

An Update on the *All of Us* Research Program

All of Us
RESEARCH PROGRAM

The
Future of
Health Begins
With You

Direct Service Tribes Advisory Committee Quarterly Meeting



National Institutes
of Health

Dr. Stephanie Devaney
Deputy Director, *All of Us* Research Program

October 2, 2019

AllofUs.nih.gov/TribalEngagement

#JoinAllofUs

Status of Tribal engagement activities

- Per the NIH Consultation protocol, the Dear Tribal Leader letter & Framing letter were sent and Federal Register Notice was published – May/June 2019
- **Recent and upcoming Consultation & listening sessions**
 - ✓ 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
 - ✓ September 18: HHS Region 3 Consultation in Providence Forge, VA
 - October 22: Oklahoma City Listening Session
 - Additional session being explored with Inter Tribal Council of Arizona
- **Other meetings:**
 - ✓ June 3: NCAI background webinar - video and event material available at <http://www.ncai.org/policy-research-center/events/webinars>
 - **October 2: Direct Service Tribes Advisory Committee (DSTAC) Quarterly Meeting in Washington, DC**
 - Exploring “deeper dive” sessions & workshops via national meetings, webinars, etc.
- **Published a Request for Information (RFI) to welcome additional input – see <https://grants.nih.gov/grants/guide/notice-files/NOT-PM-19-004.html>**
 - Released September 3, 2019
 - **Open until October 31, 2019 – please help us share with Tribal leaders**

All of Us Research Program: Mission

To accelerate health research
and medical breakthroughs, enabling individualized prevention, treatment,
and care for all of us

Nurture relationships
with one million or more
participant partners, from all
walks of life, for decades

**Deliver the largest,
richest biomedical
dataset ever,**
making it as easy, safe, and
free to use as possible

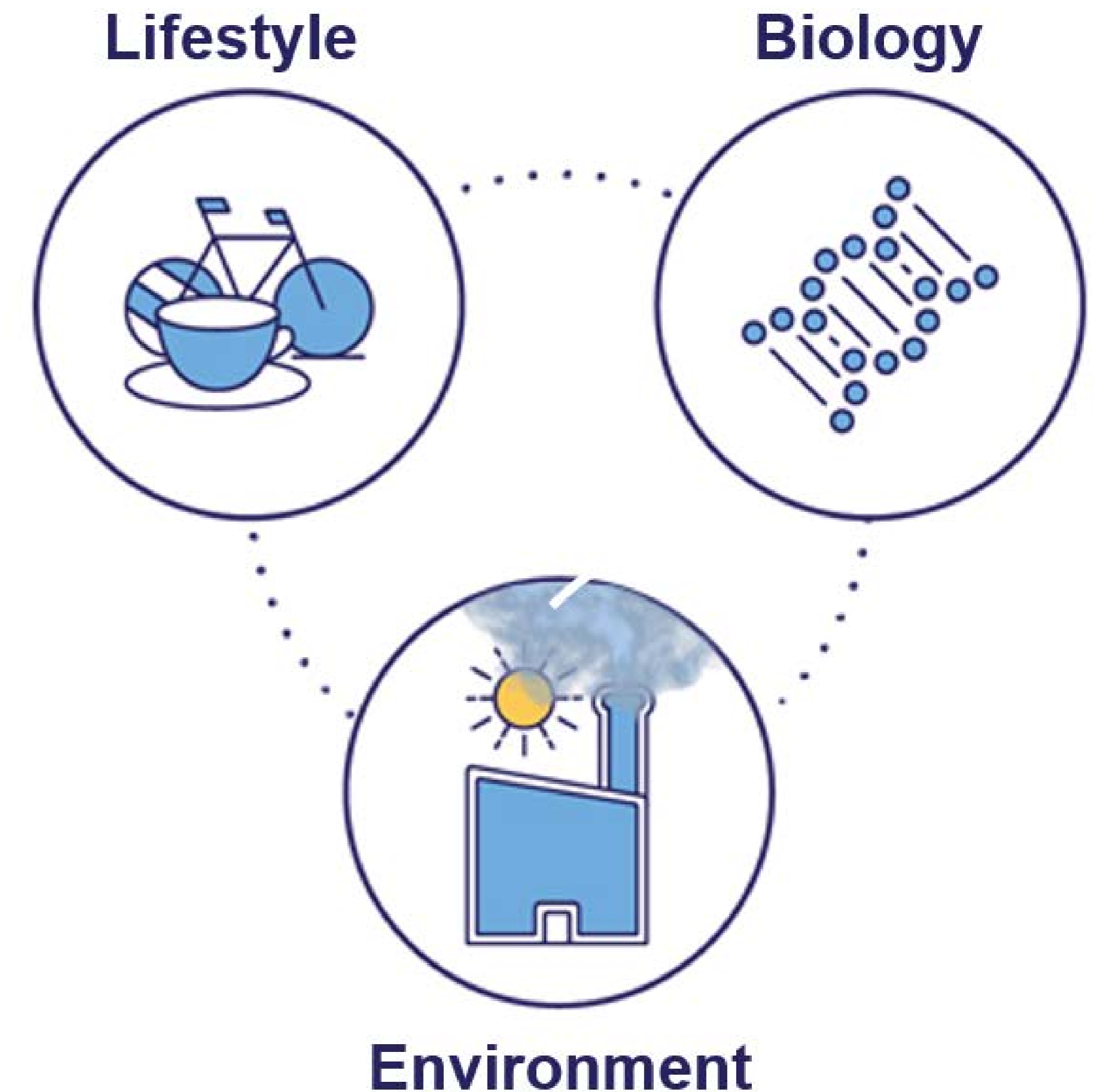
**Catalyze a
robust ecosystem**
of researchers and funders
hungry to use and support it

What is Precision Medicine?

Precision medicine is an emerging approach for health care that takes into account individual variability in lifestyle, environment, and biological makeup.

It is medicine *tailored to you*.

There is early promise in areas like cancer, but researchers still have much to learn about prevention, resilience, and cures for all conditions and all people.



For a helpful intro to what is precision medicine, biomedical research, and more, visit:
https://allofus.nih.gov/sites/default/files/aou_tribal_fact_sheet.pdf.

Overview: *All of Us* Research Program at NIH

- ◎ **Goal: 1 million or more volunteers, reflecting the broad diversity of the U.S.**
 - Lifelong study to understand health and disease; advance precision medicine
- ◎ **A research resource to generate studies: Research Hub not yet open for researcher access**
 - Researchers apply to access the data with specific studies
 - 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**
 - 305k+ participants have started the process
 - 194k+ 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

Current protocol



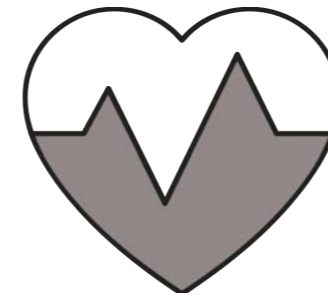
Enroll, Consent & Authorize EHR

- Recruiting 18+ years old initially; plan to include children in 2019
- Online, interactive consent
- Includes authorization to share Electronic Health Record (EHR) data



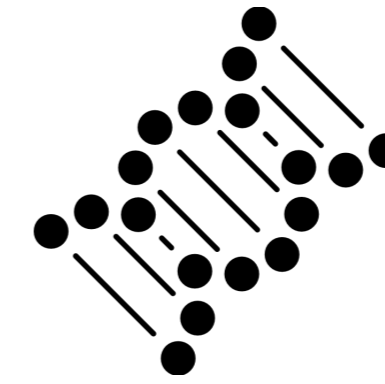
Answering Surveys

- Initial surveys: The Basics, Overall Health, Personal Habits, Health Care Access & Utilization, Family Medical History
- Additional surveys released on an ongoing basis.



Physical Measurements

- Blood pressure
- BMI
- Heart rate
- Height
- Hip circumference
- Waist circumference
- Weight



Provide Biosamples

- Blood (or saliva, if blood draw is unsuccessful)
- Urine specimen
- Biosamples will be stored at the program's biobank



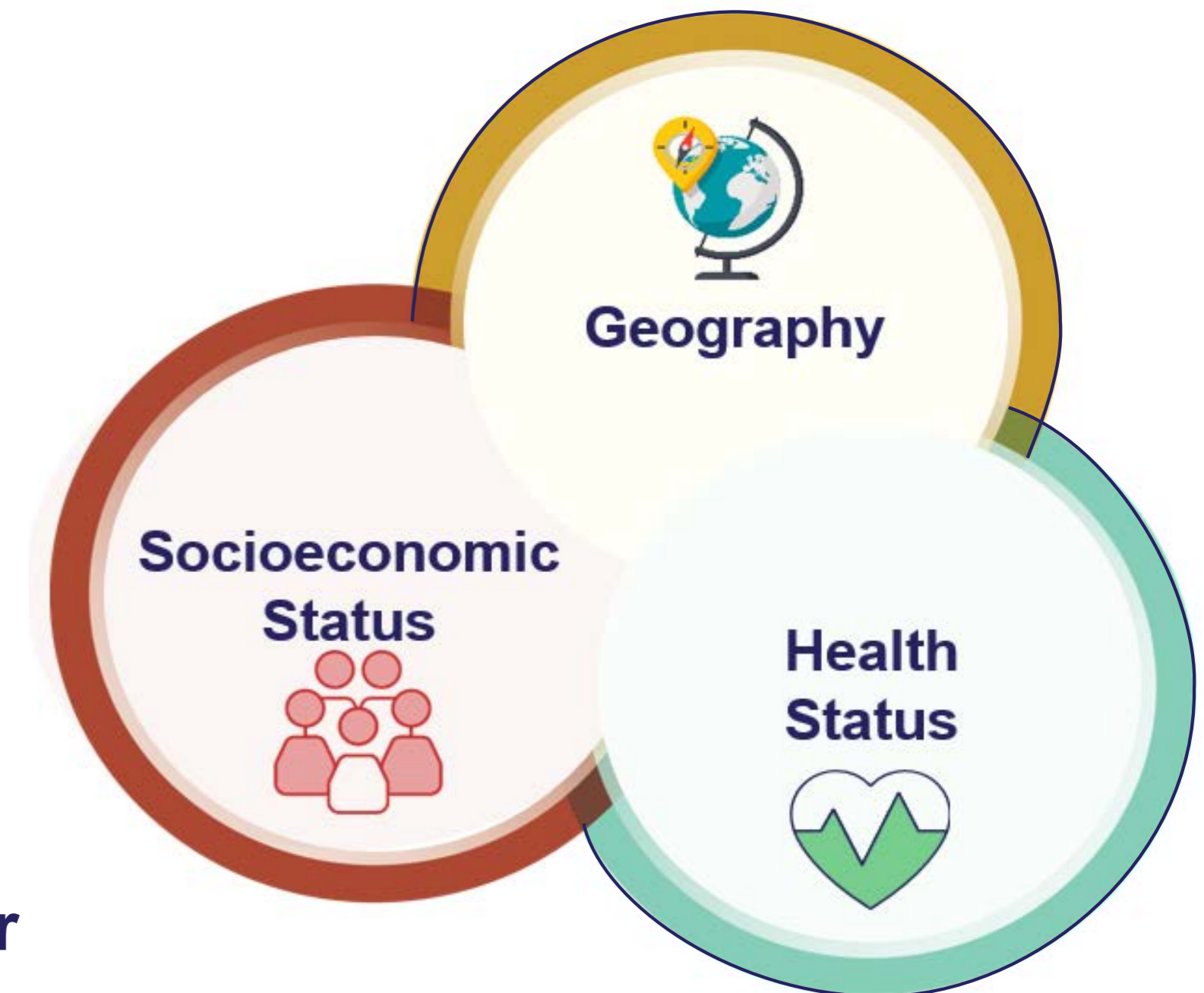
Wearables and Digital Apps

- Share data from wearable fitness devices, starting with FitBit
- Share data about mood & cardio-respiratory fitness through integrated apps
- More integrations to come

Participants can choose to complete some or all of the available activities. Some participants have chosen to answer surveys, but not provide measurements & biosamples.

Who can participate?

- Goal: Ensure that research benefits all communities
 - Open to anyone ages 18+, not incarcerated, any health status
 - Plan to **oversample communities historically underrepresented in biomedical research**, e.g., rural communities, racial/ethnic minorities
 - Participants can withdraw anytime
- Currently, **self-identified AI/AN individuals**:
 - Are **NOT being recruited** – partners are prohibited from recruitment of AI/AN
 - **Will not be turned away** if they choose to enroll themselves
 - Long term goal, after Consultation, is to identify opportunities to **partner with Tribal nations** to enroll Tribal members
- **Data is not yet available to researchers** – anticipate initial release this winter
 - Data browser with summary statistics launched May 6, 2019 – **does not allow analysis using AI/AN race/ethnicity, Tribal affiliation, or zip code**



How does *All of Us* protect participant data?

- Names & other identifiers are removed
- Data is tiered according to sensitivity – with greater protections for more sensitive data
- Researchers must register to access data
 - Verify their identity
 - Complete training on ethical research
 - Agree not to conduct stigmatizing research or try to re-identify participants
- Researchers must provide a description of their research project to post on the *All of Us* Research Hub
 - Anyone, including participants, can flag studies that are potentially stigmatizing for *All of Us* Resource Access Board to review



Highlights of Concerns and Feedback Heard (1 of 3)

Cultural respect, understanding, and trust

- ⦿ Importance of acknowledging past harm 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

Highlights of Concerns and Feedback Heard (2 of 3)

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 (3 of 3)

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
- Tribes would need resources to support added activities *All of Us* may generate
- Tribal Epidemiology Centers would be critical partners for *All of Us* (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
- *All of Us* consent may not be sufficient for research using data that includes members of Tribal Nation

Request for Information (RFI)

The *All of Us* 2019 Tribal Consultation Request for Information (RFI)
is now open for comments until October 31, 2019

Request for Information (RFI): Soliciting Additional Input to the
All of Us Research Program 2019 Tribal Consultation

Notice Number: NOT-PM-19-004

Key Dates

Release Date: September 3, 2019

Response Date: October 31, 2019

Related Announcements

None

Issued by

All of Us Research Program, Office of the Director, National Institutes of Health (NIH)

Link available at: AllofUs.nih.gov/TribalEngagement
Comments should be submitted via email to AoUTribal@nih.gov.

Thank you!



National Institutes
of Health

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



@All of Us Research
#JoinAll of Us



[JoinAll of Us.org](https://www.joinallofus.org)

Visit our website to communicate with us via email, call, or text, and sign up for a listserv for email updates: [All of Us.nih.gov/TribalEngagement](https://www.all of us.nih.gov/TribalEngagement)

Discussion
