June 24, 2019

All of Us RESEARCH PROGRAM | The Future of Health Begins With You

Policy Implementation

NIH National Institutes of Health

Ericka Thomas, NIH

John Wilbanks, Sage Bionetworks

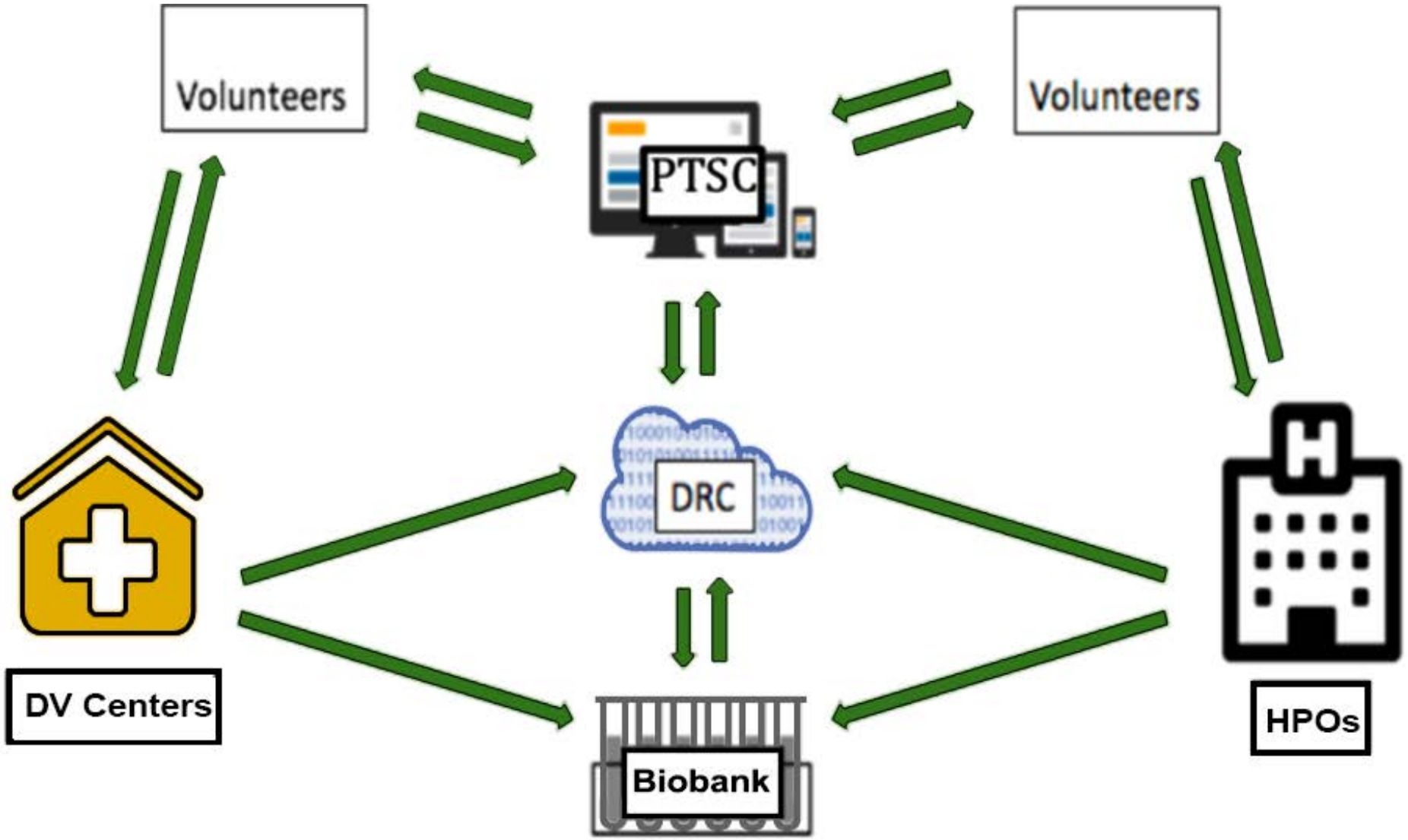
Purpose

- Explain the core protocol design and implementation
- Walkthrough of informed consent process + available data
- Policy overview

Sage Bionetworks governance team

Tori Allen
Vanessa Barone
Megan Doerr
Sarah Moore
Ann Novakowski
Allie Seroussi
Christine Suver
Amy Truong

Protocol Integration Process



http://bit.ly/AOUProtocol

Mental model of the protocol

- 80-20 principle
  - National core protocol
  - Site-specific amendments
- Separation of concerns
  - Standalone protocol elements for key functional areas (DRC etc)
  - Isolate ”bugs” so they don’t spread
- Leverage national core protocol as best practices emerge
  - Communications
  - Engagement

Airtable

Core Protocol- Shared

Hide fields | Filter | Grouped by 1 field | Sort | ...

	Name	Original Submission to IRB	Submitted by	IRB Status	Sent to Josh Denny- PI	Approved by Josh Den...	IRB Approval Date
IRB STATUS Submitted to IRB	Count 1						
1	Pre-Review Genomic resu...	3/29/2019	Sarah Moore	Submitted to IRB			
IRB STATUS In Development	Count 2						
2	PPI- Appendix G1, G2		Sarah Moore	In Development	✔		
3	Core Protocol V1.11		Tori Allen	In Development	✔		
IRB STATUS Approved	Count 10						
4	PPI - Appendix G4	4/20/2018	Christine Suver	Approved			4/23/2018
5	PPI - Appendx G5, G6	4/20/2018	Christine Suver	Approved			4/26/2018
6	Core Protocol v1.8	6/29/2018	Christine Suver	Approved			7/11/2018
7	Core Protocol v1.9	9/27/2018	Christine Suver	Approved			10/18/2018
8	Core Protocol v1.10	12/7/2018	Tori Allen	Approved	✔	✔	3/5/2019
9	Core Protocol v1.7	2/20/2018		Approved			3/28/2018
10	Core Protocol v1.6	12/8/2017		Approved			2/13/2018
11	Core Protocol V1.5	10/28/2016		Approved			5/20/2017
12	Website App and Privacy ...	3/31/2019	Tori Allen	Approved	✔	✔	5/22/2019
13	Core Protocol Renewal 2	4/3/2019	Tori Allen	Approved	✔	✔	5/1/2019

13 records

Screenshot

A U Protocol

- Overview
- Blog
- Calendars
- Space Settings

PAGES

- All Things IRB
- IRB-Approved Core Materials
- Other Pages
- Old HPO Script Page

Protocol

Protocol and IRB submissions

Share ••• Add to My Spaces

News:

The IRB has approved Protocol 1.10 as of March 5th, 2019.

Please check our new page, which links to statuses of IRB submissions.

There is a new version of the ISIA annual update template posted here.

Please check the Annual Update Calendar and Strategy Guide 2019/2020 to find your institution's annual update deadline.

Shortcuts to:

- Status of IRB Submissions
- Consent documents
- Core Protocol
- IRB-Approved Core Materials
- Scripts for partner organizations

Space Content

- All Things IRB
  - IRB Submission Status
  - IRB Best Practices & Lessons Learned
  - IRB Templates/Forms
  - IRB SOPs
  - Local Site Incident Reports
- IRB-Approved Core Materials
  - Core Protocol Corner
    - Getting to Protocol V1.5
  - Consent
  - HPO Scripts
  - IRB-Approved ISIAs - Page Maintained by NIH

Screenshot

Space contributors

- Tori Allen (30 days ago)
- Allie Seroussi (46 days ago)
- Sarah Moore (46 days ago)
- Christine Suver (108 days ago)
- Holly Garriock (208 days ago)
- ...

what do people want to know about?

How to?
- Where is the research taking place?
- Will transportation be provided?
- Who can participate in *All of Us*?
- Is there a cost involved?

How does it work?
- What is research? (generally/specifically)
- How will *All of Us* interact with participants?

Why is this part of the research?
- Why do you want my blood and what are you going to do with it?
- Why is DNA included?
- Why do you need my medical records?
- What are you looking for?

What are yout not telling me?
- What are they trying to do with people?
- Who else will have access to my medical records?

Privacy concerns
- Who will see this?
- What protections are there?
- Why are you putting my privacy at risk?

Results
- Will I have access to my test results?
- What will the results tell me?
- Who will have access to the results?

what words make sense to people?

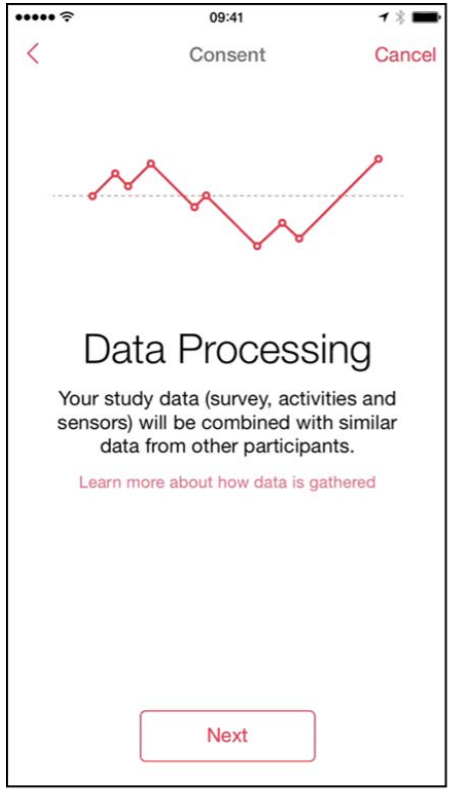
Don’t know/not familiar	Kind of know/ maybe familiar	Know/comfortable
Biobank	Electronic Health Record	DNA
Certificate of Confidentially	Genetic testing information	Doctor
Data breach	Research program	Family history
Database	Risk to privacy	Medicine
De-identify personal information	Participant portal	
EHR		
Withdraw		

9

The biggest lie on the internet: "I have read and understood the terms of service"

On July 7, two US academics published a paper entitled "The Biggest Lie on the Internet: "Ignoring the privacy policies and terms of service policies of social networking services" which details an experiment they carried out on 543 students, asking them to open

Delay start
Temperature
OK
Spin speed
Start
Stop
Tide
Cottons
Minimum iron
Woollens
Proofing
Further programmes



- Mobile or web-app highlight reel of the informed consent form (“long form”)
- Series of participant self-navigated, self-paced screens
- May include animation, video, other interactive elements
- May include summative or formative assessment
- One of three major user agreements for app-mediated research
  - eConsent
  - Long form
  - Privacy Policy/Terms of Use

MGH
1811
OHSU
Y
NYU Langone
MEDICAL CENTER
Y
DAM
ASAA
UNI
FREIBURG
UNIVERSITY OF THE PACIFIC
1851
VE RI
TAS

All of Us informed consent requirements

- Single national consent that is also compliant with all state/territory-specific regulations*
- Accommodate both at home and in person completion
- Scalable
- Comprehensible
- Transparent

*see PMID: 30963079

NATIONAL, SCIENCE, HEALTH & SAFETY

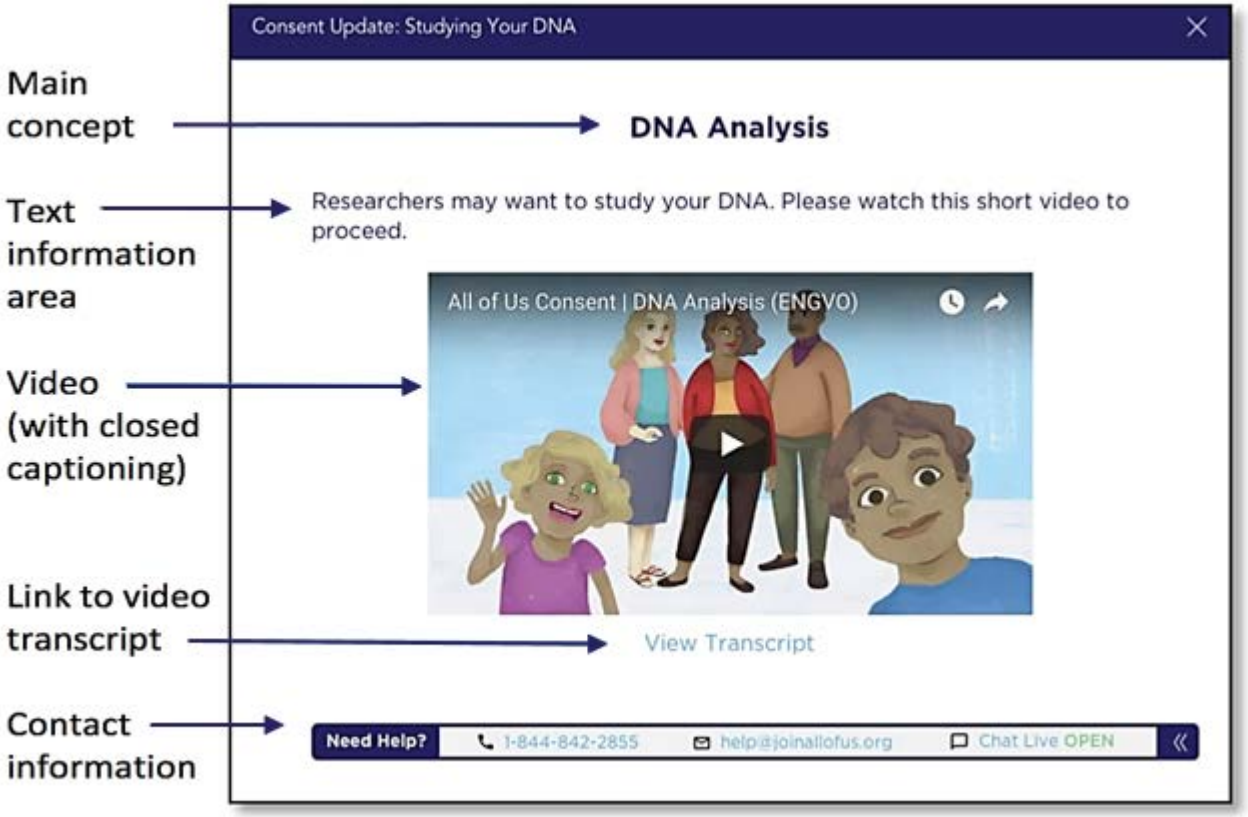
Scientists Work To Overcome Legacy Of Tuskegee Study, Henrietta Lacks

by Rob Stein 7:22pm Oct 25, 2017

View Slideshow

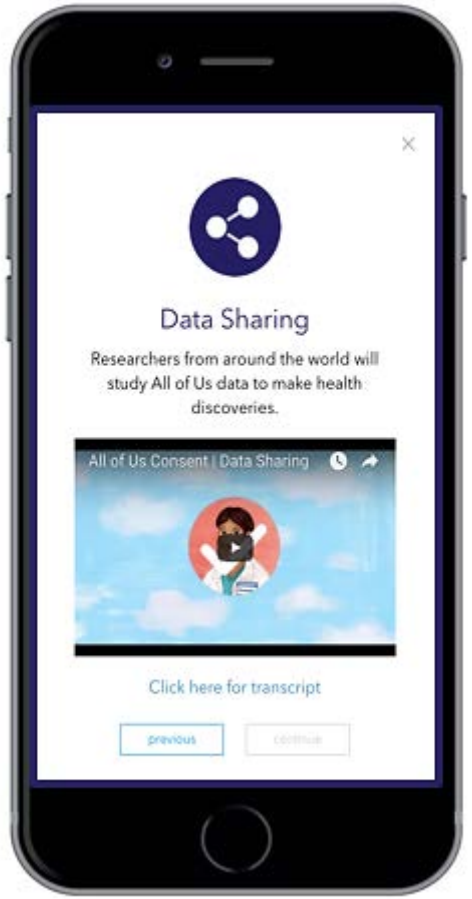
Kolbi Brown (left), a program manager at Harlem Hospital in New York, helps Karen Phillips sign up to receive more information about the All of Us medical research program, during a block party outside the Abyssinian Baptist Church in Harlem. *Elias Williams for NPR*

All of Us eConsent structure



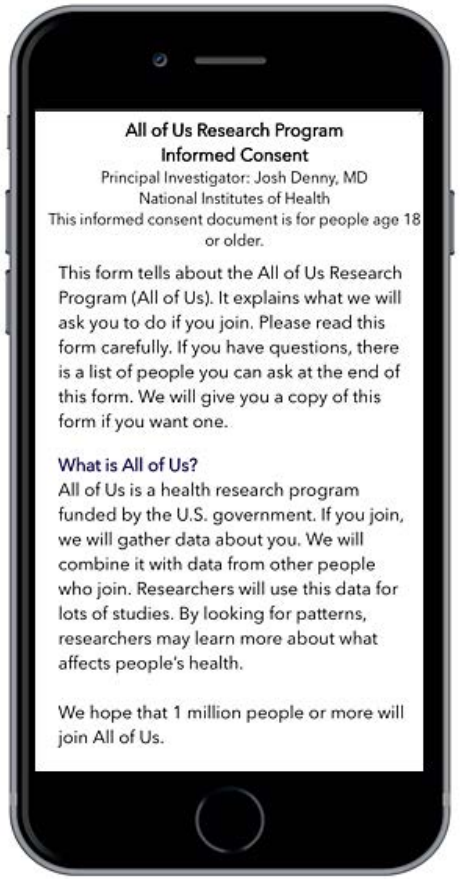
All of Us eConsents

- Consent is modular
  - Primary consent
  - HIPAA Authorization
  - Others as needed
- Written at the 5th grade reading level
- Primary eConsent includes nine 15-45 second videos
- Linear navigation
- “Get help” buttons link to national support center



All of Us primary long form & HIPAA Auth

- Primary long form and HIPAA Auth each written at the 5th grade reading level
  - Primary consent reading ease 77
  - HIPAA Auth reading ease 74
- Lots of white space
- 14 point type
- No sections in all caps



All of Us Research Program
Informed Consent
Principal Investigator: Josh Denny, MD
National Institutes of Health
This informed consent document is for people age 18 or older.

This form tells about the All of Us Research Program (All of Us). It explains what we will ask you to do if you join. Please read this form carefully. If you have questions, there is a list of people you can ask at the end of this form. We will give you a copy of this form if you want one.

What is All of Us?
All of Us is a health research program funded by the U.S. government. If you join, we will gather data about you. We will combine it with data from other people who join. Researchers will use this data for lots of studies. By looking for patterns, researchers may learn more about what affects people's health.

We hope that 1 million people or more will join All of Us.

Primary Consent

May 1, 2019 - May 31, 2019

Filters

- Metro Area
- Campaign utm
- Source / Medium
- Channels
- Content utm

Links

- Join Report
- User Journey Screenshots

Primary Consent Dropoffs

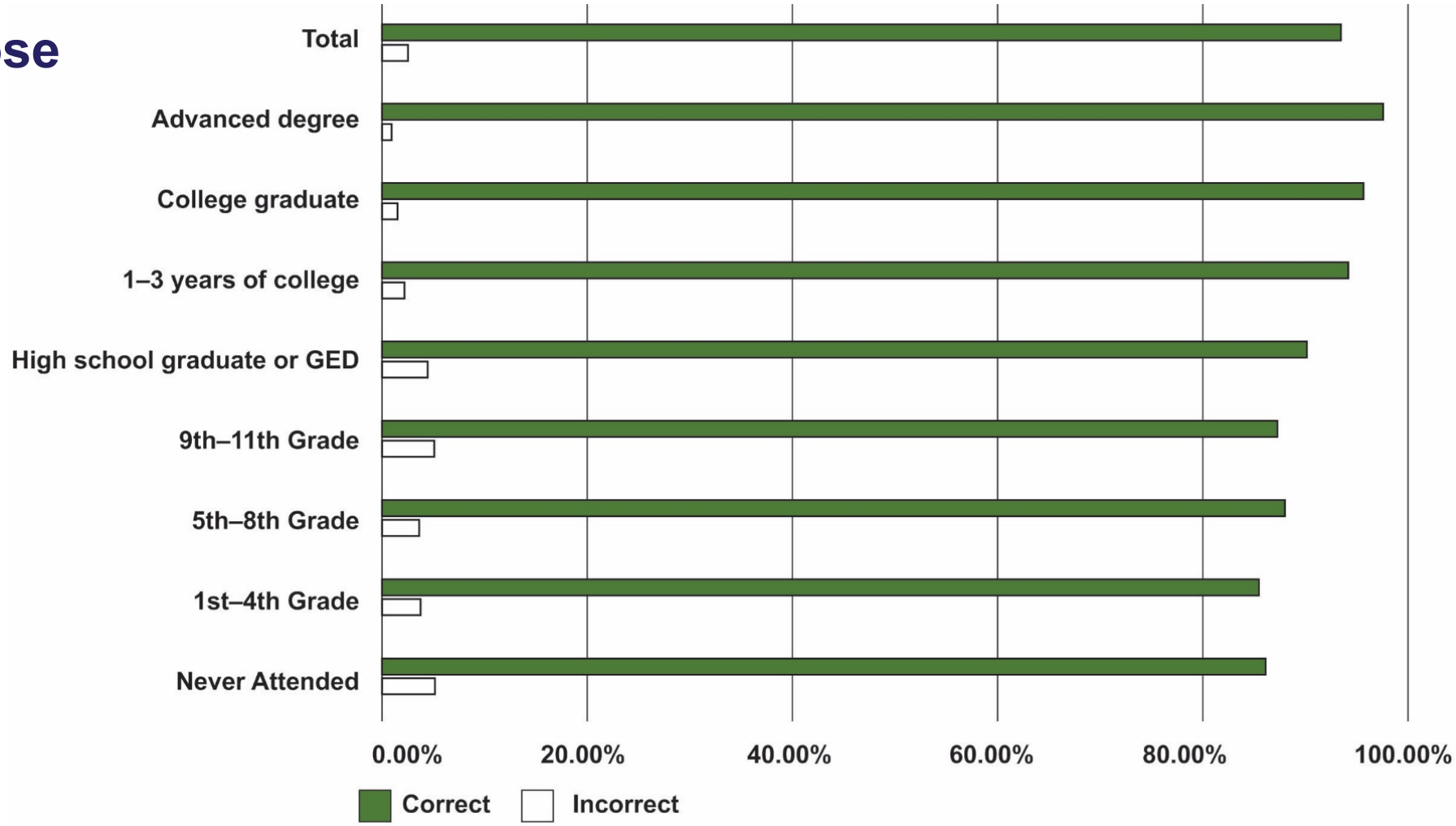
Page # - Name - Detail	Count of User ID	Avg Time on Page hh:mm:ss
01 - welcome - video	17,295	00:00:01
02 - are you ready?	16,267	00:00:13
03 - just so you know	16,241	00:00:08
04 - you're about to make history	16,082	00:00:21
05 - state of residence	16,030	00:00:13
06 - where you get healthcare	15,995	00:00:12
07 - check your understanding	15,955	00:00:09
08 - what will i do?	15,960	00:00:05

Screenshot

does it work?

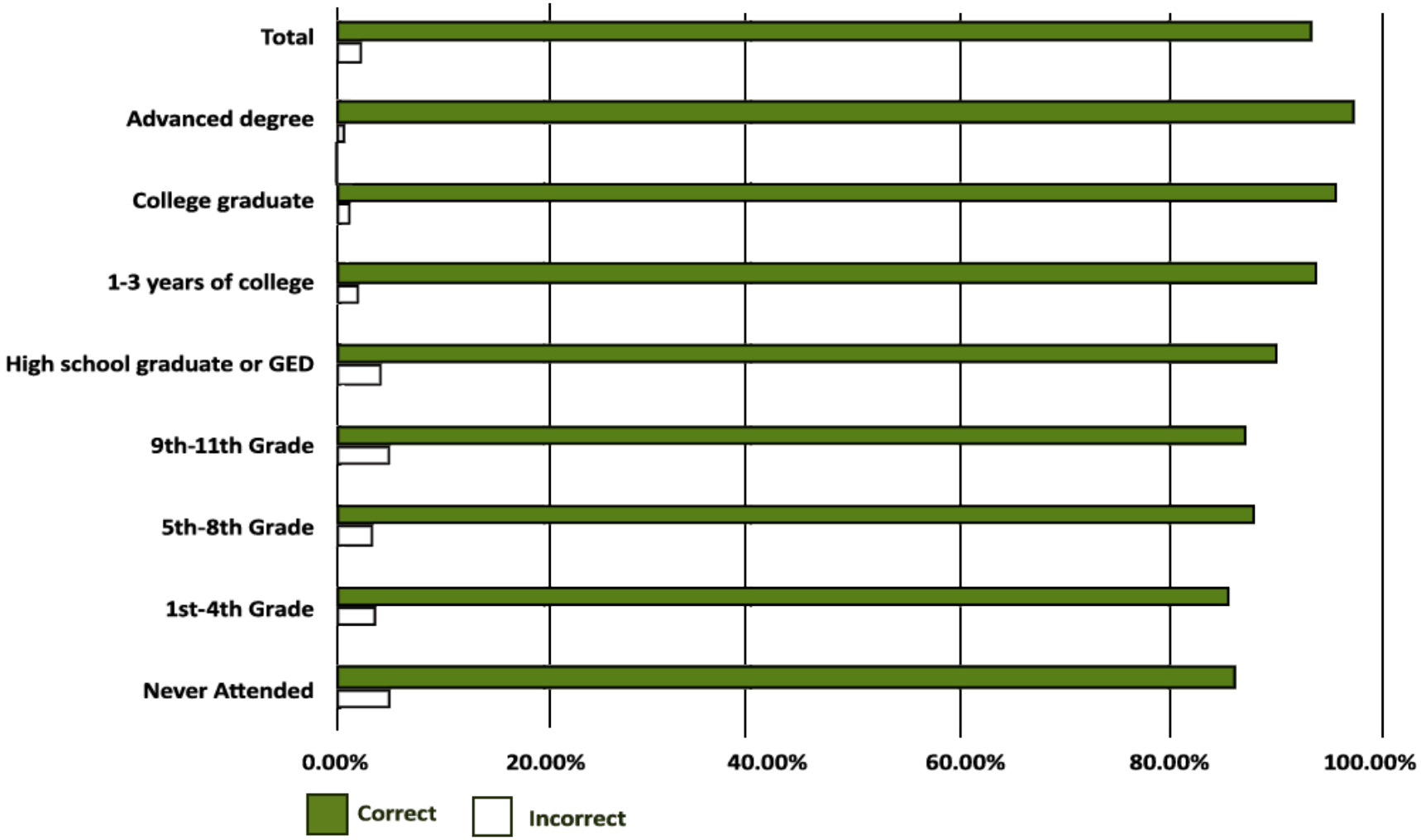
What is the purpose of *All of Us*?

- **To help scientists make discoveries about health.**
- To give medical advice and treatment.



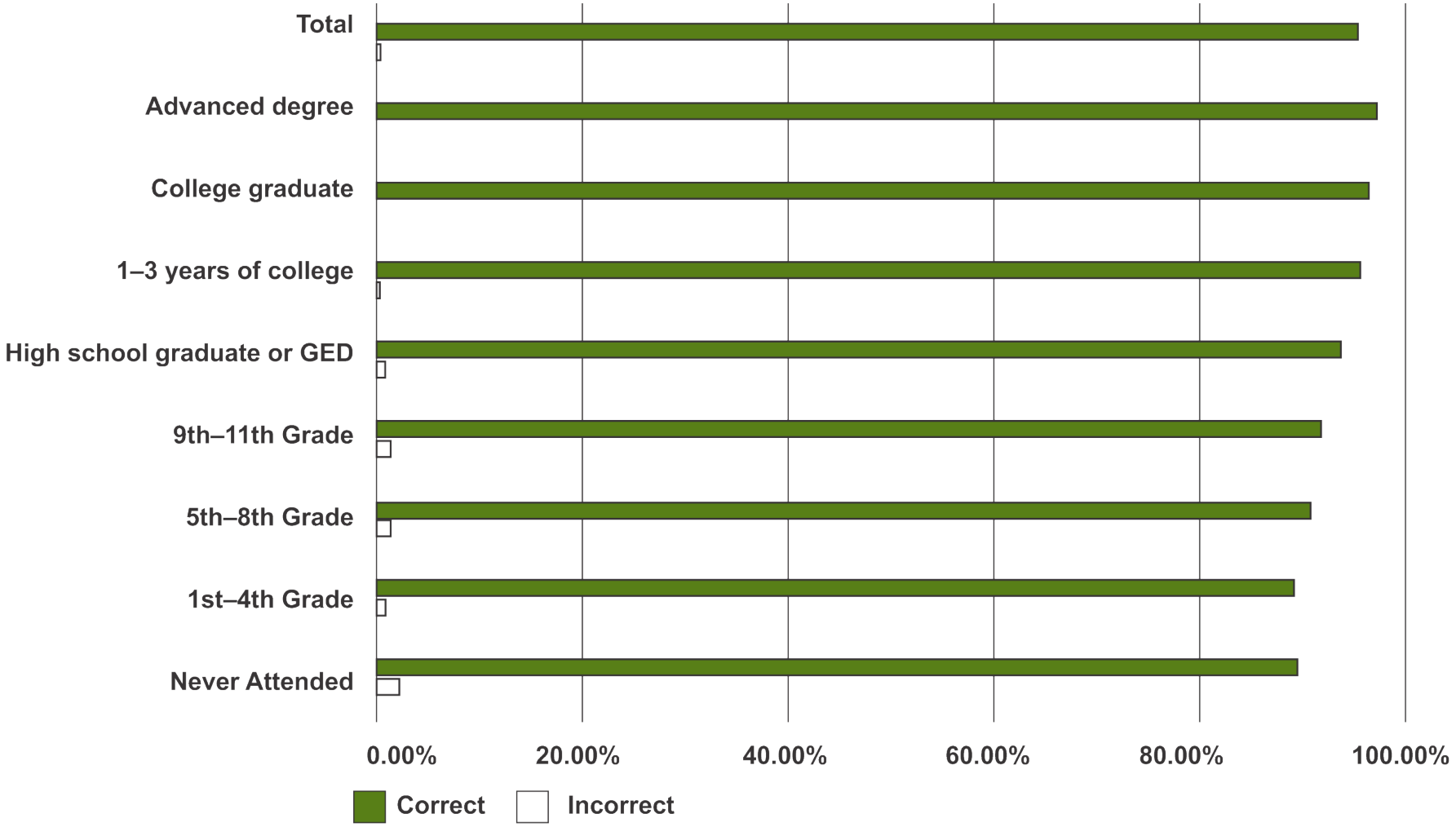
Do I have to take part in *All of Us*?

- **Taking part is voluntary. I get to choose if I want to do it.**
- Taking part is required. I have to do it.



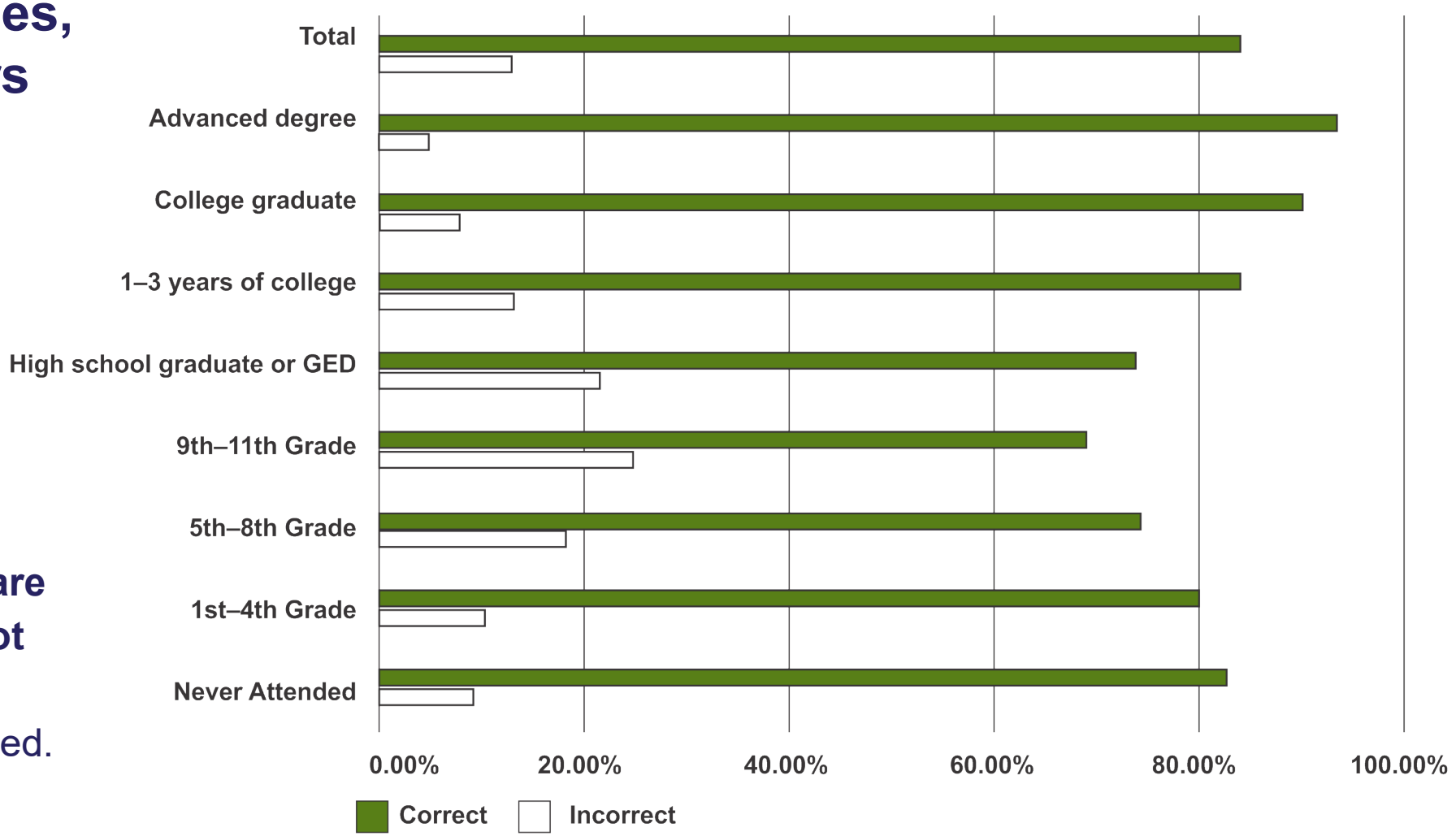
If I join, can I withdraw (“quit”)?

- **I can withdraw at any time.**
- I can’t withdraw ever.



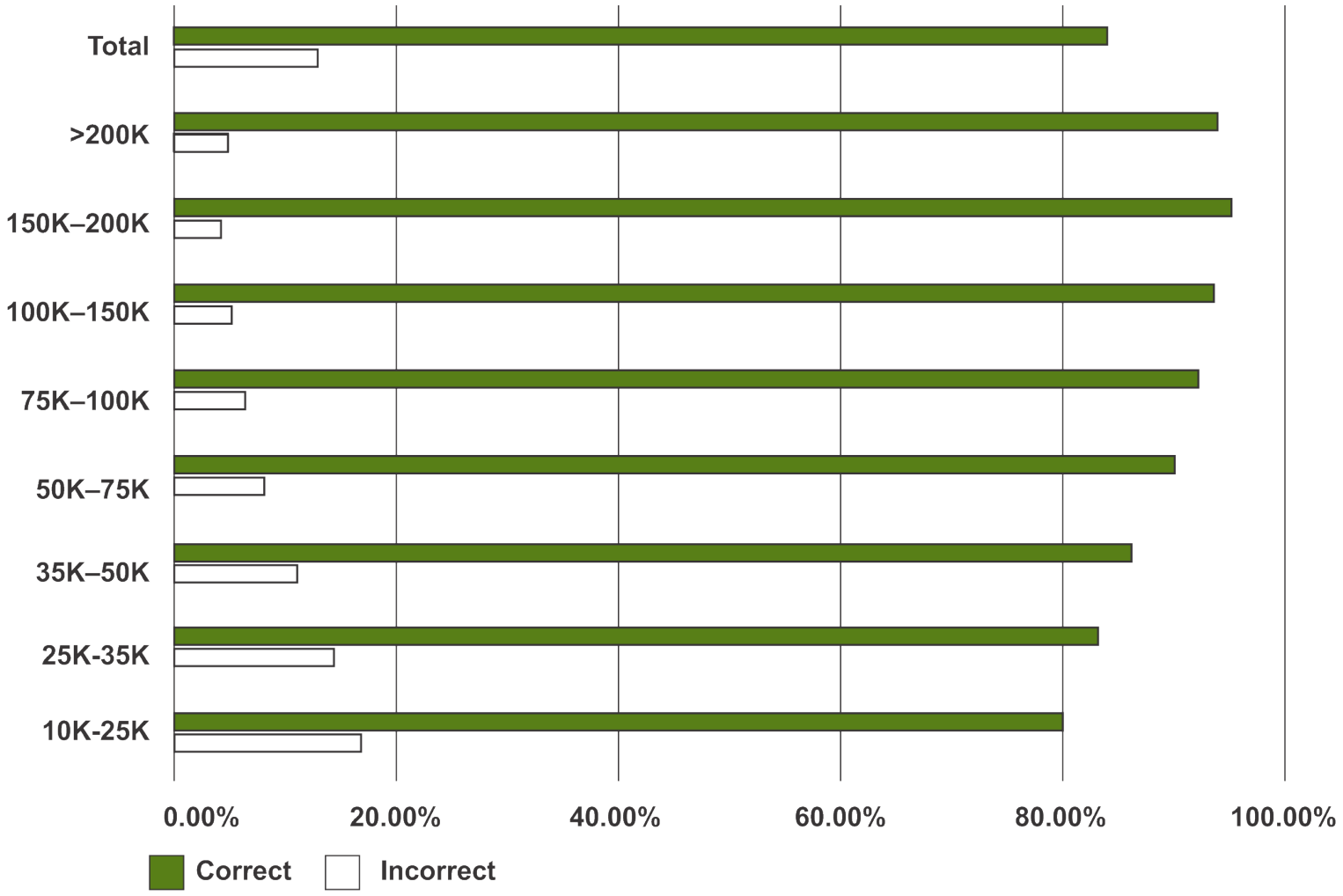
Using smartphones, apps, and sensors are always a potential risk to privacy. Can *All of Us* guarantee your privacy?

- **Risks to my privacy are minimized, but are not zero.**
- My privacy is guaranteed.



Using smartphones, apps, and sensors are always a potential risk to privacy. Can *All of Us* guarantee your privacy?

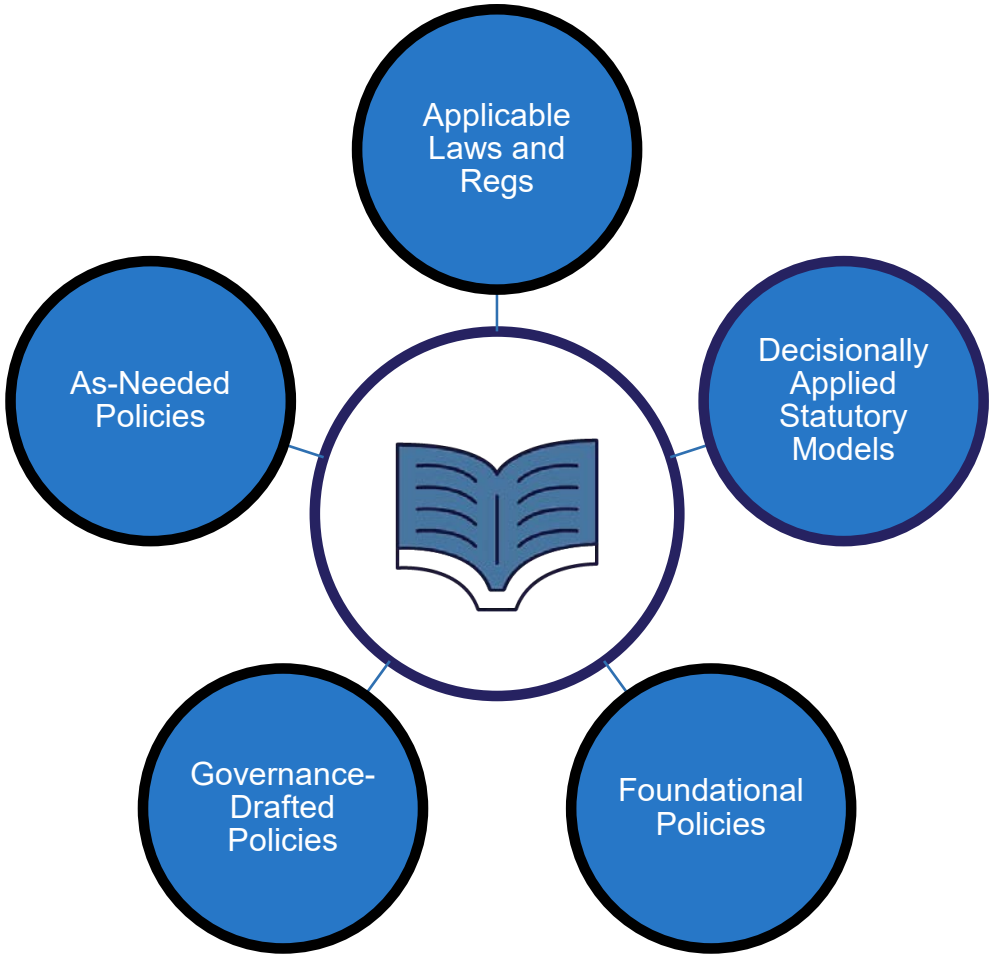
- **Risks to my privacy are minimized, but are not zero.**
- My privacy is guaranteed.



Policy Implementation

Policy Development

- Federal/State laws and regulations that apply
- Federal laws and regulations that do not strictly apply but are adopted as policy choices
- Policies that were written to shape the program
- Policies drafted by *All of Us* Governance bodies
- Policies derived from need



Policy Development

- **Federal/State laws and regulations that apply**
- Federal laws and regulations that do not strictly apply but are adopted as policy choices
- Policies that were written to shape the program
- Policies drafted by *All of Us* Governance bodies
- Policies derived from need

Federal/State Laws and Regulations that Apply

e.g., State Laws and Informed Consent

All "flavors" available in both English and Spanish

Primary Consent

"Parent" CA-Specific Vet-Specific

HIPAA Authorization

"Parent" 80 yr Expiry IL-Specific

30 mo Expiry Vet-Specific

12 mo Expiry

Return of Genomic Results Consent

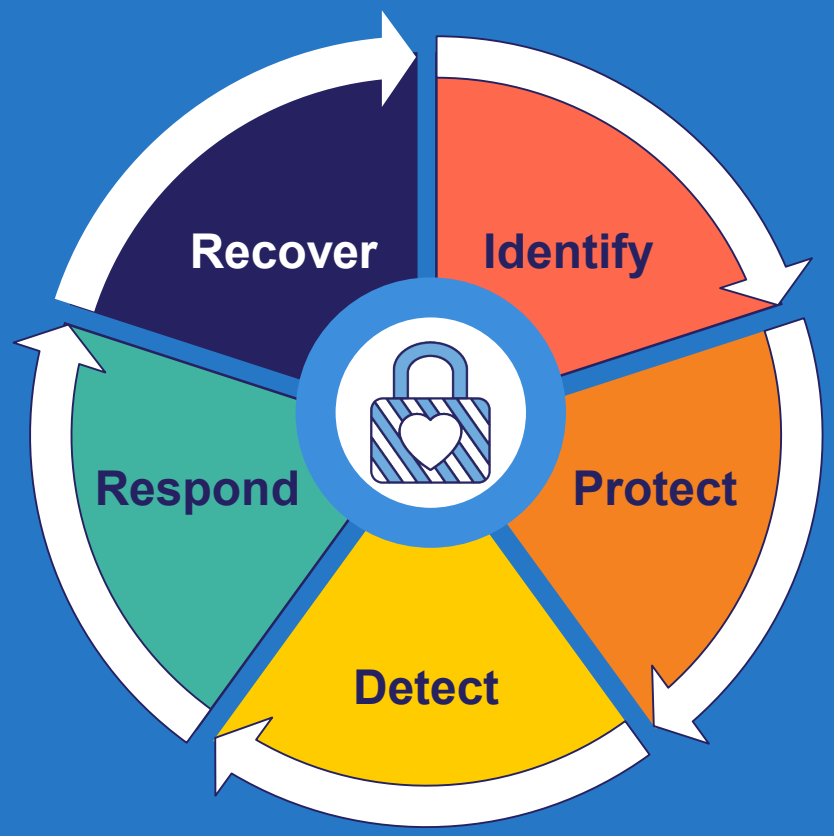
"Parent" FL-Specific

Policy Development

- Federal/State laws and regulations that apply
- **Federal laws and regulations that do not strictly apply but are adopted as policy choices**
- Policies that were written to shape the program
- Policies drafted by *All of Us* Governance bodies
- Policies derived from need

Federal Laws and Regulations that Do Not Strictly Apply but are Adopted as Policy Choices

e.g., FISMA and Security Practices

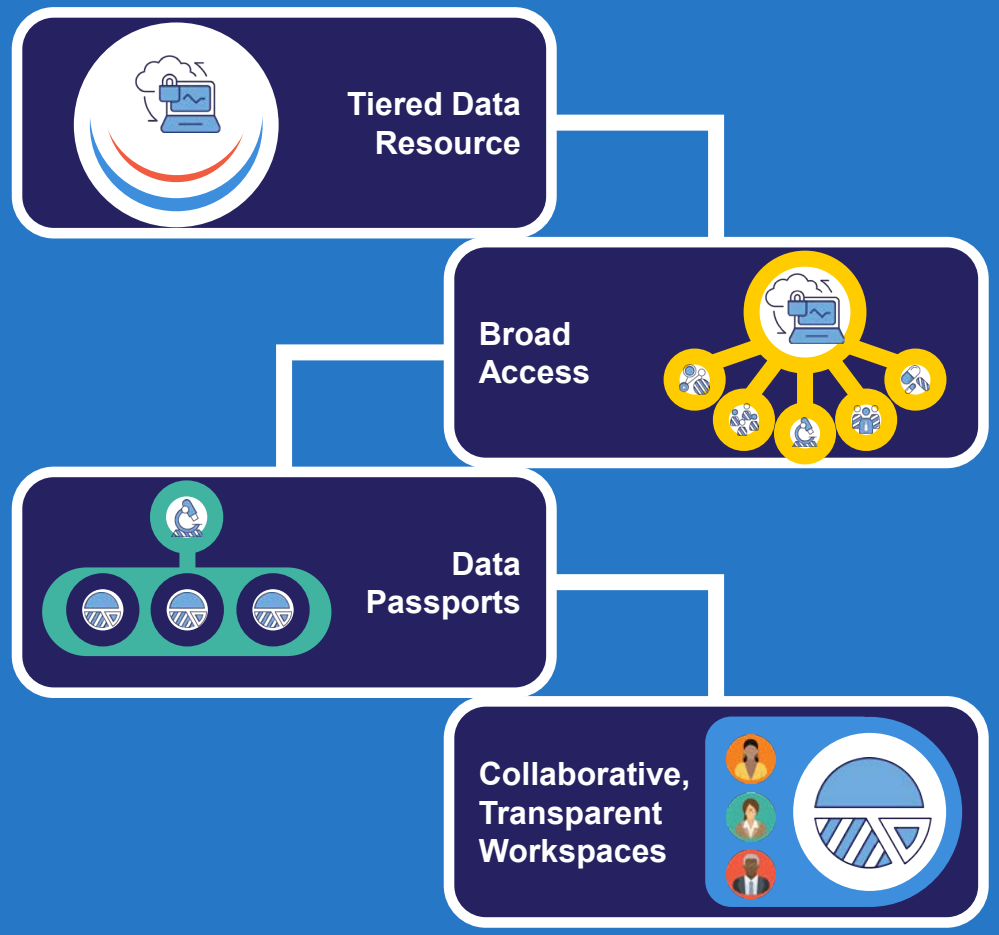


Policy Development

- Federal/State laws and regulations that apply
- Federal laws and regulations that do not strictly apply but are adopted as policy choices
- **Policies that were written to shape the program**
- Policies drafted by *All of Us* Governance bodies
- Policies derived from need

Policies Written to Shape the Program

e.g., PMI Privacy and Trust Principles and Data Resource Structure

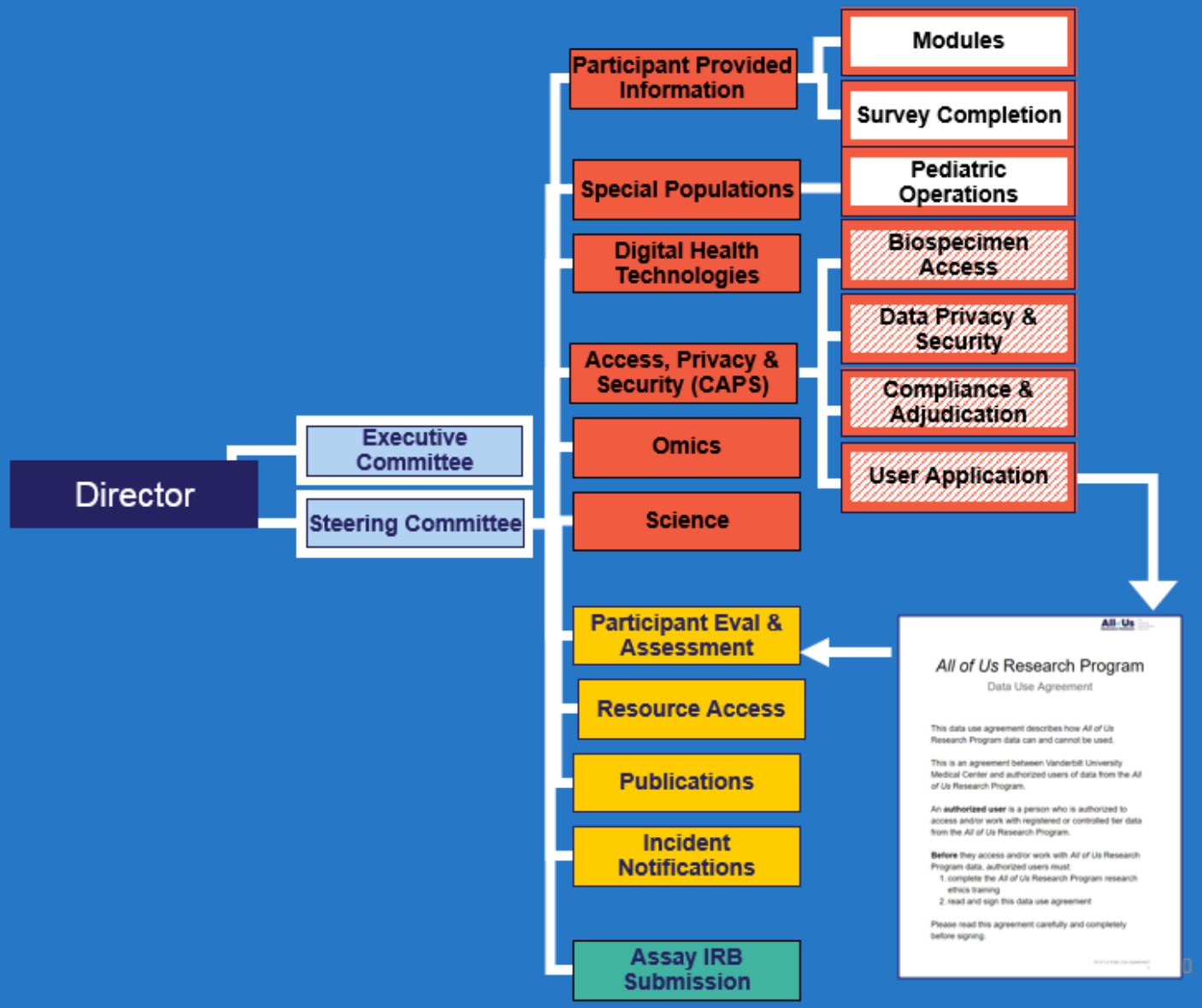


Policy Development

- Federal/State laws and regulations that apply
- Federal laws and regulations that do not strictly apply but are adopted as policy choices
- Policies that were written to shape the program
- **Policies drafted by *All of Us* Governance bodies**
- Policies derived from need

Policies Drafted by *All of Us* Governance Bodies

e.g., CAPS and the Data Use Agreement



Policy Development

- Federal/State laws and regulations that apply
- Federal laws and regulations that do not strictly apply but are adopted as policy choices
- Policies that were written to shape the program
- Policies drafted by *All of Us* Governance bodies
- **Policies derived from need**

Policies Derived from Need

e.g., Stigmatizing Research and the RAB

All of Us RESEARCH PROGRAM

POLICY STATEMENT

AUTHOR: Katherine D. Blizinsky, PhD
DATE: 7/16/2018
TOPIC: Stigmatizing Research

ISSUE

Central to the mission of the *All of Us* Research Program is the collection of information from diverse groups of people within the U.S. population. However, the Program must recognize the potential for resources collected in good faith to be used towards social detriment. In order to take steps to minimize and/or prevent such actions, the Program must establish a working definition upon which to base preventative measures.

RULE AND ANALYSIS

Stigma may be understood as convergence of the following components:[1]

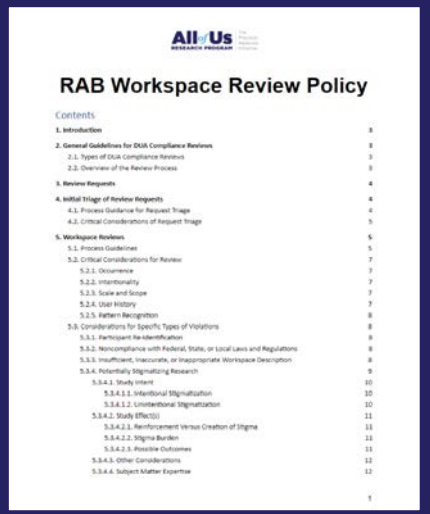
1) **The identification and labeling of human differences.** Not all differences are deemed socially relevant. Certain differences—such as differences in skin color, ethnicity, country of origin, ancestry, sex, gender, sexual orientation, socioeconomic status, educational attainment, disability status, and body type—are considerably more prone to stigma than others. Salience of labels in such domains are dependent on a process during which gross oversimplification of an attribute or characteristic creates artificial categories, upon which contextually-specific social selection occurs.
2) **The linking of labeled persons by dominant cultural belief to undesirable characteristics and formation of negative stereotypes.** A key feature in this process is the provision of characteristics that may be linked to one or more social labels. Scientific research can provide just such fodder, and the result can be arbitrary stereotypes socially perpetuated under the banner of science.
3) **Separation of people into categories of "us" and "them" by applying said stereotypes.** The logical next step after the perpetration of a negative stereotype is the use of that stereotype to define in-groups and out-groups.
4) **The experience of loss of status and discrimination by labeled persons.** This is the ultimate output of the stigma process. Here, "out-group" members are downwardly placed, with regards to the "in-group," and subjected to detrimental treatment, consideration, or distinction based upon label(s), rather than merit.[2] Discrimination can be leveraged by an individual or group towards an individual or collection of individuals. However, discrimination is particularly dangerous in its structural form, when discriminatory behavior becomes culturally accepted and

[1] Link BG and Phelan JC. (2001). Conceptualizing Stigma. *Ann Rev Sociology*. 27:363-385.
[2] Discrimination. (n.d.) *Black's Encyclopedia of American Law, edition 2*. (2008).

1

Stigmatizing research is any research proposal, project, or question that has ***the potential to instigate or promote marginalization, discrimination, or loss of status by a person or group of people.*** Stigma may be inherent in the research design (i.e. the formation of a research question based on prejudicial biases) or a byproduct of the research findings (i.e. the interpretation of findings in such a way as to promote negative stereotypes) and may be intentional or unintentional. While complete elimination of stigmatizing research based on use of the *All of Us* data resources is likely impossible, ***the Program should take steps in earnest to prevent resource use with the potential to stigmatize and to punish bad actors,*** as appropriate.

For claims of potentially stigmatizing research… RAB members… should feel empowered to inspect ***whatever workspace components or related information they deem necessary*** to make their determination... Regardless of this latitude, evaluations of the potential to stigmatize may be frustrated by the sheer subjectivity of such judgements. However, the review should consist of, but is not limited to, consideration of ***a project's intent to stigmatize*** (Section 5.3.4.1) and ***the effect(s) a study or its findings may have*** (Section 5.3.4.2)… The RAB is actively encouraged, particularly in the case of potentially stigmatizing research, to ***request input from subject matter experts*** either within or outside the consortium.



All of Us RESEARCH PROGRAM

RAB Workspace Review Policy

Contents

1. Introduction 3
2. General Guidelines for DUA Compliance Reviews 3
2.1. Types of DUA Compliance Reviews 3
2.2. Overview of the Review Process 3
3. Review Requests 4
4. Initial Triage of Review Requests 4
4.1. Process Guidance for Request Triage 4
4.2. Critical Considerations of Request Triage 5
5. Workspace Reviews 5
5.1. Process Guidelines 5
5.2. Critical Considerations for Review 7
5.2.1. Occurrence 7
5.2.2. Intentionality 7
5.2.3. Scale and Scope 7
5.2.4. User History 7
5.2.5. Pattern Recognition 8
5.3. Considerations for Specific Types of Violations 8
5.3.1. Participant Re-identification 8
5.3.2. Noncompliance with Federal, State, or Local Laws and Regulations 8
5.3.3. Insufficient, Inaccurate, or Inappropriate Workspace Description 8
5.3.4. Potentially Stigmatizing Research 9
5.3.4.1. Study Intent 10
5.3.4.1.1. Intentional Stigmatization 10
5.3.4.1.2. Unintentional Stigmatization 10
5.3.4.2. Study Effect(s) 11
5.3.4.2.1. Reinforcement Versus Creation of Stigma 11
5.3.4.2.2. Stigma Burden 11
5.3.4.2.3. Possible Outcomes 11
5.3.4.3. Other Considerations 12
5.3.4.4. Subject Matter Expertise 12

1

Questions?

joinallofus.org

@AllofUsResearch | #JoinAllofUs

Precision Medicine Initiative, PMI, All of Us, the All of Us logo, and The Future of Health Begins With You are service marks of the U.S. Department of Health and Human Services.