Ethical considerations in the

All of Us Research Program

National Institutes of Health

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All of Us 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

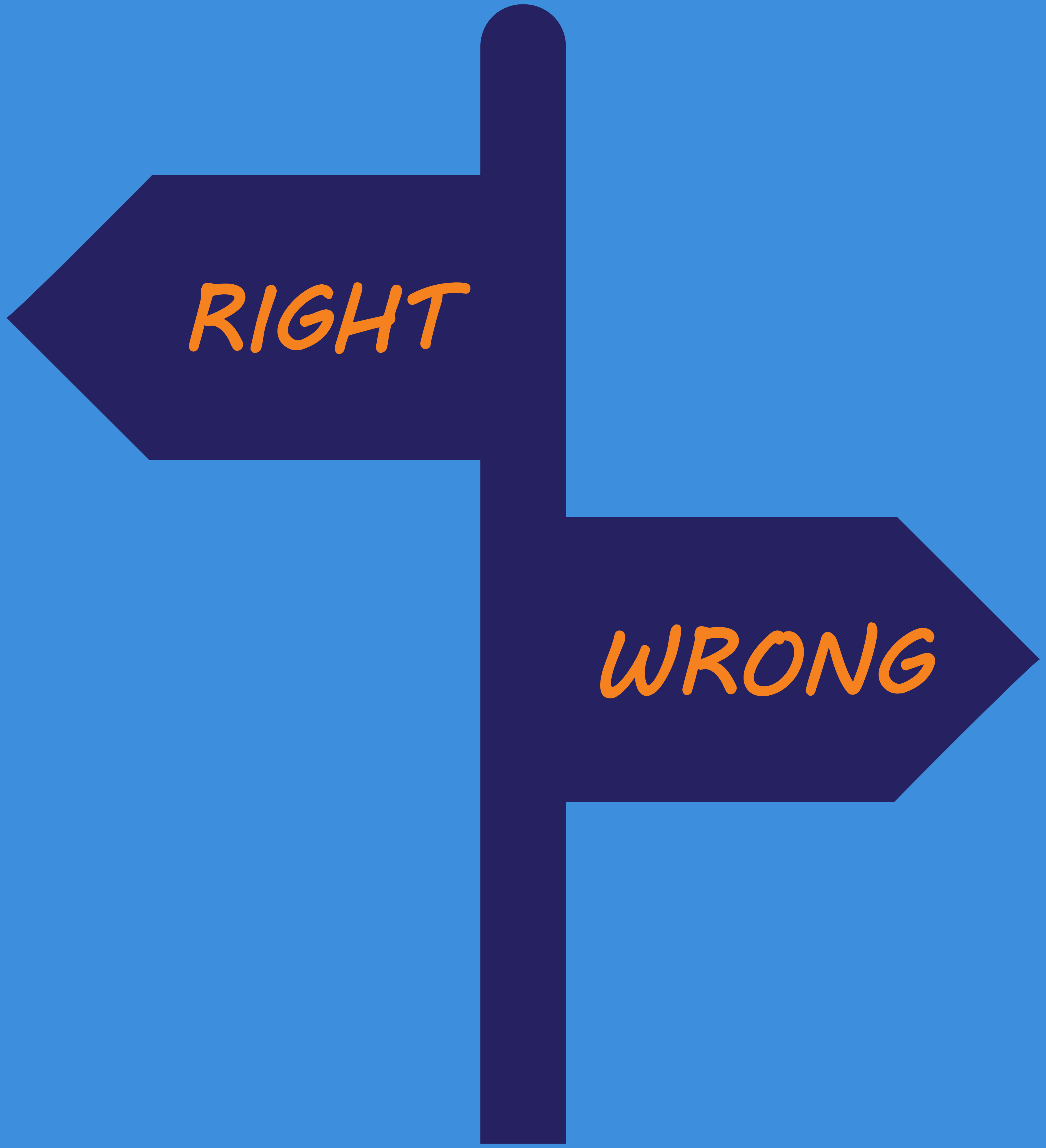
All of Us Research Program Data

- 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

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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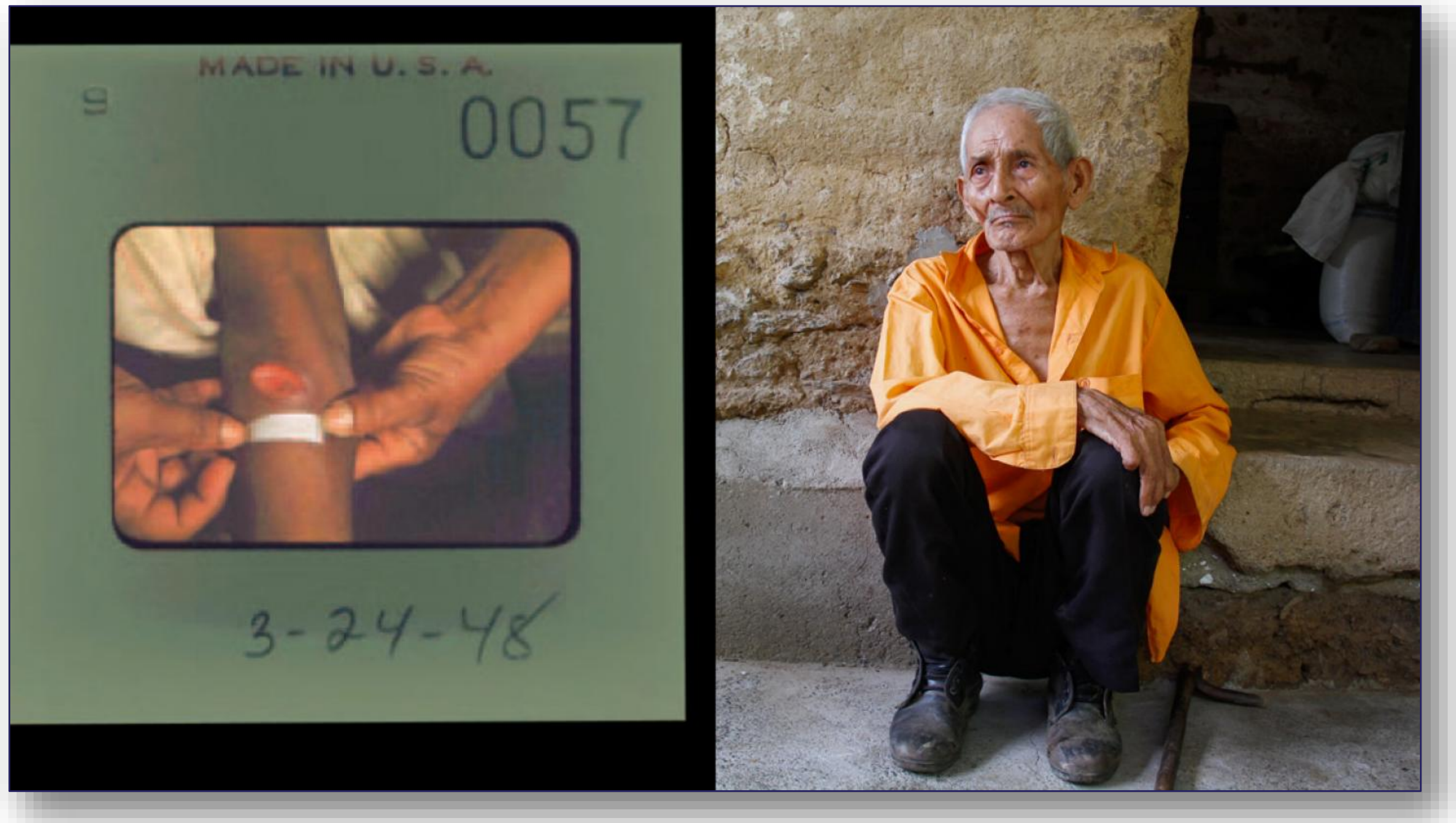
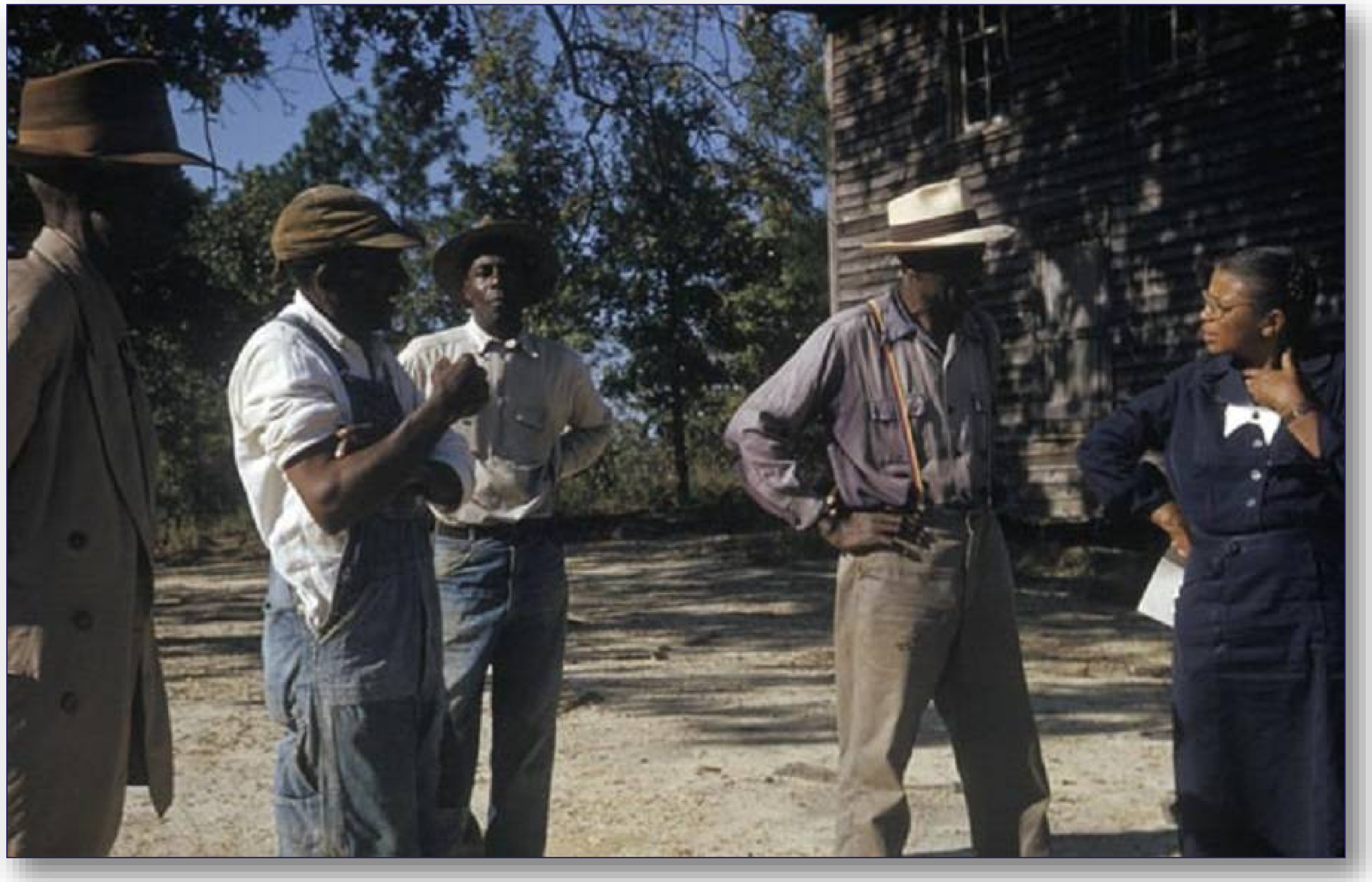
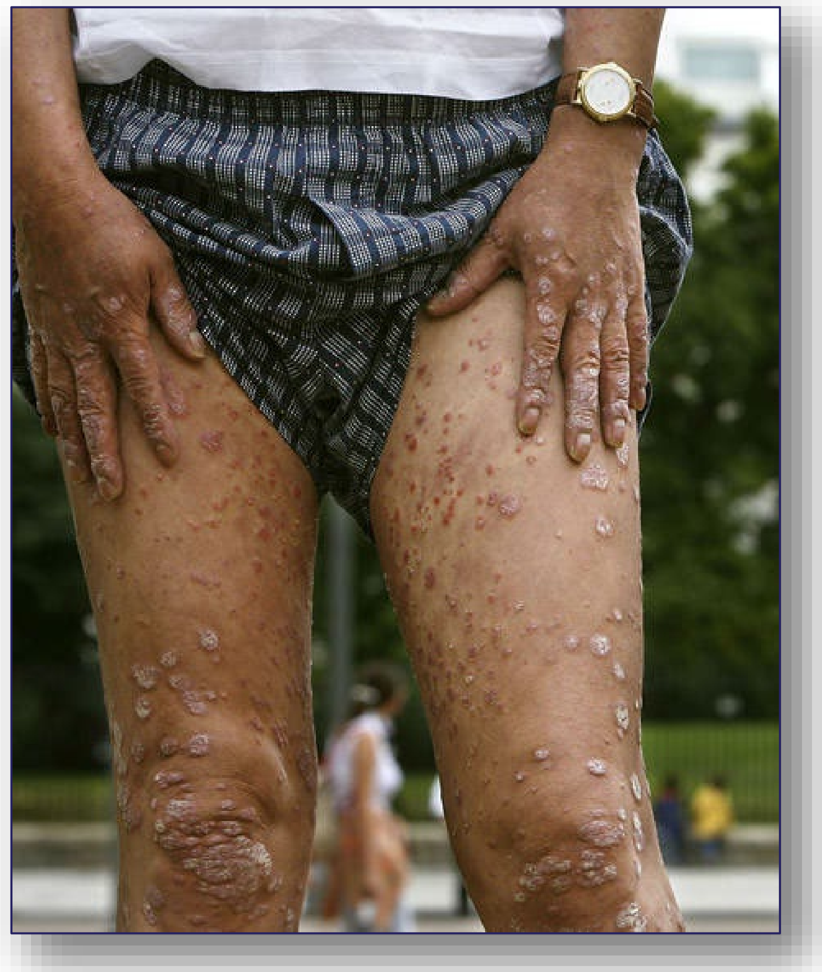
Disenfranchisement and Historical Abuses







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THE FUTURE OF HEALTH BEGINS WITH YOU

The
Precision
Medicine
Initiative

?uestions?

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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**

Kaufman DJ, Baker R, Milner LC, Devaney S, Hudson KL (2016):
A Survey of U.S. Adults’ Opinions about Conduct of a Nationwide Precision Medicine Initiative Cohort Study of Genes and Environment.
PLOS ONE 11(8): e0160461. doi:10.1371/journal.pone.0160461

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


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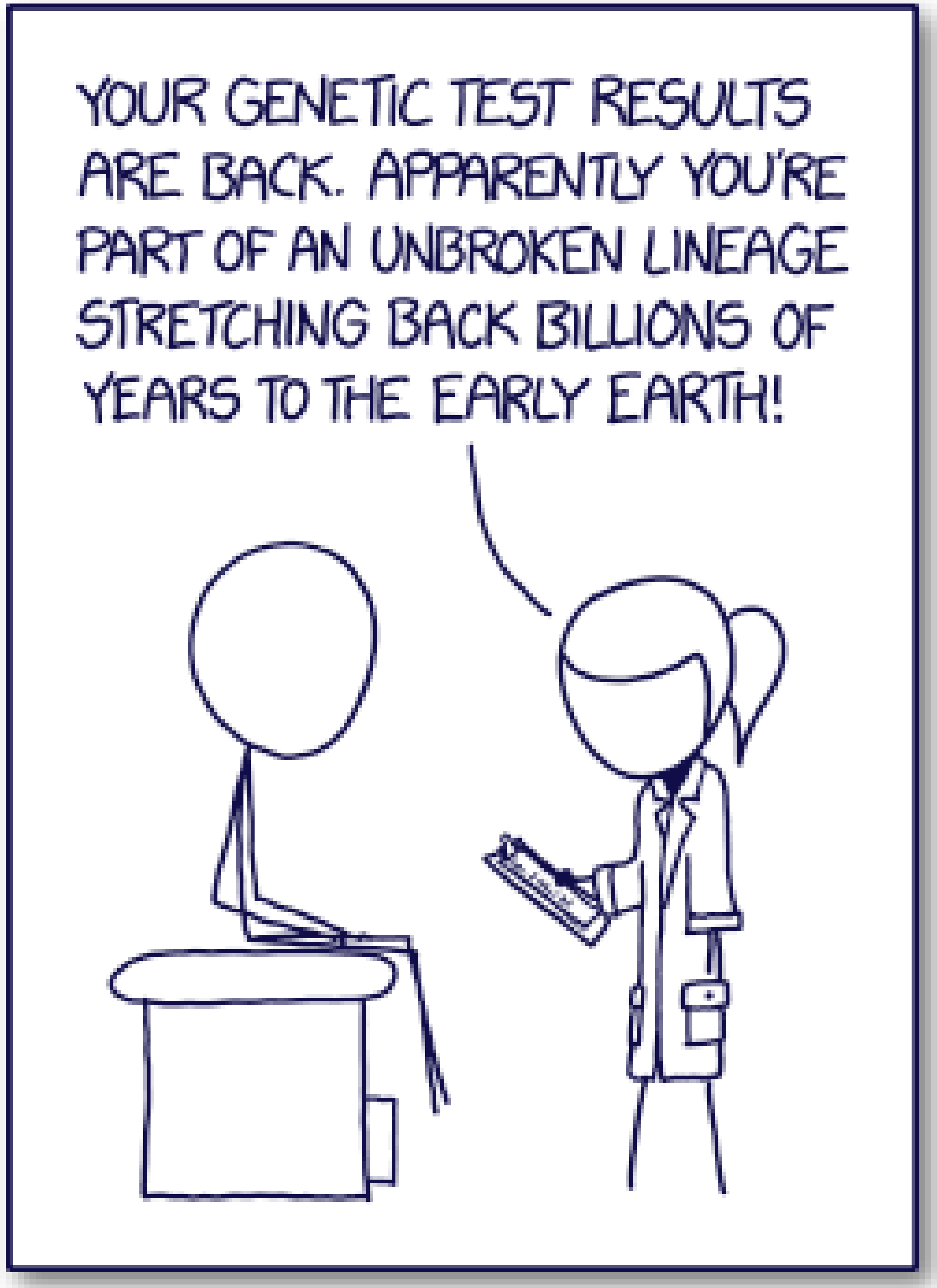
CONSENSUS STUDY REPORT

Returning Individual Research Results to Participants

GUIDANCE FOR A NEW RESEARCH PARADIGM

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