All of Us Advisory Panel Meeting: Open Session

https://allofus.nih.gov/about/who-we-are/all-us-research-program-advisory-panel

July 20, 2022
Joshua Denny, MD, MS
Chief Executive Officer
All of Us Research Program
Program Mission

Our Mission

Accelerate health research and medical breakthroughs, enabling individualized prevention, treatment, and care for all of us.

Nurture partnership for decades with at least a million participants who reflect the diversity of the U.S.

Deliver one of the largest, richest biomedical datasets that is broadly available and secure.

Catalyze an ecosystem of communities, researchers, and funders who make All of Us an indispensable part of health research.

Made possible by a team that maintains a culture built around the program’s core values.
Establishing Five Year Goals for End of 2026

- Enrollment and retention
- Gathering and curating data and specimens via the core protocol
- Ancillary studies
- Researcher access and impact
- Participant return of value
Five Year Goals
By 2026, we will:

- Enroll 1 million participants who reflect the diversity of the US, cover the lifespan, and have shared all baseline elements. Of these participants, 500,000 are actively engaged in the program.

- Expand data available for 1 million participants, to include surveys, health data streams, a whole genome sequence, environmental data, and physical measures.

- Develop and launch a scalable ancillary studies program that expands the cohort and delivers additional phenotypic, lifestyle, environmental, and biologic data.

- Establish a diverse global community of 10,000 researchers productively using All of Us data.

- Incorporate participant return of value into data collections and assess its impact, including return of information to participants on genomics and EHR.
Enrollment Update

- **510,000+** Participants
- **307,000+** Electronic Health Records
- **351,000+** Participants who have completed initial steps of the program
- **376,000+** Biosamples

Numbers current as of July 17, 2022
Status of the *All of Us* Research Program (as of July 9, 2022)

Over 80% of *All of Us* participants are underrepresented in biomedical research


researchallofus.org
Researcher Data Access

**Raw Data Repository**
- Data Curation
  - Raw Data
  - Data Harmonization
  - Privacy
  - Methodology
  - QA/QC

**Public Tier**
- (Available Now)
- Summary Statistics Aggregate Counts

**Registered Tier**
- (Available Now)
- Surveys, EHRs, Physical Measurements, shifted dates
- Exceeds HIPAA Safe Harbor Standards

**Controlled Tier**
- (Available Now)
- No obvious PII, Genomics, real dates, eventually
- Clinical Narrative data, and more

**Future Ancillary Studies**
- Could recontact participants, use biospecimens, issue new surveys or DHT, enroll in clinical trials

**Future**

**Researcher Workbench**
- ResearchAllofUs.org/Apply/

**Data Browser**
- databrowser.researchallofus.org
  - (public, no login required)

**5/2019**
- Summary Statistics Aggregate Counts

**5/2020**
- Surveys, EHRs, Physical Measurements, shifted dates
- Exceeds HIPAA Safe Harbor Standards

**3/2022**
- Surveys, EHRs, Physical Measurements, shifted dates
- Clinical Narrative data, and more

**Available Now**
- Public Tier
- Registered Tier
- Controlled Tier
Data Now Available in the Researcher Workbench

- **372,000+** Survey Responses
- **306,000+** Physical Measurements
- **258,000+** Electronic Health Records (EHR)
- **165,200** Genotyping Arrays
- **98,600** Whole Genome Sequences
  - Includes 100M+ variants with ≥ 3 occurrences not seen in gnomAD 3.0
- **12,800+** Fitbit Records

Next release (Winter 2022/23): >200K Whole Genome Sequences & updated phenotype data
All of Us will Enhance Diversity of Genomic Studies

First genomic data set

~50% diverse by race/ethnicity,

80% underrepresented in biomedical research

All Global GWAS values from www.gwasdiversitymonitor.com. Values current as of February 17, 2022
All of Us Tribal Engagement and Consultation Timeline

- **Nov 2019**
  - End of Tribal Consultation Input Period
- **Mar 29, 2021**
  - Tribal Consultation Report Release
- **Sep 30, 2021**
  - End of Participant Deliberation Period

- **May – Oct 2019**
  - Tribal Consultations & Listening Sessions Nationwide
- **May 2020**
  - AI/AN Participants Informed of Tribal Consultation and the Pause on Sharing of Data & Genomic Results

- **Coming Soon**
  - First AI/AN Participant Data in Researcher Workbench

- **To date, no data from self-identified AI/AN participants have been made available to researchers.**

- **Participants had a 6-month window to learn more about what we heard from Tribal leaders and decide whether they wanted to continue with the program.**

Link to Final Consultation Report: [bit.ly/FinalConsultation](bit.ly/FinalConsultation)
An “ancillary study” is a partnership that expands the All of Us dataset by:

- **Adding participants** outside the current recruitment audience and/or
- **Adding new data** outside the planned roadmap, either:
  - Generated from previously collected samples, images, or other sources (e.g., medical records)
  - Gathered directly from participants
  - Can be a subset of participants or the whole cohort

Ancillary studies are **not**:

- Research using existing All of Us data - surveys, EHR, genomics, etc. That’s just routine Research Workbench access
- A registry for other studies to recruit from without data return (e.g., an off-ramp)

Examples of Ancillary Studies:

- Custom questionnaires
- Devices
- Biospecimen access
- New biospecimen collection
- Participant recontact
- Observational trials
- Randomized controlled trials

Note: The assumption is that these are embedded within All of Us
Our Bold Vision for Ancillary Studies

Ancillary Studies in All of Us

- PILOT PARTNERSHIPS
- Exploring the Mind
- Nutrition for Precision Health
- COVID Serology
- ACTIV
- PREGSource

Full enrollment of 1 MILLION diverse participants covering the lifespan with all shared baseline elements

Launch >15 new studies by 2026
Researcher Workbench: By the Numbers *(Since Launch in May 2020)*

Research on the Researcher Workbench

- **2,723** Registered Researchers
- **2,108** Active Projects
- **50+ Publications** using *All of Us*

**>370 organizations, including:**
- non-profit healthcare and federal agencies
- >20 Historically Black Colleges and Universities
- >20 Hispanic Serving Institutions

Data as of 7/19/22
Recent Publications Utilizing *All of Us*

**Prevalence, Comorbidity, and Sociodemographic Correlates of Psychiatric Disorders Reported in the All of Us Research Program**

Peter B. Barr, PhD; Tim R. Bigdell, PhD; Jacqueline L. Mayers, PhD

**Proposing a Sex-Adjusted Sodium-Adjusted MELD Score for Liver Transplant Allocation**

Julia M. Sealock, PhD; Ioannis A. Ziogas, MD; Zhiguo Zhao, MS; Fei Ye, PhD; Sophoclis P. Alexopoulos, MD; Lea Matsuoka, MD; Guanhua Chen, PhD; Lea K. Davis, PhD

**Demographic differences in willingness to share electronic health records in the All of Us Research Program**

Christine L.M. Joseph\(^1\), Amy Tang\(^1\), David W. Chesla\(^2\), Mara M. Epstein\(^3, 4\), Pamala A. Pawloski\(^3\), Alan B. Stevens\(^5\), Stephen C. Waring\(^1\), Brian K. Ahmedani\(^6\), Christine C. Johnson\(^1\), and Cathryn D. Pelz-Rauchman\(^1\)

**Comparing medical history data derived from electronic health records and survey answers in the All of Us Research Program**

Lina Suliehman\(^1\), Robert M. Cronin\(^2, 3\), Robert J. Carroll\(^1\), Karthik Natarajan\(^8\), Kayla Marginean\(^8\), Brandy Mapes\(^6\), Dan Roden\(^1, 2, 3\), Paul Harris\(^1\), and Andrea Ramirez\(^6, 8\)

**Associations between healthcare utilization and access and diabetic retinopathy complications using *All of Us* nationwide survey data**

Alisson X. Chan\(^1, 5\), John J. McDermott IV\(^4, 5\), Terrence C. Lee\(^1, 5\), Gordon Y. Ye\(^1, 5\), Bita Shahrvin\(^1, 5\), Bharadhinaran Radha Saseendran\(^4, 5\), Sally L. Baxter\(^1, 5\)
Genetic Ancestry and Traits Available Now
Two Health-Related Research Report Choices Are Coming Soon

More than 100k have viewed their traits or ancestry results
Traits include bitter taste perception, cilantro preference, earwax type, lactose intolerance

Beginning in Winter 2022
59 genes for intervenable health conditions
Serious health conditions such as certain kinds of cancer or heart disease

7 genes for drug-gene interactions
Genes that can affect how medicines are used
Funding Opportunities

Current Funding Opportunities

- Research Opportunity Announcement: *All of Us* Engagement, Communications, and Enrollment Partnerships OTA-22-006
- New Investigators to Promote Workforce Diversity in Genomics, Bioinformatics, or Bioengineering and Biomedical Imaging Research RFA-HG-21-041
- Educational Hub for Enhancing Diversity in Computational Genomics and Data Science RFA-HG-22-002

Past Funding Opportunities

- Administrative Supplements to Support *All of Us* and Health Disparities-Related Pilot Research Projects at NIMHD-Funded Research Centers in Minority Institutions NOT-MD-22-015
- Administrative Supplements to Advance Precision Medicine Using the *All of Us* Research Program’s Data NOT-PM-22-002
- Network of the National Library of Medicine All of Us Program Center (U24) RFA-LM-21-002

https://allofus.nih.gov/funding-and-program-partners/funding-opportunities
Thank you to our Participants!!!

Thanks to you, we’ve reached 500K participants!
A half million people who reflect the diversity of the U.S. have started their journey with the National Institutes of Health’s All of Us Research Program. We look forward to learning more about your health story in the years to come. Look for new opportunities to share health data and receive information about your own health—including DNA results at no cost if you choose! Thanks again, and share All of Us with friends and family. Here’s to 500,000 more participants in the future!

Thank You Video: bit.ly/thankyou500k
AllofUs.NIH.gov
JoinAllofUs.org
ResearchAllofUs.org