaders when recruitment does begin, including recruitment of Urban Indians
 - Engage with Tribal orgs when recruiting individuals who reside outside of federally defined Tribal lands

Data and biological samples

- Conversations with IHS regarding RPMS / EHR access are critical
- Importance of proper handling of AI/AN biospecimens
- Many prefer to use existing AI/AN biobanks and/or Tribal control of specimens
- Data protection, security and privacy are critical, particularly with EHR use
 - Protections need to extend to future use of data and research results

Highlights of Concerns and Feedback Heard (2 of 2)

Science

- ◉ Importance of including Tribally guided research in *All of Us*
 - Recognition of traditional medicine as precision medicine in Tribal communities
- ◉ Some Tribes want direct control to approve both the research and its publication/distribution
- ◉ Recommend leveraging existing AI/AN IRBs & processes (e.g., Alaska permissions processes)
- ◉ Tribes would need resources to support added activities AOU may generate
- ◉ Tribal Epidemiology Centers would be critical partners for *All of Us*
 - Seek expertise in scientifically valid research in the context of small sample sizes
- ◉ Importance of helping AI/AN communities have full understanding of genomic research and its potential to link data back to AI/AN communities
- ◉ Desire for clarity around researchers' funding sources and publications
- ◉ Community-based research practices may be most effective to partner locally with Tribal Nations
- ◉ NIH *All of Us* broad consent coupled with researchers' home IRB reviewing specific studies may not be sufficient for research using data that includes members of Tribal Nation

Many Have Asked for Clarification of AOU's Broad Consent

*Data from self-identified AI/AN individuals will **not** be released to researchers until Tribal Consultation process is complete*

- AOU is a resource and research platform- not a research study in and of itself
- AOU IRB reviews participant-facing materials for the program, not individual studies using AOU data
- Individual studies will be reviewed and approved by a local IRB
- Individual studies will be required to develop a publicly posted description of their research for the AOU website, allowing anyone to request review of any aspects seeming inappropriate or stigmatizing

Potential solutions to explore with TAC:

- Implementing educational content around AI/AN research ethics into AOU training/approval for access?
- Add AI/AN expertise to the AOU IRB to help advise AI/AN participant facing activities?
- Identify and fund expertise in A/AN research as resource to help local IRBs?

For future collaborations to recruit with and in Tribal communities:

- Will outline a set of principles/guidelines AOU will aspire to (in accordance with THRO/NIH policies)
- Each Tribal collaboration may have unique, local characteristics appropriate to Tribal sovereignty & process
- Each collaboration may want to handle Tribal identification & verification of participants very differently

Specific Advice Requested from TAC

Key Questions

- How best to share & disseminate AOU's "summary, response & implementation paper" for maximum reach & readability?
- Advice on the approach and cadence of ongoing Tribal engagement after release of this paper?
- How should the program address Tribal sovereignty in identifying currently enrolled members who self-identify as AI/AN?
 - In identifying individuals who may enroll in the future?
- Once any kind of AI/AN recruitment collaboration begins, how to approach recruiting urban AI/AN individuals while respecting Tribal sovereignty?
- How to split up responsibilities between AOU TCWG and TAC? Ask TCWG to help generate and author reports and recommendations? And ask TAC for feedback of near-final products, if you are willing?

Thank you for your guidance, patience, and wisdom!

Discussion
