Ethical considerations in the

All of Us Research Program

Katherine D. Blizinsky, Ph.D.
Policy Director, All of Us Research Program
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
- Physical Measurements
- Mobile/Wearable Tech
- Electronic Health Records
- Biospecimens and Assays
- Geospatial/Environmental Data

Data types will grow and evolve with science, technology, and trust
NIH will invest to level the playing field so diverse researchers can play

- *All of Us* data will be available to *all types of users*
- The *All of Us* Data Resource will employ a *cloud-based analysis platform*
- Access will be *tiered*
- Users will be granted *data passports*
- Project information will be made *public and auditable*
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.
ethics!

There's no right way to do the wrong thing.
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Disenfranchisement and Historical Abuses
Sharing Data with Researchers

- Control of sharing and use
- Participant privacy
- Identifiability of data
- Data access
- Data use and misuse
“They’re harmless when they’re alone, but get a bunch of them together with a research grant and watch out.”
considerations

- Legal and regulatory obligations
- Data types
- Paternalism and autonomy
- Feasibility

Sharing Data with Participants
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?
questions?

katherine.blizinsky@nih.gov
allofus.nih.gov | @AllofUsResearch | #JoinAllofUs

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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
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