Ethical considerations in the

All of Us Research Program

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overview
What is the *All of Us* Research Program?

- **Rich, Longitudinal Resource**: Deliver a national resource of deep clinical, environmental, lifestyle, & genetic data from one million participants who are consented & engaged to provide data on an ongoing, longitudinal basis (60+ years!)

- **Diversity of Participants**: Reflect the broad diversity of the U.S.—all ages, races/ethnicities, gender, SES, geographies, & health status—by over-recruiting those underrepresented in biomedical research

- **Diversity of Researchers**: Build the tools & capabilities that make it easy for researchers from community scientists to premier university labs to make discoveries using the data & biosamples and through ancillary studies w/ the cohort
All of Us Research Program Data

- Participant Surveys
- Electronic Health Records
- Physical Measurements
- Biospecimens and Assays
- Mobile/Wearable Tech
- Geospatial/Environmental Data

Data types will grow and evolve with science, technology, and trust
ethics!

There’s no right way to do the wrong thing.
“They’re harmless when they’re alone, but get a bunch of them together with a research grant and watch out.”
All of Us Core Values

- Participation in the All of Us Research Program is open to interested individuals
- The program will reflect the rich diversity of the United States
- Participants are partners in the program
- Trust is earned through robust engagement and full transparency
- Participants will have access to information and data about themselves
- Data from the program will be broadly accessible to empower research
- The program will adhere to the PMI Privacy and Trust Principles and the PMI Data Security Policy Principles and Framework
- The program will be a catalyst for innovative research programs and policies
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Disenfranchisement and Historical Abuses
The All of Us Data Resource Code of Conduct (examples)

**I WILL:**
- know and follow all applicable federal, state, and local laws regarding human data access and privacy.
- contact the All of Us Research Program Resource Access Board (RAB) within 24 hours if I become aware of any uses or disclosures of All of Us data that endanger the security or privacy of research participants, including any unintended re-identification of participants through the process of my work.

**I will NOT:**
- use All of Us Research Program data for research that is discriminatory or stigmatizing of individuals, families, or communities.
- attempt to re-identify research participants or their relatives.
- use or disclose the information other than as permitted by this DUA.
- make copies of or download individual-level data resources outside of the All of Us research environment without approval from RAB.
Research Participants Want Information Back

**PLOS ONE** published a public opinion survey conducted by the Foundation for the NIH.

2,601 responses were analyzed.

79% supported the program after reading a short description.

54% said they would definitely or probably participate if asked—not predictive of enrollment numbers, but encouraging.

- Little variability among demographic groups
- Most important incentive for participation: **learning about one’s health information**

National Academies Report

- Support decision making regarding the return of results on a study-by-study basis
- Promote high-quality individual research results
- Foster participant understanding of individual research results
- Revise and harmonize current regulations
Balancing Paternalism with Autonomy

- What information should participants receive? What information do participants have a right to receive?
- What are the potential benefits and harms to the receipt of that information?
- Are there means of mitigating negative outcomes resulting from the return of information?
- Where is the apposite limen between research and clinical care?
- Is there an obligation to provide participants with a choice to receive some or all of the information?
Last thoughts…

- Times are changing, and change is good… but complicated
- Without our participants, we are nowhere
- The answer to almost anything will be, “It depends”
- When in doubt, ask