Session 2: How Researchers Access and Use *All of Us* Data

June 13, 2023

Logistics

- **Links and resources will be posted in the chat**

- **Please pose questions in the chat**

- **Please keep yourself on mute - at the end of the program, we'll address questions in the chat and open up for live questions**

- **The Questions and Discussion section will be recorded for our notes but not posted online**

- **Slides and a recording will be posted online afterwards**

- **Contact the Tribal Engagement team at AOUTribal@nih.gov**

Data Governance in the *All of Us* Research Program

13 June 2023
Policy Office Staff
All of Us Research Program

National Institutes of Health

Sonya Jooma, M.A.
(she/her)
Deputy Policy Director

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Policy Director

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Thank you!

***All of Us* Participants & Participant Ambassadors**

***All of Us* Program Staff and Partners**

- Community Partners
- Consortium Members

***All of Us* Advisory and Governance Bodies**

- ELSI Brain Trust
- Committee on Access, Privacy and Security
- Resource Access Board

***All of Us* IRB**

NIH Office of Science Policy

NIH Office of the General Counsel

Presentation Overview

1   **Introduction**

- The History of *All of Us*
- *All of Us* Basics (Review)
- The Policy Office

2   **Considerations**

- Historical Context
- Important Considerations for Policy-Making
- Data Governance Principles

3   **Data Governance** *Logistics*

- Database Compilation and Structure
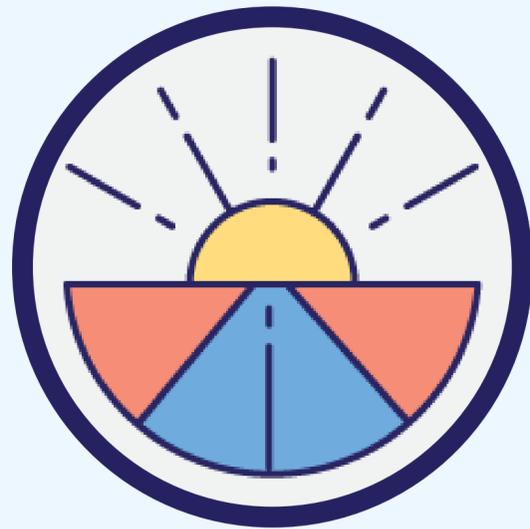- Data Access Process
- Privacy and Security Measures

4   **Data Governance** *Policies*

- Conceptual Model
- Education
- Accountability
- Assistance and Oversight

5   **Discussion and Questions**

Introduction

- The History of *All of Us*
- *All of Us* Basics (Review)
- The Policy Office

- **2015 |** White House announces the Precision Medicine Initiative with the mission to:

  "…enable a new era of medicine through research, technology, and policies that empower patients, researchers, and providers to work together toward development of individualized care."

  - Privacy and Trust Principles
  - Security Framework

  To read more, please visit
  allofus.nih.gov/protecting-data-and-privacy

- **2016a |** Codified and statutorily mandated by the 21st Century Cures Act

- **2016b |** Initial work on the "PMI Cohort Program" begins at NIH, what will become All of Us

ACCELERATED MEDICAL RESEARCH …FUELED BY *you.*

The *All of Us* Research Program
Diversity at Scale

Diversity of Resources | Deliver a national resource of deep **clinical, environmental, lifestyle, & genetic data** from one million or more participants who are consented & engaged to provide data on an ongoing, longitudinal basis

Diversity of Participants | Reflect the broad diversity of the U.S.— **all ages, races, ethnicities, sexes, genders, SES's, geographies, & health and disability statuses**—and over-recruit those historically underrepresented in biomedical research

Diversity of Researchers | Build the tools & capabilities that make it accessible to the public and easy for researchers—**from citizen and community scientists to scientists from premier university labs**—to make discoveries using *All of Us*

The *All of Us* Research Program | Comprehensive Research Resources

Participant Surveys
- The Basics
- Lifestyle
- Overall Health
- Personal & Family Medical Hx
- Health Care Access & Utilization
- Social Determinants of Health
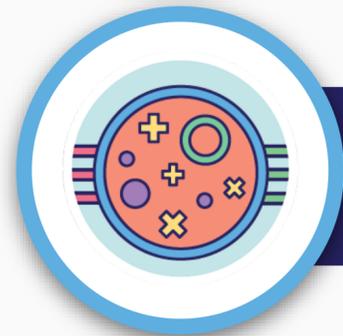- *Mental Health and Wellbeing*

Electronic Health Records
- Medical Records
- *Claims Data*
- *Pharmacy Data*
- *Vision and Dental Records*

Physical Measurements
- Blood Pressure
- BMI
- Heart Rate
- Height
- Hip Circumference
- Waist Circumference
- Weight

Biospecimens
- Blood
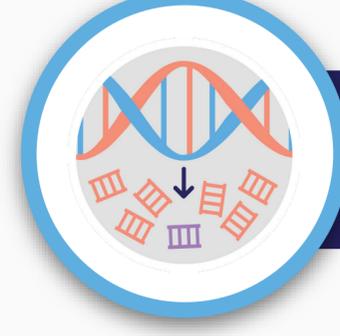- Saliva
- Urine
- DNA (from blood or *saliva*)
- *RNA*

Mobile/Wearable Tech

Assays
- COVID Serology
- *HbA1c*
- *Heavy Metals*

Omics
- WGS Arrays
- *Other Omics*

For more on upcoming data types, please visit the Data Road Map at *allof-us.org/Roadmap*

Policy

noun

pol·i·cy   'pä-lə-sē
plural **policies**
often attributive

1   **a :** prudence or wisdom in the management of affairs
b : management or procedure based primarily on material interest

2   **a :** a definite course or method of action selected from among alternatives and in light of given conditions to guide and determine present and future decisions
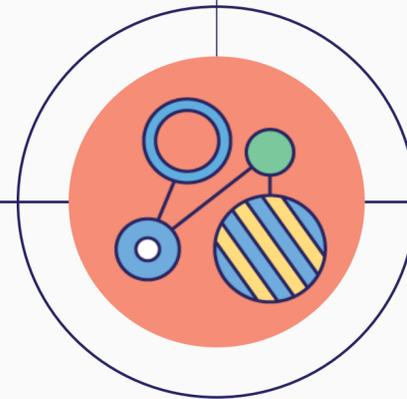
b : a high-level overall plan embracing the general goals and acceptable procedures especially of a governing body

The *All of Us* Research Program | Program Development Roles

Program leadership
decides to pursue a
program development
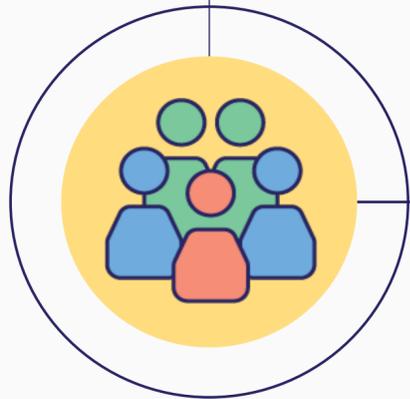
**Program and consortium
staff** plan, build, and
implement the development

Policy Office determines
the boundaries within
which development occurs

Research Compliance
ensures program activities
stay within the boundaries

FUNCTIONAL areas

	CONSIDERATION	**INTERPRETATION**	**PROMULGATION**
	Evaluating ethical and social obligations for the program	Setting the terms for legal, regulatory, and policy compliance	Establishing and overseeing program-wide policies and principles

TOPICAL areas

|	CONSIDERATION	INTERPRETATION	PROMULGATION
	Evaluating ethical and social obligations for the program	*Setting the terms for legal, regulatory, and policy compliance*	*Establishing and overseeing program-wide policies and principles*
PROGRAM OPERATIONS	**How the program itself approaches its mission and objectives**		
AGREEMENTS	**How the program enables participants (or their authorized representatives) to exercise their right to make autonomous, informed choices**		
PARTICIPANT PROTECTIONS	**What the appropriate measures are to protect participants from foreseeable, preventable harm**		
RESOURCE GOVERNANCE	**How and under what conditions individuals may access and use research resources**		
GENOMICS	**How and under what conditions the program shares genetic and genomic information with participants and researchers**		

Considerations

- Historical Context
- Important Considerations for Policy-Making
- Data Governance Principles
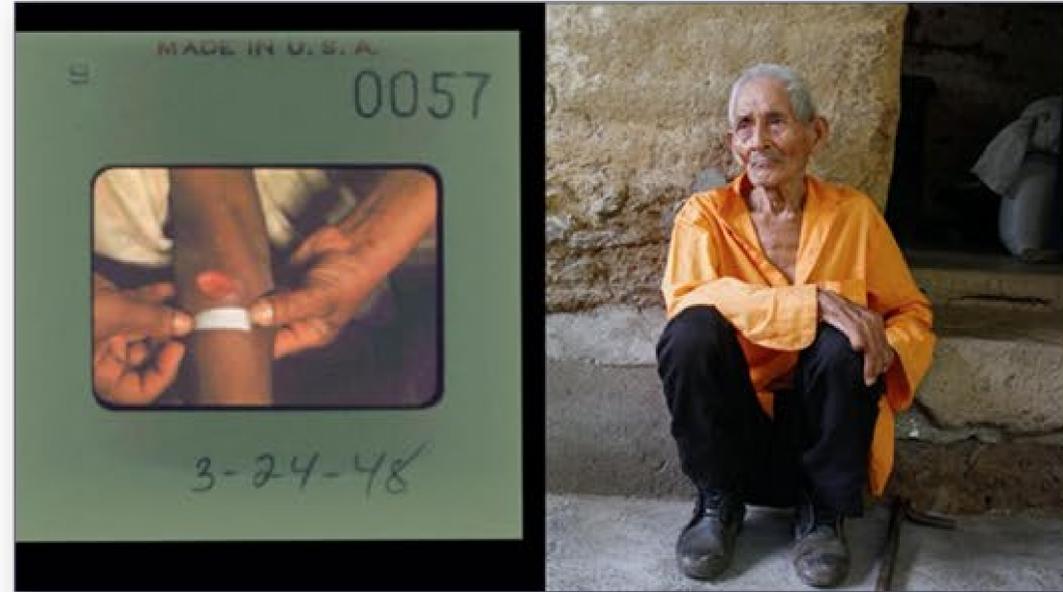
how can we rebuild
TRUST?
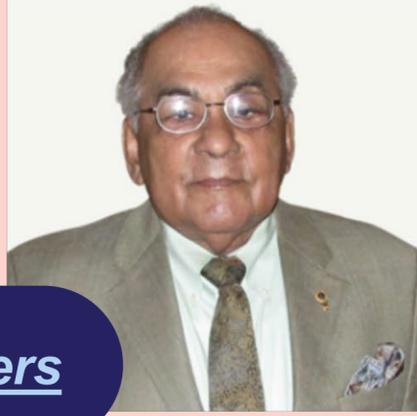
learn more at *allofus.nih.gov/about/who-we-are/all-of-us-participant-partners*

Considerations for Meaningful Inclusion

- Work within the legal, regulatory, and ethical framework
- Balance responsibilities: participants' interests and maximal use of their donation
- Provide mechanisms for engagement across axes of diversity
- Exercise cultural humility
- Respect participant autonomy
- Ensure risks and benefits are distributed equitably
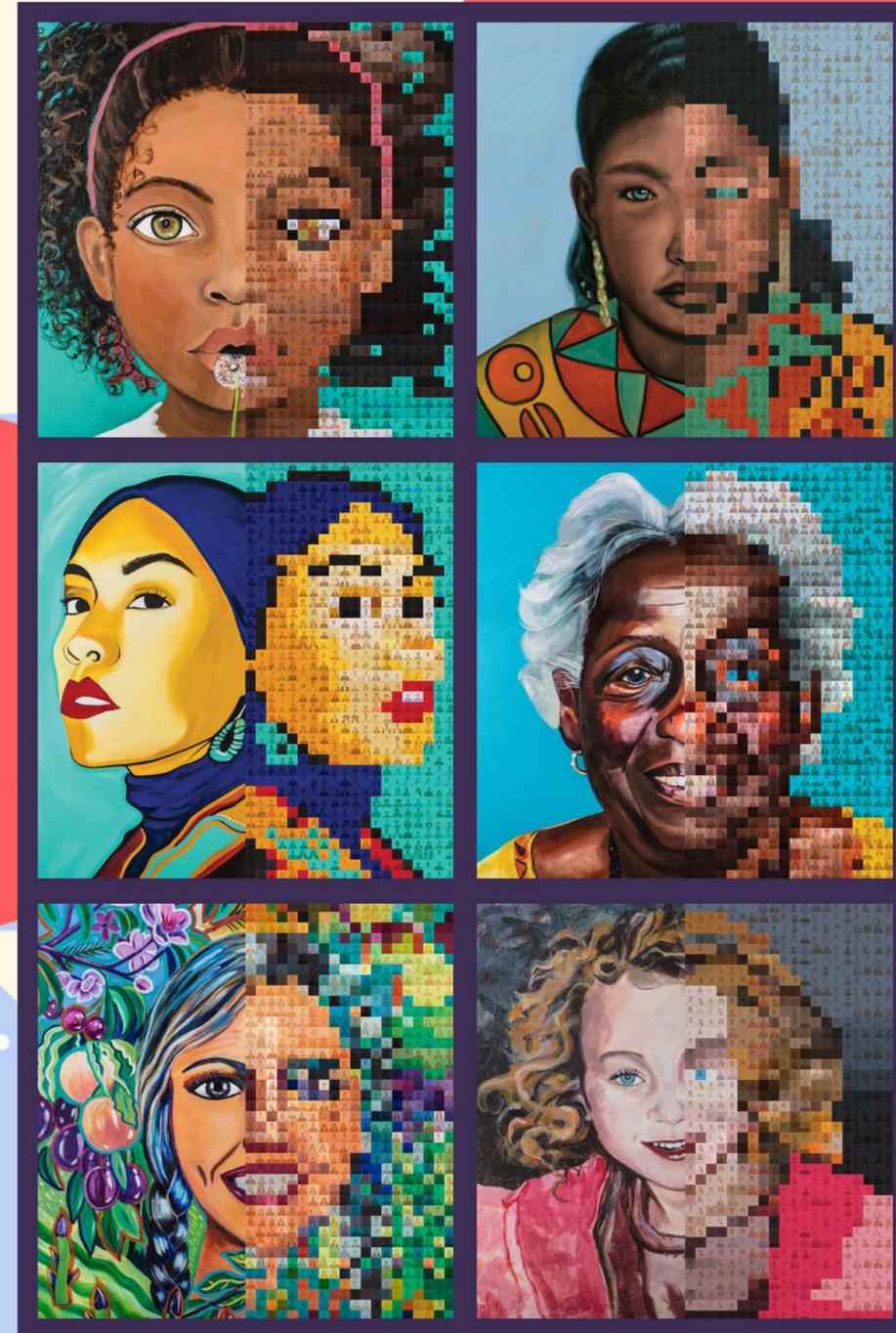
All of Us Data Access Framework | Principles

Data is a non-scarce resource

- Therefore, data should be as accessible as possible
- Accessibility includes researchers outside of academic medical centers and industrial biosciences

Participants are research partners

- Must protect people to the greatest extent possible
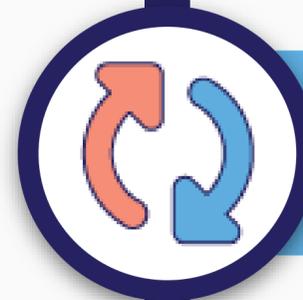
Barriers to access must be periodically reappraised

- Aim for minimum necessary barriers to access
- No group of users should have privileged access to the resources

Data Governance | Logistics

- Database Compilation and Structure
- Data Access Process
- Privacy and Security Measures

The *All of Us* Research Program Database

Collection of data from a wide variety of sources

Processing of the data to preserve participant privacy and usability

Harmonization

Curation

Ingress

Refinement

Standardization of data formats to ensure consistency across participant records

Filtration of data to make it viewable in the appropriate part of the database

23
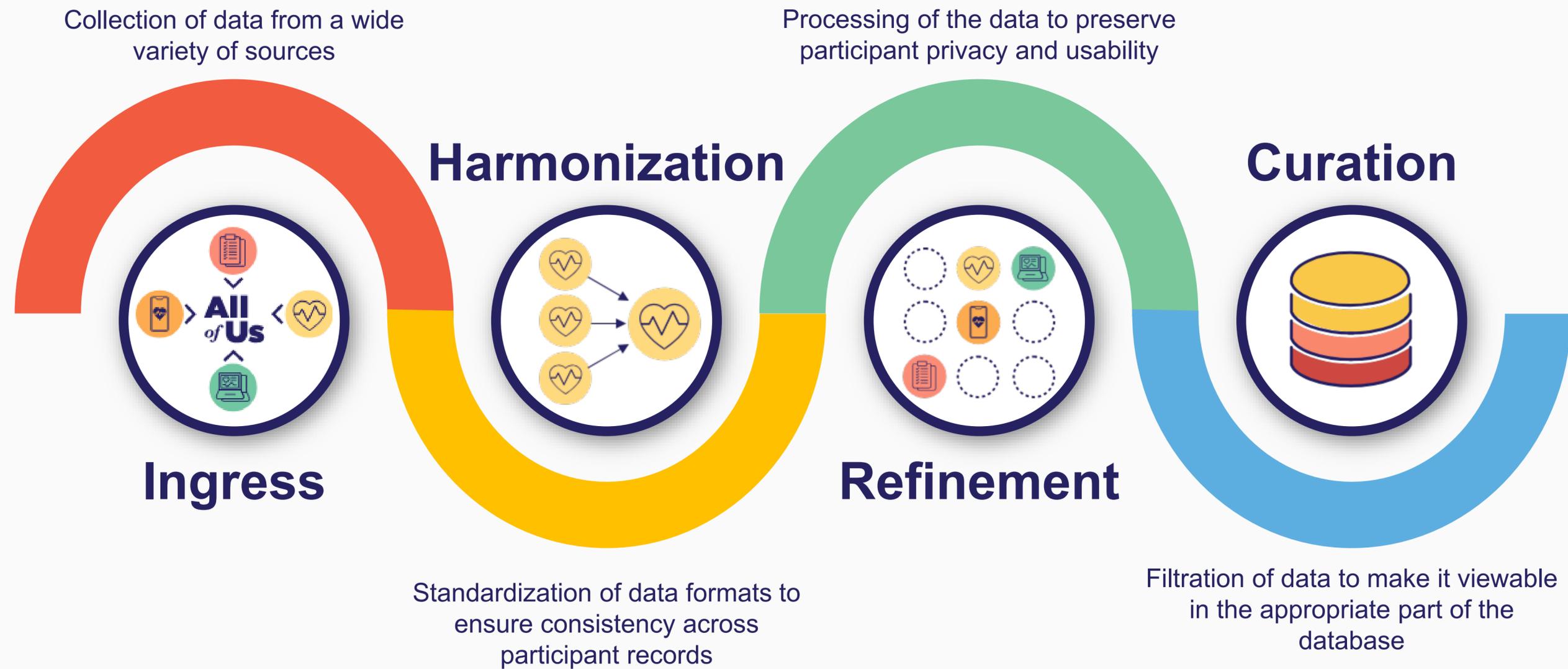
The *All of Us* Research Hub | Data Access Tiers

Researcher Workbench

Data Browser

Controlled Tier
Participant-Level Data
Additional Data Types (e.g. genomic data)

Registered Tier
Limited Participant-Level Data

Public Tier
Summary Statistics
Aggregate Counts
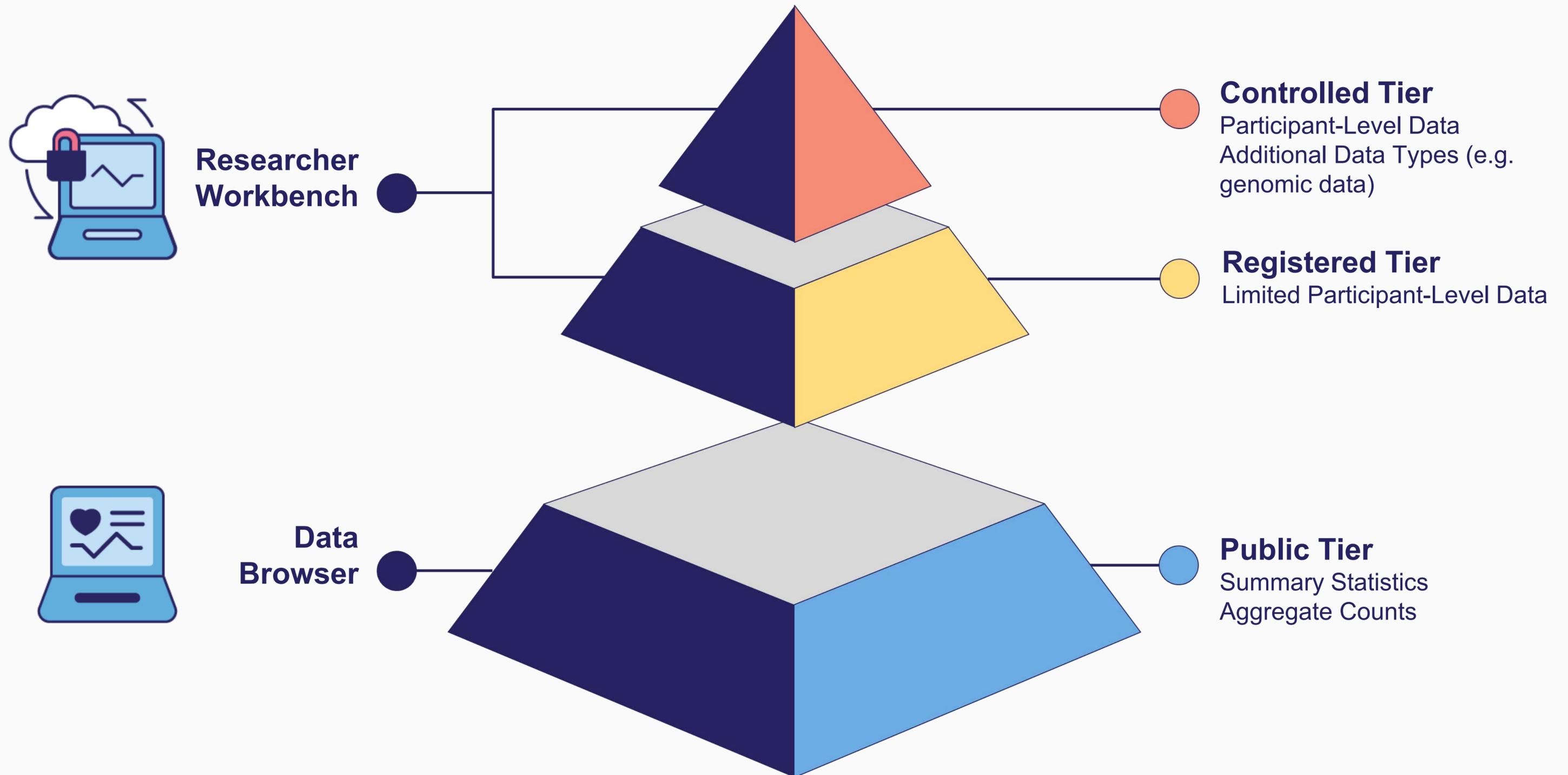
The *All of Us* Research Hub | The Researcher Workbench

Controlled Tier
Granular Participant-Level Data
Registered Tier Data PLUS
Additional EHR Fields
Genomic Data

Fewer Data Transformations
Unshifted Dates (except Year of Birth)
More Precise Geographic Information
(3-Digit Zip Codes)
Fewer Generalizations and Ontological
"Roll-Ups"

Registered Tier
Limited Participant-Level Data
Physical Measurements
Some Electronic Health Record
Data
Survey Data
Fitbit Data

Many Data Transformations
Date Shifting
Generalization (e.g. State-Level
Geographic Information)
Ontological "Roll-Ups"

The *All of Us* Research Hub | Access Process

Learn more about the data available **1**

2 Check for a valid institutional agreement

Register as a researcher **3**

4 Verify identity

Complete the *All of Us* Responsible Conduct of Research Training **5**

6 Attest to the Data User Code of Conduct
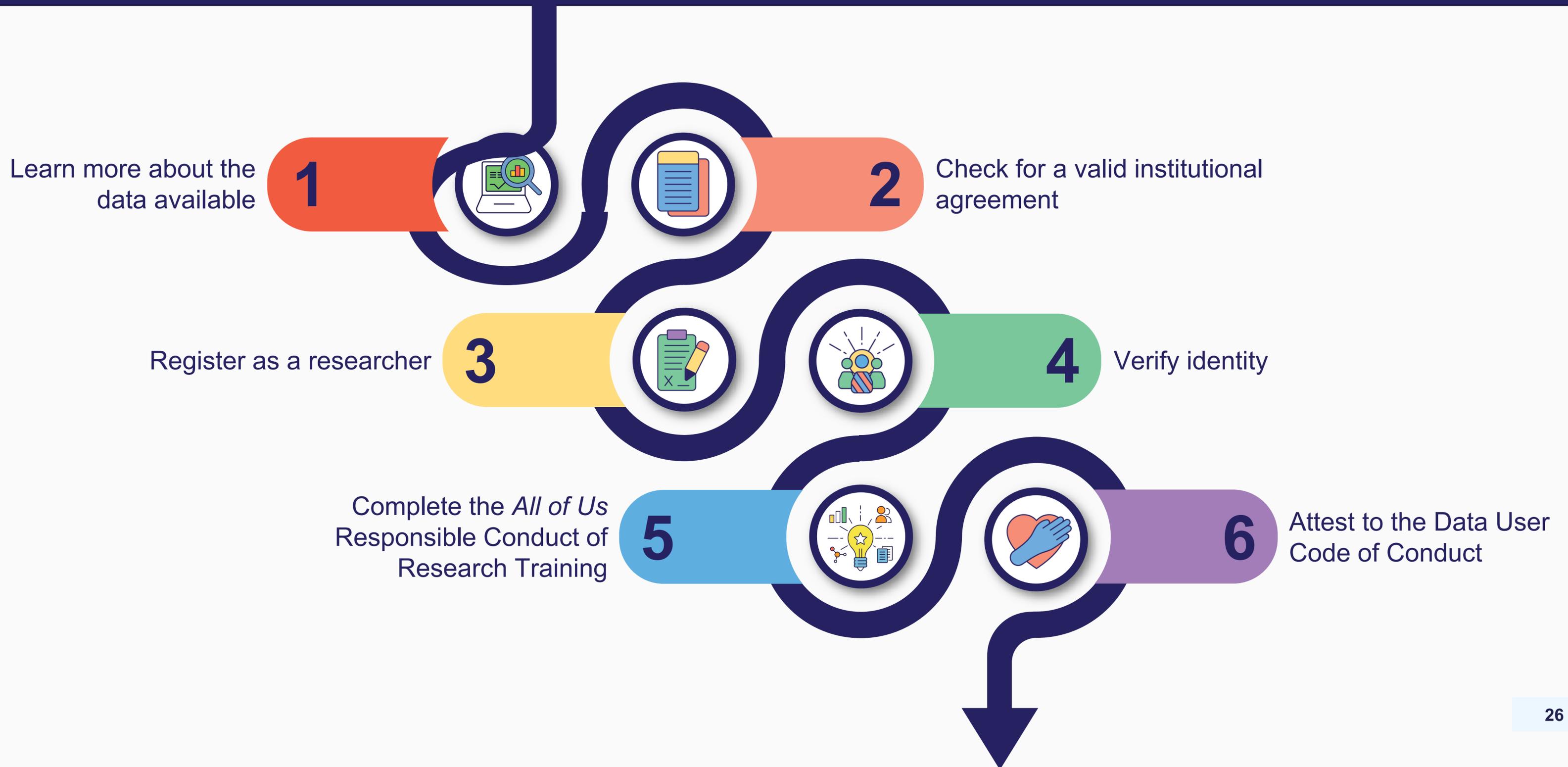
All of Us Data Passports

The *All of Us* Researcher Workbench uses a "data passport" model to give registered researchers broad access to the Researcher Workbench rather than granting data access on a **project-by-project** or **question-by-question** basis.

- Once they complete the requisite steps, researchers can create workspaces in the tier or tiers to which they have access—no pre-approval required
- When researchers set up their workspaces, they are required to provide public-facing project descriptions on the platform
- Researchers must ensure that their research complies with the program's data use policies

All of Us Research Program Privacy and Security Measures

Partner organizations must meet strict data security standards before they may collect, transfer, or store information from participants

All participant data is encrypted and obvious identifiers are removed from data used for research

Researchers must register with the program, complete ethics training, and agree to a code of conduct for responsible data use

Independent reviewers to check plans and test systems on an ongoing basis to ensure the program has effective security controls in place
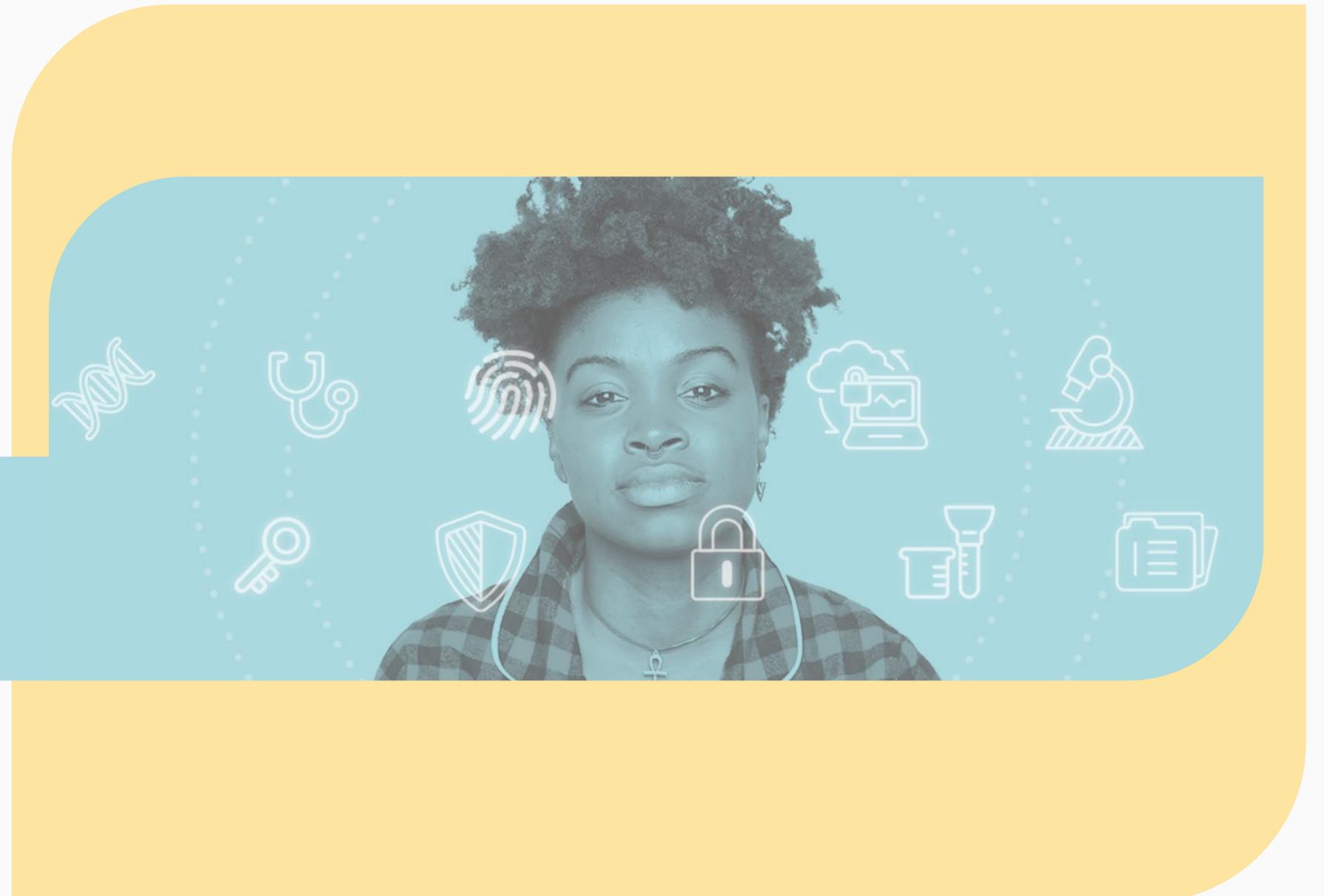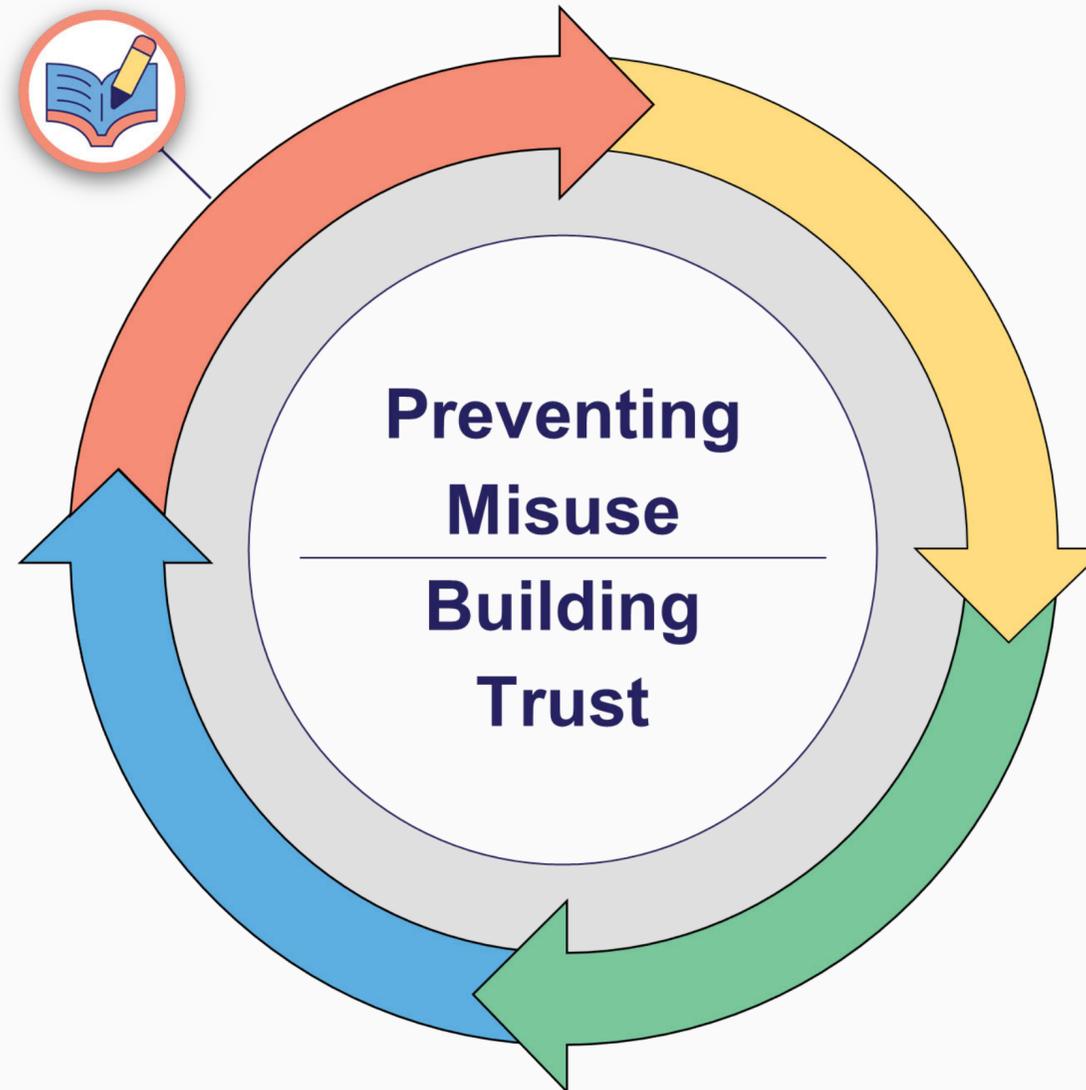
Data Governance | Policies

- Conceptual Model
- Education
- Accountability
- Assistance and Oversight

All of Us Data Access and Use | Conceptual Model

Education

Raising Awareness and Setting Expectations in the **Responsible Conduct of Research Training**

Accountability

ID Verification; mandatory compliance with the...
- **Data User Code of Conduct**
- **Data Use and Registration Agreement***
- **Data Access and Use Policies**

Preventing Misuse
_____
Building Trust

Oversight

Continual monitoring of curated data enclave by Data and Research Center; **periodic audits**, **internally-** and **publicly-initiated reviews** conducted by the Resource Access Board

Assistance

User-initiated reviews and **assistance** from the Resource Access Board available at any stage

Education

Raising Awareness and Setting Expectations in the
Responsible Conduct of Research Training

Preventing
Misuse
―――――
Building
Trust

Education | Considerations for Training Development

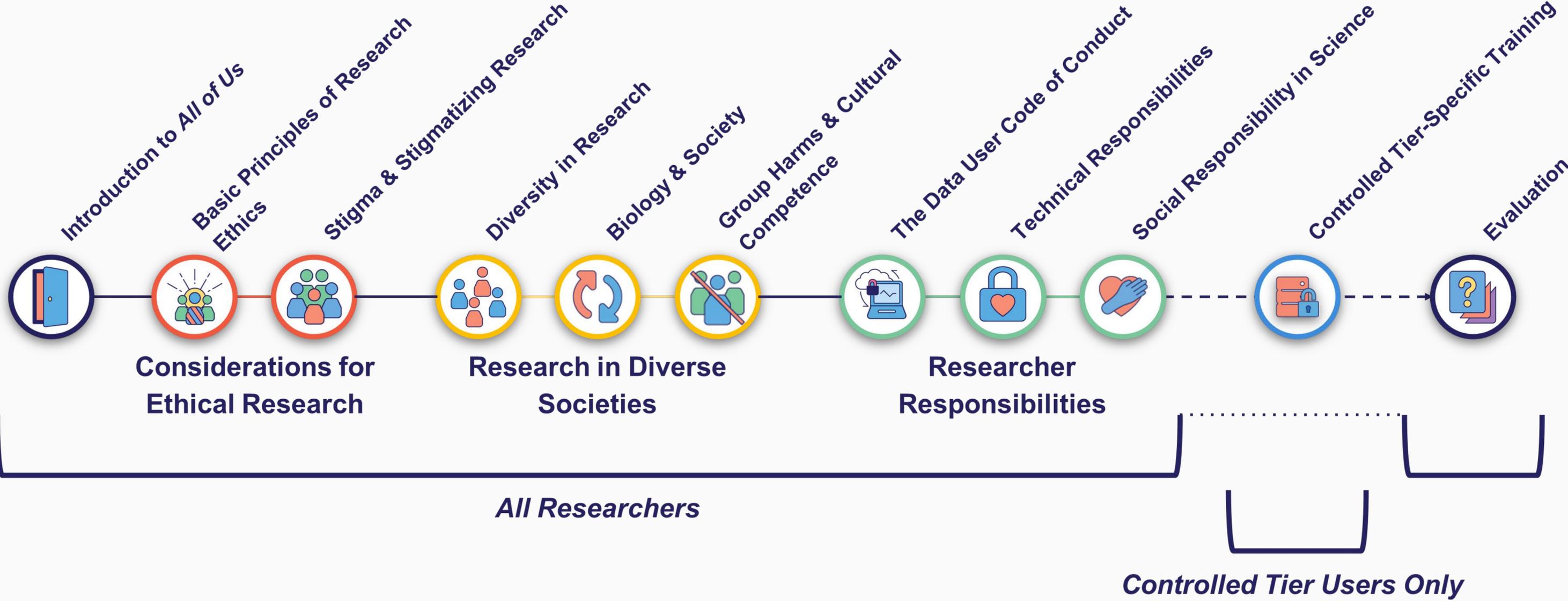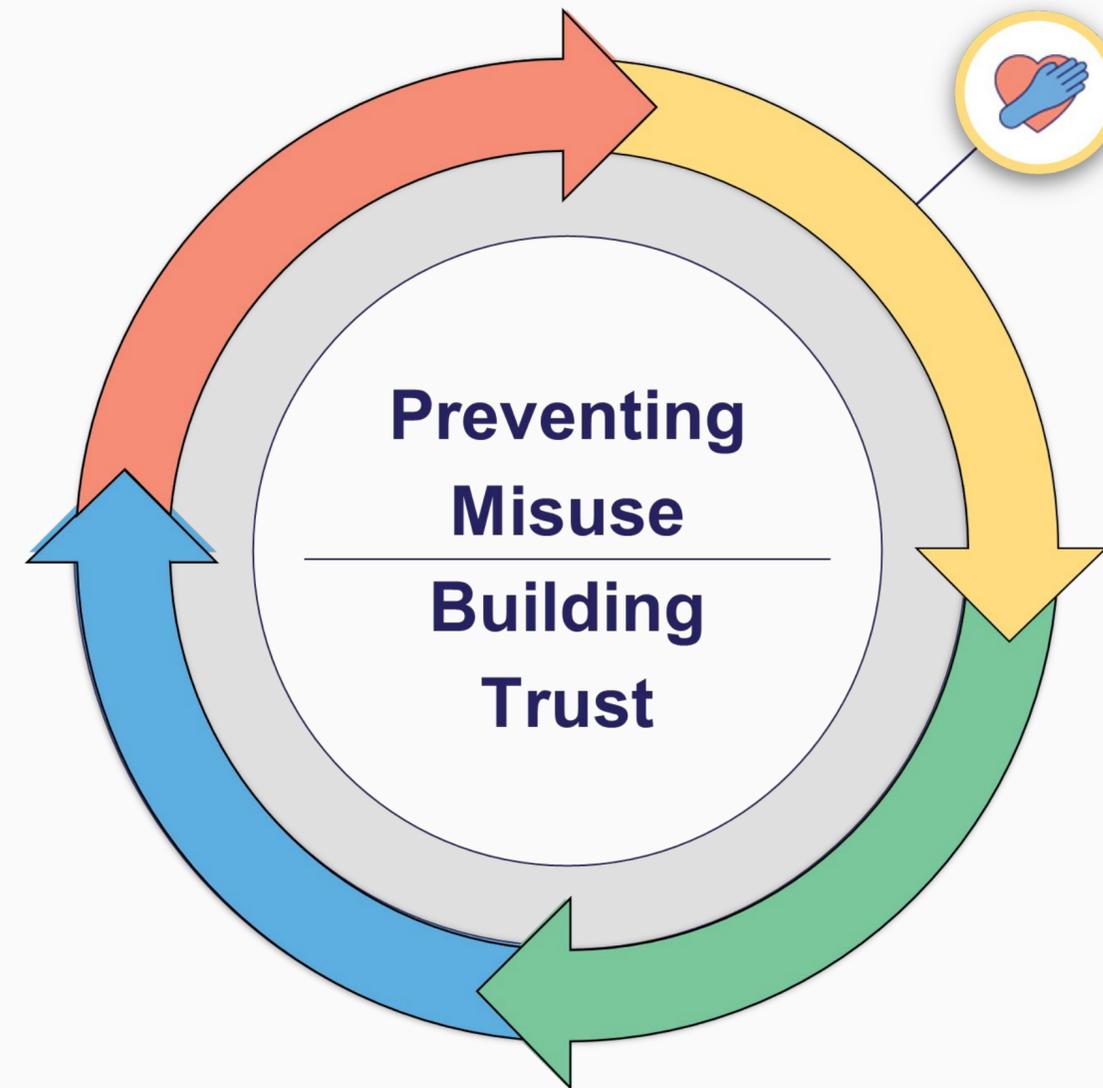| What's different about *All of Us*?	What do we want to achieve?	How do we accomplish it?
• Focus on UBR recruitment • Diversity of data user backgrounds • Data users do not interact with research participants	• Instill in data users a responsibility to *All of Us* participants • Contextualize Belmont Principles for research with *All of Us* data • Include contemporary conversations on responsible research practices • Provide tools for data users to put content into practice	• RCR learning objectives

Introduction to All of Us

Basic Principles of Research Ethics

Stigma & Stigmatizing Research

Diversity in Research

Biology & Society

Group Harms & Cultural Competence

The Data User Code of Conduct

Technical Responsibilities

Social Responsibility in Science

Controlled Tier-Specific Training

Evaluation

Considerations for Ethical Research

Research in Diverse Societies

Researcher Responsibilities

All Researchers

Controlled Tier Users Only

All of Us Data Access and Use | Accountability

Preventing Misuse / Building Trust

Accountability

ID Verification; mandatory compliance with the...

- **Data User Code of Conduct**
- **Data Use and Registration Agreement***
- **Data Access and Use Policies**

Accountability | Data Use Contracts and Policies

DURA

Data Use and Registration Agreement
Institutional contract outlining institutional responsibility for affiliated researcher(s)

DUCC

Data User Code of Conduct
Individual agreement outlining individual use responsibilities

Accountability | *All of Us* Data User Code of Conduct

respect the privacy of research participants at all times.
- I will **NOT** use or disclose any information that directly identifies one or more participants.
  - If I become aware of any information that directly identifies one or more participants, I will notify the *All of Us* Research Program immediately using the appropriate process.
- I will **NOT** attempt to re-identify research participants or their relatives.
  - If I unintentionally re-identify participants through the process of my work, I will contact the *All of Us* Research Program immediately using the appropriate process.
  - If I become aware of any uses or disclosures of *All of Us* Research Program data that could endanger the security or privacy of research participants, I will contact the *All of Us* Research Program immediately using the appropriate process.

For more on other data use policies, visit
www.researchallofus.org/data-tools/data-access

Accountability | Data Use Contracts and Policies (continued)

DURA
Data Use and Registration Agreement
Institutional contract outlining institutional responsibility for affiliated researcher(s)

DUCC
Data User Code of Conduct
Individual agreement outlining individual use responsibilities

Policies
Collection of detailed directives for appropriate use, compliance with which is required by the DUCC

Ethical Conduct of Research

Stigmatizing Research

AI/AN Research Materials Use

Data and Statistics Dissemination

Publications and Presentations

User Appeals

For more on data use policies, visit
www.researchallofus.org/data-tools/data-access

Accountability | AI/AN Research Materials Use Policy (Overview)

- Take actions that acknowledge and protect against **historical (and contemporary) sources of harm:**
  - **MUST** review and agree to abide by the DUCC, Policy on Stigmatizing Research, and Policy on the Ethical Conduct of Research
  - **MUST NOT** attempt to reidentify AI/AN individuals, the region(s) from which they originate, or the tribe(s) to which they belong
  - **MUST** fulfill all technical and logistical requirements for authorized usership, including annual RCR training comprised of the basic modules and any future modules specific to the use of data from AI/AN individuals, as appropriate
  - **MUST** use respectful and appropriate language and preferred terminology, as dictated by the forthcoming guidance
- Comply with all applicable **federal, state, and local laws**
- Abide by all applicable **program policies and procedures** for access to data and non-data resources originating from participants who self-identify as AI/AN
- Agree to **additional scrutiny** of research focusing on AI/AN populations that is conducted using All of Us research resources

Preventing Misuse
Building Trust

Oversight

Continual monitoring of curated data enclave by Data and Research Center; **periodic audits**, **internally-** and **publicly-initiated reviews** conducted by the Resource Access Board

Assistance

User-initiated reviews and **assistance** from the Resource Access Board available at any stage

5,700+ Registered Researchers

Comparing registered researchers	2/2022	6/2023
Total Registered Researchers	1,015	5,705
Researchers from UBW communities SGM, race/ethnicity, disability status, & career stage	56%	72%
Researchers from UBW communities By race/ethnicity alone	14.3%	28%

530 Institutions
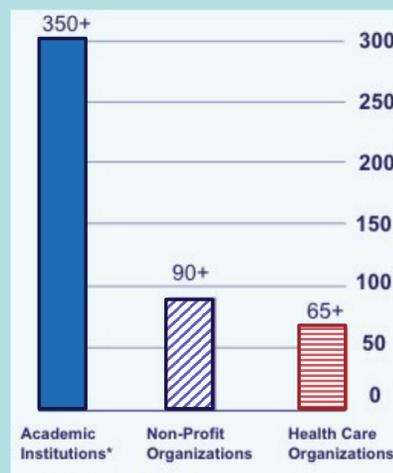
5,300+ Active projects

160 Publications in peer-reviewed journals

Top conditions being studied
- Cardiovascular disease
- Hypertension
- Mental Health
- Cancer
- Diabetes
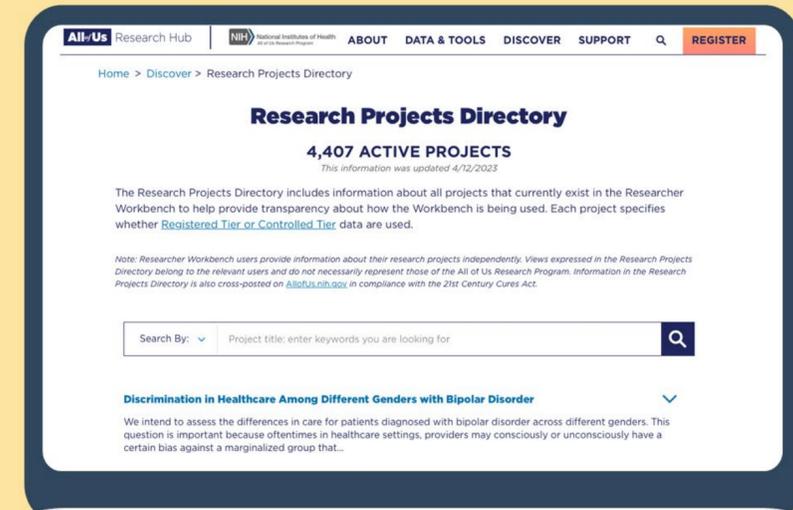
See the research currently underway by visiting

researchallofus.org/research-projects-directory

Assistance | Researcher Support Hub

Visit the Support Hub to find answers to common questions about becoming a registered researcher, using the *All of Us* dataset, and more. **NO LOGIN REQUIRED**

researchallofus.org/support

Find instructional materials about the *All of Us* Researcher Workbench

- Includes video tutorials, educational resources, release notes, and more

Search 280+ articles

- Find information about data dictionaries, the Controlled Tier directory, how WGS and Array data are organized, and more

Connect with experts during weekly live office hours

- Explore our calendar of dedicated office hours where researchers can talk about data types and tools with experts

Assistance and Oversight | The *All of Us* Resource Access Board

The *All of Us* Resource Access Board (RAB)

User-Initiated Workspace Reviews
Reviews proactively requested by Authorized Data Users to facilitate DUCC compliance

Periodic Workspace Audits
Cadenced reviews conducted on (mostly) randomly selected workspaces

+

Publicly- Initiated Workspace Reviews
Reviews requested by members of the public through the workspace directory

Internally- Initiated Workspace Reviews
Potential compliance issues flagged by *All of Us* personnel

Anyone can flag research for RAB review by visiting:

researchallofus.org/research-projects-directory

Assistance and Oversight
ELSI Considerations

Issues of…

- **Subjectivity**
  - Who should determine what is and is not compliant? What is and is not stigmatizing?
  - What happens when people disagree about what is or is not compliant? What is and is not stigmatizing?
- **Intent vs. Application**
  - What should be the limitations on data use where there is good intent but high potential for the downstream misapplication or misuse of findings?
  - Can/how do we control downstream use?
  - Are there topics that should always be off limits?
- **Protections vs. Rights**
  - When should the potential benefit (or harm) to an individual, group, or community outweigh researchers' rights and freedoms?

Assistance and Oversight | RAB Review Considerations

Has a violation actually occurred?

Occurrence

Is it reasonable to believe that the perceived violation was intentional?

Intentionality

Has the user always otherwise been in good standing with *All of Us*?

User History

1 **2** **3** **4** **5** **6**

Type

Scale and Scope

Patterns

What is the type of the perceived violation?
- *Legal or Regulatory Violation*
- *Re-identification*
- ***Stigmatizing Research***
- ***Individual or Group Harm***
- *Insufficient Workspace Description*
- *Other*

Type specific-considerations

How many individuals or how much information was affected?
How significant was the effect?

Are there patterns in violations in the user's history or across users (either total or affiliated with a particular institution)?
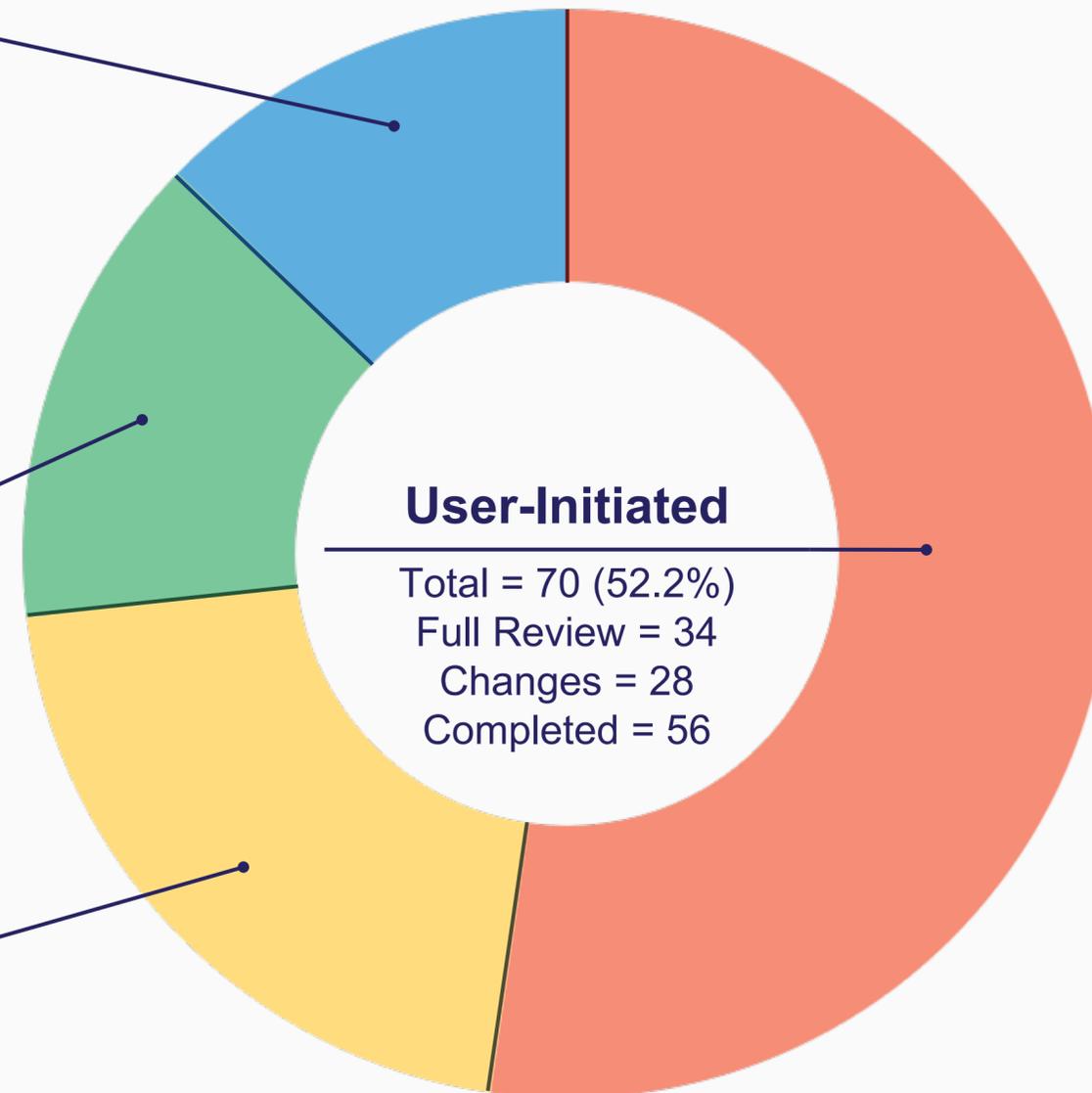
Internally-Initiated

Total = 17 (12.7%)
Full Review = 3
Changes = 16
Completed = 11

Publicly-Initiated

Total = 19 (14.2%)
Full Review = 10
Changes = 10
Completed = 18

User-Initiated

Total = 70 (52.2%)
Full Review = 34
Changes = 28
Completed = 56

Periodic Audits

Total = 28 (20.9%)
Full Review = 7
Changes = 7
Completed = 15

134 reviews

- Most RAB-identified problems were with clarity and/or detail of Workspace Description or data obfuscation measures

Among RAB members significant agreement about…

- The potential for research to stigmatize individuals or groups
- Which workspaces were adequately described*

Researchers have overwhelmingly been receptive and willing to make change(s)

Total: Total reviews initiated (completed and in progress)

Full Review: Initiated reviews requiring full RAB review

Changes: Number of workspaces requiring changes

Completed: Total number of resolved reviews

New Challenges Ahead!

- Recent rollout of the Controlled Tier, with more granular and more sensitive data types

- Growing and diversifying user base

- Addition of new data and other research resources, like biospecimens and direct access to participants

Data Access, Use, and Tribal Engagement

Diverse Perspectives in *All of Us* Program Governance

AI/AN Governance Representation:

- Research Program Advisory Panel

- Institutional Review Board

- Steering Committee

- Participant Ambassadors

- Science Committee

- Resource Access Board

- Ethical, Legal, and Social Implications (ELSI) Brain Trust

- Biospecimen Access Policy Task Force (past)

Suggested Opportunities for Input:

- Augment the expertise available to the Resource Access Board with Indigenous knowledge for data or research projects focusing on AI/AN peoples

- The program strongly encourages AI/AN researcher participation and will aim to collaborate with Tribal leaders to hold presentations on how to use the *All of Us* Research Hub at tribal events, AI/AN-focused scientific conferences and workshops, and webinars.

Researcher Spotlights on ResearchAllofUs.org

10
Research Spotlights

Featuring
16
Researchers

Like this one from Younga "Heather" Lee, PhD,
Postdoctoral Research Fellow at Massachusetts General and Harvard/MIT

All*of*Us Research Hub | NIH National Institutes of Health / All of Us Research Program

Meet the Researchers

Studying the link between discrimination and depressive symptoms

📅 *August 23, 2022*

Meet Dr. Heather Lee, a researcher at Massachusetts General Hospital exploring the mental health impact of everyday discrimination during the COVID-19 pandemic.

https://allof-us.org/HeatherLee

Stay in touch to learn more

Sign up for our bimonthly newsletter

Subscribe to
Research Roundup

Stay up-to-date on the latest
news and insights from the
All of Us Research Hub through
our bimonthly email newsletter.

allof-us.org/RRSignup

Create an *All of Us* account

Register to be an *All of Us* Researcher

STEP 1 — LEARN MORE ABOUT THE DATA AVAILABLE

STEP 2 — CHECK FOR YOUR INSTITUTION'S AGREEMENT

STEP 3 — REGISTER AS A RESEARCHER

STEP 4 — VERIFY YOUR IDENTITY

STEP 5 — COMPLETE *ALL OF US* RESPONSIBLE CONDUCT OF RESEARCH TRAINING

STEP 6 — SIGN DATA USER CODE OF CONDUCT

allof-us.org/Register

Purpose of the ROA

Area of Interest 1:
Participant Engagement and Enrollment

Task 1: Participant outreach and engagement

Task 2: Enrollment and retention

Task 3: Pediatric outreach and engagement

Task 4: Computer access

Task 5: Healthcare provider outreach and engagement

Area of Interest 2:
Researcher Engagement

Task 1: Researcher Hub awareness and researcher engagement

Task 2: Building research capacity

Task 3: Promote team science

Area of Interest 3:
Tribal Nations, American Indian and Alaska Native populations, and Indigenous Communities

Task 1: Outreach and engagement

Task 2: Training and career development

Task 3: Education and culturally appropriate resource development

Task 4: Research infrastructure and capacity building

Area of Interest 4:
Participant as Partners

Task 1: Oversight of consortium participant partner related activities

Task 2: Full integration of participants and advocates

Task 3: Facilitation of ongoing input from participant representatives

Task 4: Assess the impact of participant engagement

Area of Interest 3: Engagement with Tribal Nations, American Indian and Alaska Native Populations, and Indigenous Communities

The *All of Us* Research Program initiated **tribal consultation in 2019** to engage Tribal Nations about the inclusion of AI/AN populations in this research program. The information received during consultation has been used to guide our work with AI/AN communities and Tribes.

Technical Objectives

- **Outreach and engagement** to AI/AN and Indigenous communities
- **Training and career development** in research as it relates to precision medicine
- **Education and culturally appropriate resource development** for AI/AN populations and partners
- **Research infrastructure and capacity building** within AI/AN and Indigenous communities **ensuring sustainability of precision medicine research**

➡️ **Review SAM.gov for full submission requirements**

Informational Presentation and Discussion Schedule

Session 1: *All of Us* **Research Program Overview and Tribal Engagement**
Tuesday, June 6, 2023, 1:00 - 3:00 pm ET

Session 2: How Researchers Access and Use *All of Us* **Data**
Tuesday, June 13, 2023, 1:00 - 3:00 pm ET

Session 3: Describing Self-Identified AI/AN Participants in *All of Us* **Data**
Tuesday, June 20, 2023, 1:00 - 3:00 pm ET

Session 4: Data and Partnerships in *All of Us*
Tuesday, June 27, 2023, 1:00 - 3:00 pm ET

All of Us **Tribal Consultation**
Thursday, September 28, 2023, 1:00 - 3:00 pm ET

Logistics

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- **Please pose questions in the chat**

- **Please keep yourself on mute - at the end of the program, we'll address questions in the chat and open up for live questions**

- **The Questions and Discussion section will be recorded for our notes but not posted online**

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