All of Us Research Program
Research Opportunity Announcement - Informational Webinar
ROA No. OTA-23-002

Date: February 2, 2023; 2:00-3:30 P.M. ET
All of Us Research Program

NIH National Institutes of Health

Today's Presenters

Chris Lunt
Chief Technology Officer

James McClain, PhD, MPH
Chief, Participant & Partner Services Branch

LaMeshia Billington, MBA
Director of Awards Management

Webinar Agenda: *All of Us* Participant and Partner Services Center ROA

1. **Provide overview of the *All of Us* Research Program**

    - Protocol, Cohort and Program Partners

2. **Share highlights of the current participant experience**

3. **Outline the Participant and Partner Services Center (PPSC) ROA**

    - Purpose and overview

    - PPSC cores

        - Research technology systems core

        - Program management and delivery core
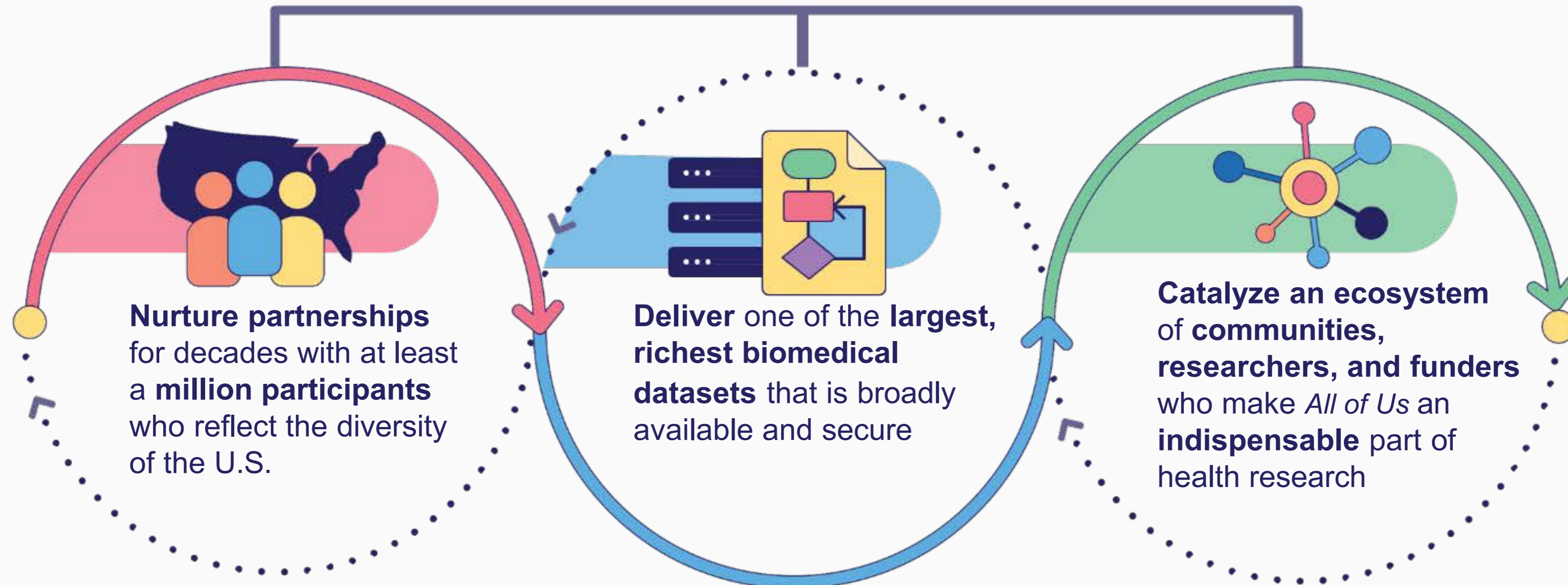
4. **Review the submission requirements and timelines**

5. **Address questions and answers**

All of Us Research Program Overview

Our Mission

**Accelerate health research and medical breakthroughs,
enabling individualized prevention, treatment, and care for all of us**

Nurture partnerships for decades with at least a **million participants** who reflect the diversity of the U.S.

Deliver one of the **largest, richest biomedical datasets** that is broadly available and secure

Catalyze an ecosystem of **communities, researchers, and funders** who make *All of Us* an **indispensable** part of health research

Made possible by a team that maintains a culture built around the program's core values

All of Us Consortium Members *(as of August 2022)*

The Participant Center, Communications & Engagement, HPO Network, RMCs, and various consortium member logos.
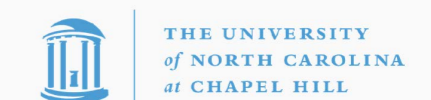
All of Us Community and Provider Partner Network *(as of August 2022)*
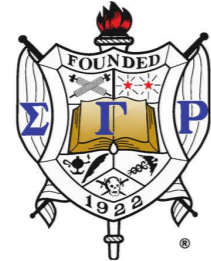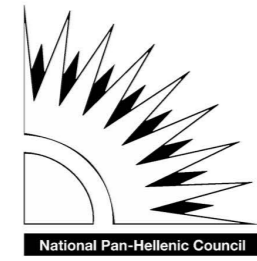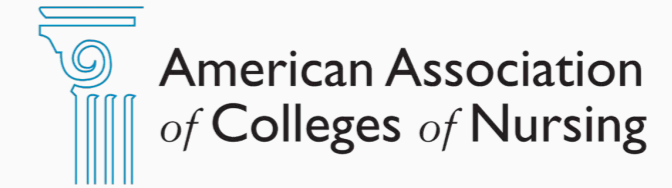
All of Us Aims to Enroll 1M+ Participants Who Complete Initial Program Opportunities

(Updated 1/25/23)

588,000+

Participants

410,000+

Participants who have completed initial steps of the program

Enrollment Numbers

*The following numbers are approximated to protect participants' privacy.
Numbers are updated as of January 25, 2023.*
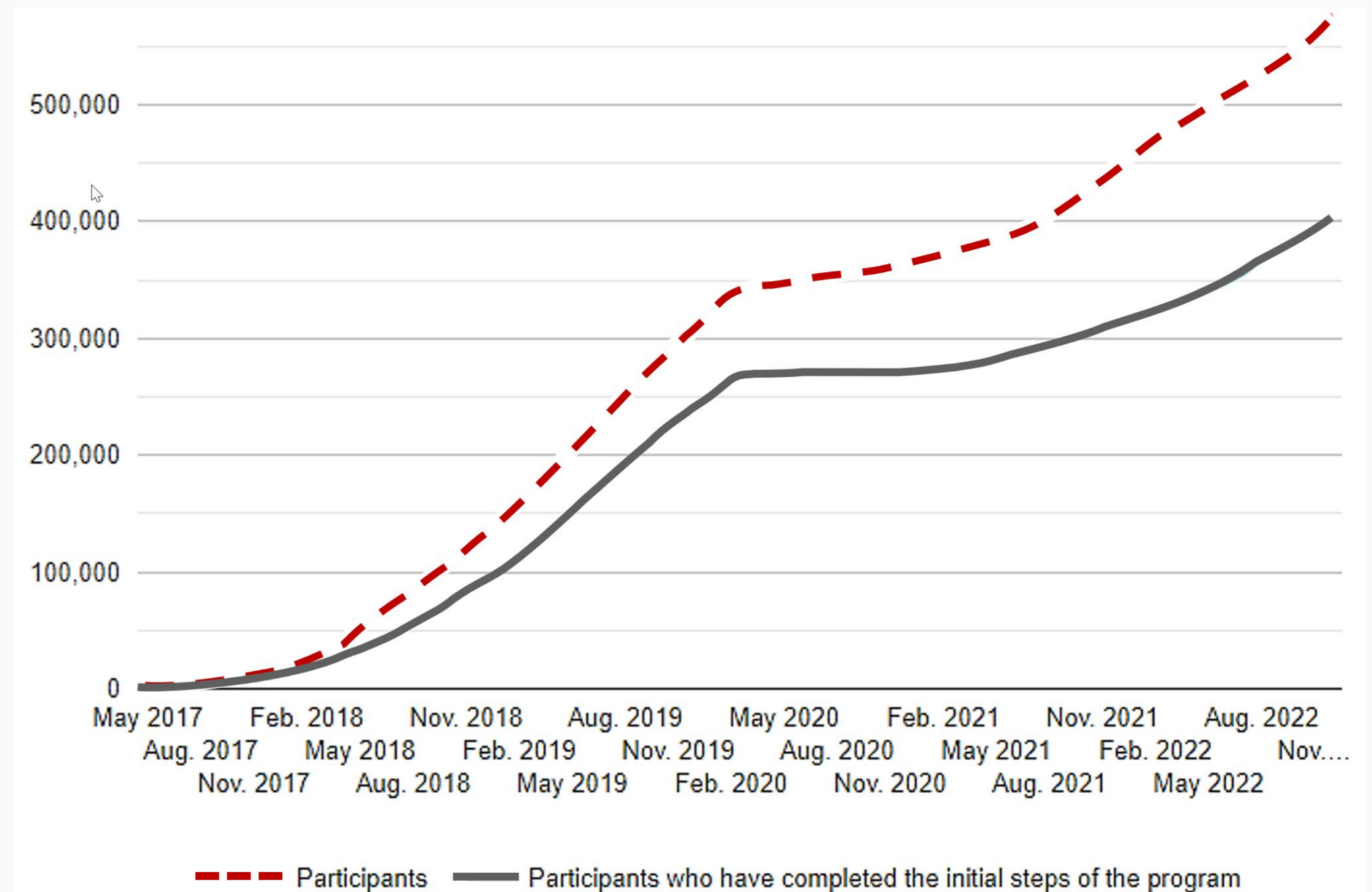
All of Us Supports Regional Enrollment Centers & Nationwide Virtual Participation

All of Us supports nationwide enrollment in all 50 states through a combination of virtual recruitment, regional enrollment centers, and interactive mobile exhibits. Participants can currently enroll and participate in English or Spanish.

0 ▭ 58,660
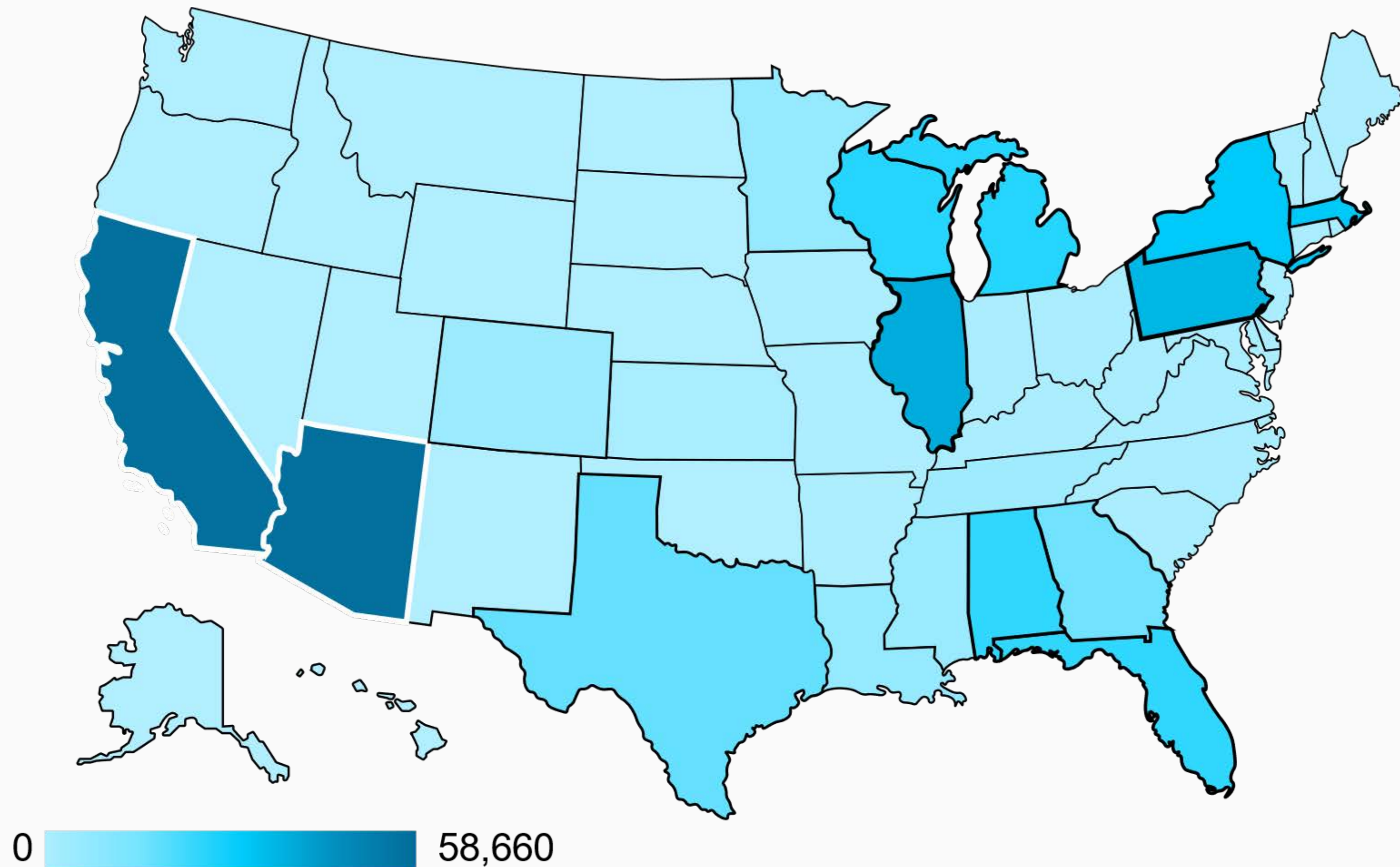
All of Us Strives to Enroll a Cohort that Reflects the Diversity of the U.S.

Race & Ethnicity of Participants

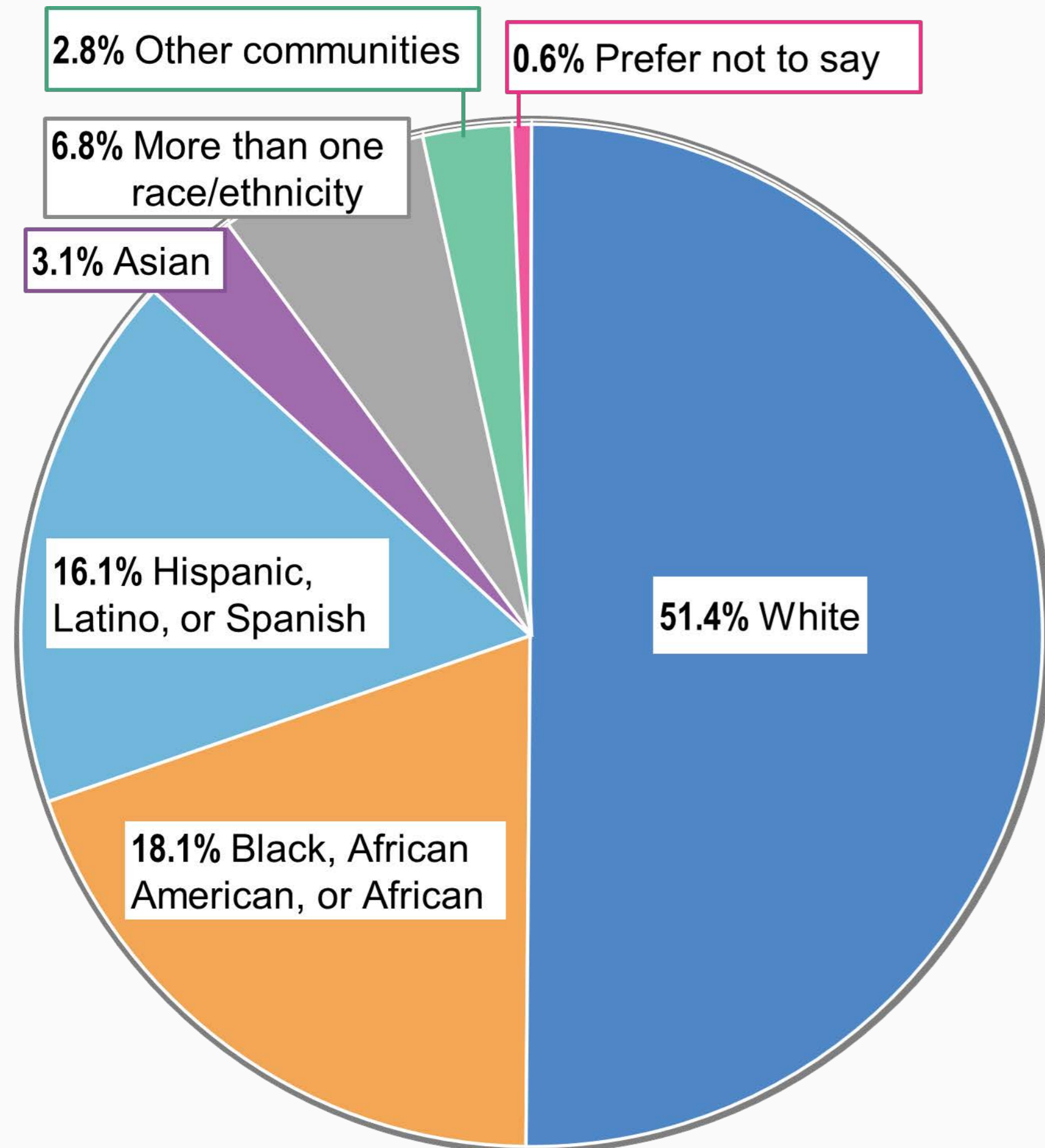- **2.8%** Other communities
- **0.6%** Prefer not to say
- **6.8%** More than one race/ethnicity
- **3.1%** Asian
- **16.1%** Hispanic, Latino, or Spanish
- **18.1%** Black, African American, or African
- **51.4%** White

UBR Category

Category	Percentage
Age at Consent	25.6%
Race/Ethnicity	49.6%
Sex Assigned at Birth	0.02%
Gender Identity	1.0%
Sexual Orientation	9.4%
Educational Attainment	9.6%
Income	25.7%
Geography	7.0%
Disability	15.6%
SGM	9.8%
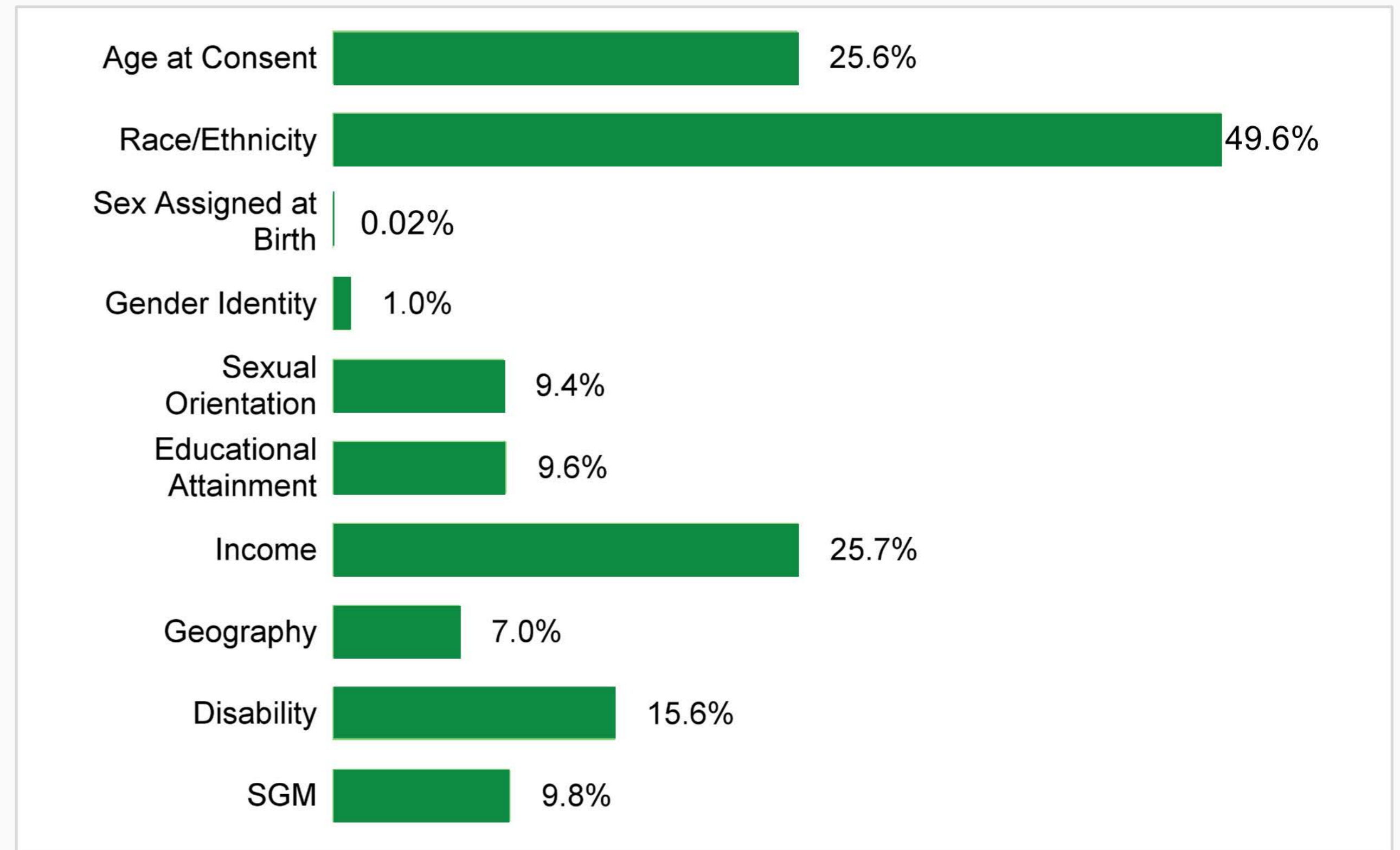
About 80% of *All of Us* participants identify with a group that is underrepresented in biomedical research (UBR)

Numbers current as of January 31, 2023

Current Participant Experience Highlights

All of Us Participant Journey

Ancillary Study Participation (Optional)

Discovery & Enrollment*	Participation	Return of Value	Reassessments** & Lifetime Engagement

Participant discovers All of Us through health provider, community partner, advocacy group, event, or digital message/ad
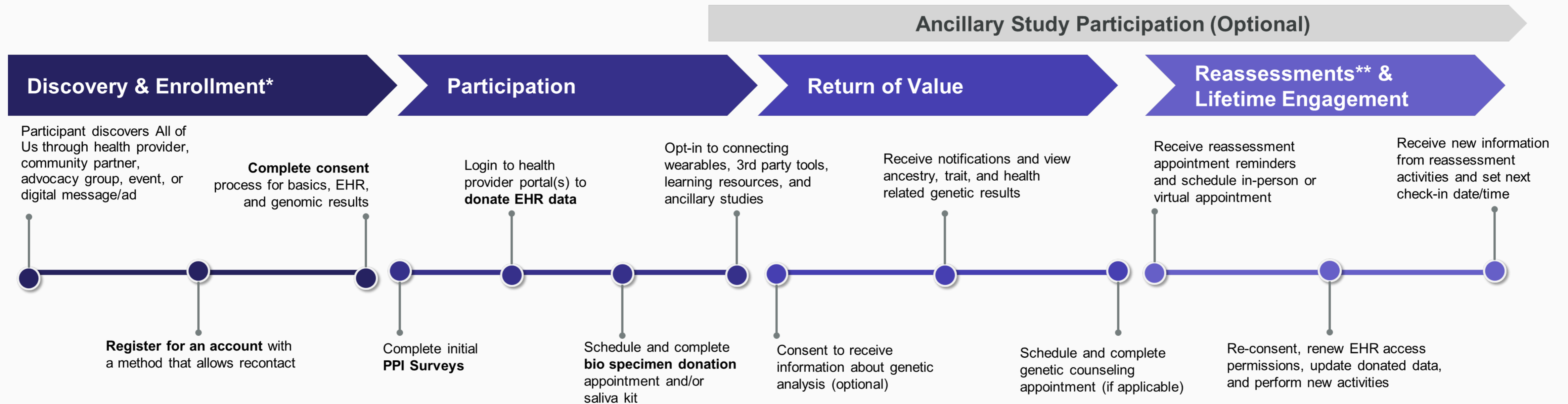
Complete consent process for basics, EHR, and genomic results

Login to health provider portal(s) to **donate EHR data**

Opt-in to connecting wearables, 3rd party tools, learning resources, and ancillary studies

Receive notifications and view ancestry, trait, and health related genetic results

Receive reassessment appointment reminders and schedule in-person or virtual appointment

Receive new information from reassessment activities and set next check-in date/time

Register for an account with a method that allows recontact

Complete initial **PPI Surveys**

Schedule and complete **bio specimen donation** appointment and/or saliva kit

Consent to receive information about genetic analysis (optional)

Schedule and complete genetic counseling appointment (if applicable)

Re-consent, renew EHR access permissions, update donated data, and perform new activities

Key Challenges

- Consent process is lengthy with many modules and decision that are likely unfamiliar to potential participants. Need to balance comprehension & speed
- Difficult to maintaining participant contact, attention and interest in a long-term study
- Efficiently enable, test and deploy ancillary study opportunities for participants and acquire new research data

Key Opportunities

- Streamline and simplify consent and data donation process
- Enhance the "stickiness" and value of digital experience
- Expand modes of participation including non-digital and remote methods based on preference
- Standardize and enable integrations to third party tools and experiences to expand the capabilities of the platform
- Provide or integrate meaningful analytics to inform future improvements and optimize participant engagement

12

All of Us Initial Participant Protocol Opportunities

Enroll, Consent, and Authorize EHR

Adults 18+ years old are currently eligible to enroll, but plan to include children in future

Online, interactive consent includes authorization to share EHR data

Answering Surveys

Current Surveys:
· The Basics
· Overall Health
· Lifestyle
· Health Care Access & Utilization
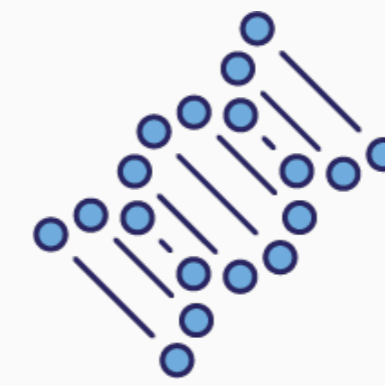· Personal & Family Health History
· Social Determinants of Health

Additional surveys will be released on an ongoing basis

Physical Measurements*

Blood pressure

Heart rate

Height

Weight

BMI

Hip circumference

Waist circumference

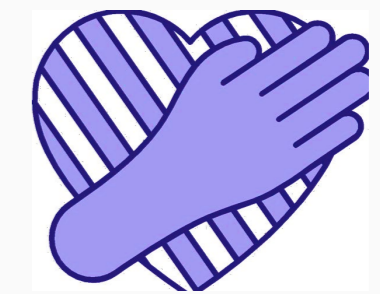**Based on diverse sampling and capacity*

Provide Biosamples*

Blood, saliva, and urine

Biosamples are stored at the program's biobank

*Based on diverse sampling and capacity

Wearables and Digital Apps

Share data from wearable devices and mobile apps, starting with Fitbit & Apple Health integrations.

Future:
Integrated or companion apps for physiologic and behavioral monitoring

Current Participant Experience

- *All of Us* participants engage with the program through existing web content, participant portal platforms, and program communications

- The PPSC will continue these current experiences and evolve them by developing and integrating new technology systems, partner data, and other services to enable:

  - Participant consent

  - Survey completions

  - Physical measurements and biosample donation

  - Data authorization and sharing

  - Return of information

  - Enrollment of special populations, including children

  - Participation in ancillary studies

# *All of Us* Consent and Authorization Process Overview

Program platforms enable participant consent processes and workflows

- Available in English and Spanish language
- Form variations account for federal and state requirements

Electronic consent delivery and signature

- Multimedia experience
  - Short text summaries
  - Video content
  - Digital long-form consent documents

Example: *All of Us* Participant Electronic Consent Process Samples
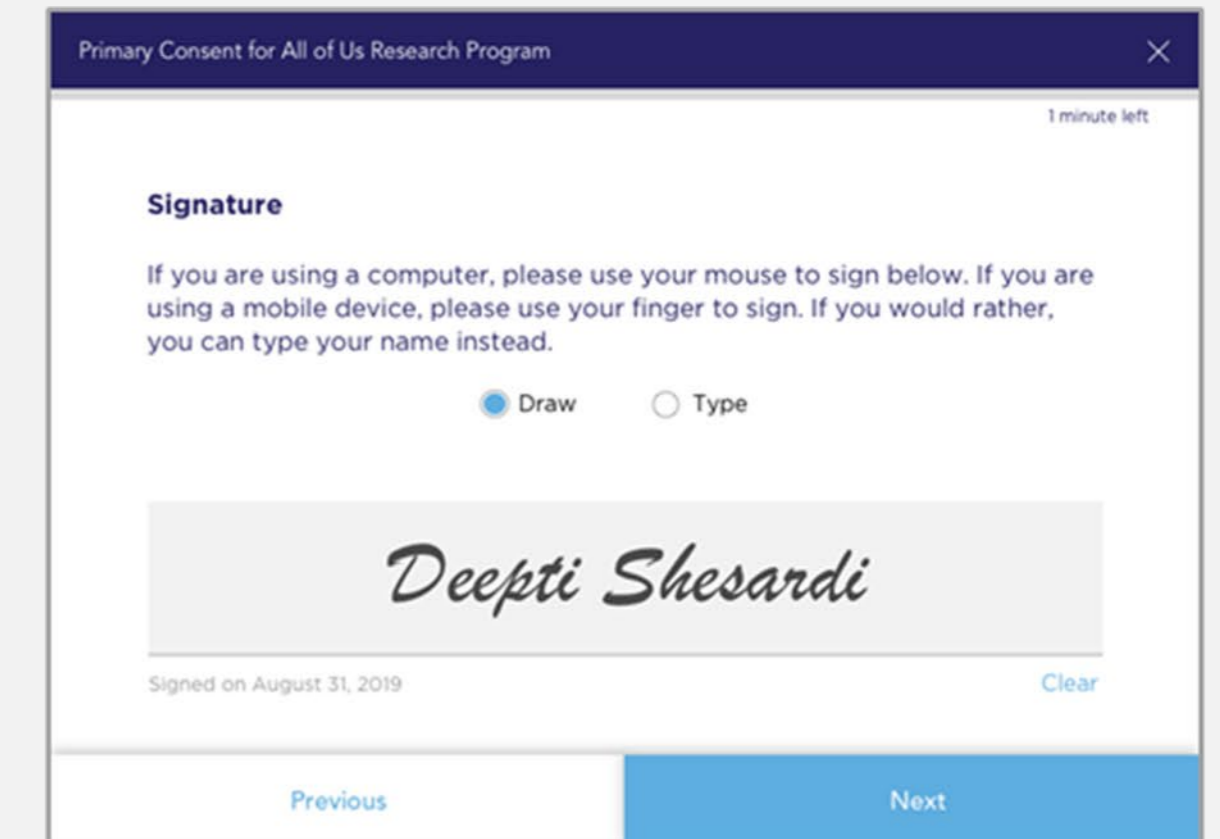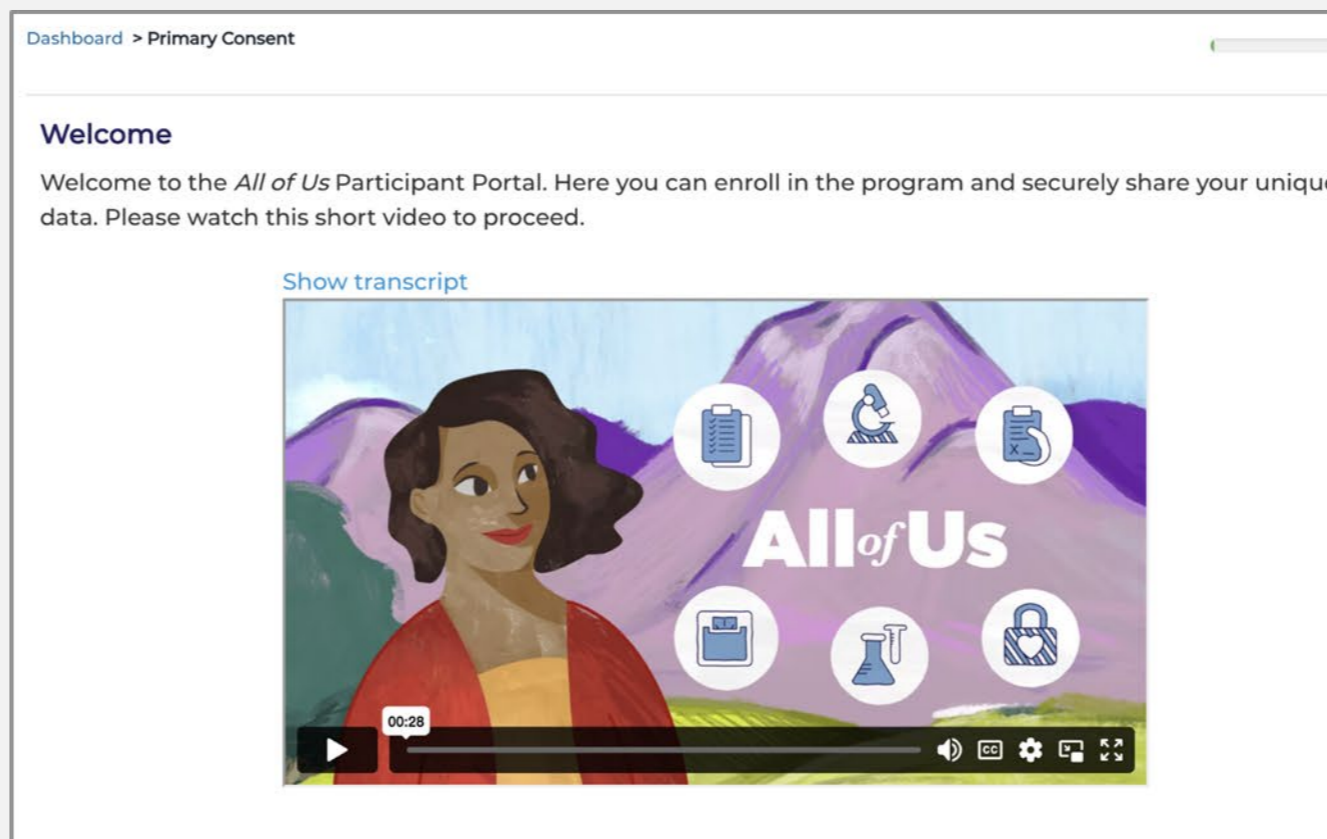
Enrollment Method	Primary Consent	Authorization to Share Electronic Health Records	Genetic Return of Results Consent	Sub-Study Consents	Ancillary Studies Consents	Special Purpose Consents
Standard	• Program Consent • Primary Consent - Cohort 1 Update	• Four versions (variation in content authorization process & expiry period)	• Single consent to perform genetic testing	Current Ex.: • WEAR Study • Exploring the Mind	Anticipated support for future ancillary studies conducted on *All of Us* Platforms	California Experimental Subject's Bill of Rights
U.S. Veterans Affairs (VA)	• VA Program Consent • VA Primary Consent - Cohort 1 Update	• VA specific version				

All of Us Biosample Collection Locations, Methods, & Processes

All of Us strives to support participant preference and access for protocol opportunities such as physical measurements & biosamples (PM&B) collection. Below are the platforms and processes currently in use.

Protocol Option In-Person: Partner Collected

Location	Collection Kit Order	Appointment Scheduling	Verify Identity	Collect Biosamples	Collect Physical Measures	Biosamples Returned
AoU Collection Sites	NA	In-Portal / Phone / Walk-in	In-Person	Blood / Urine	Directly Measured	By Collection Partner
Blood Banks	NA	In-Portal / Phone / Walk-in	In-Person	Blood / Urine (Full Collection or Diversion Pouch)	Directly Measured / Self-Reported	By Collection Partner
AoU Journey Tour (Mobile Units)	NA	In-Portal / Walk-in	In-Person	Blood / Urine	Directly Measured	By Collection Partner
ExamOne (Home Visits)	In-Portal / Phone	Phone	In-Person	Blood / Urine	Directly Measured	By Collection Partner
Bring Your Own Kit (At select Quest sites)	In-Portal / Phone	In-Portal	In-Person	Blood / Urine	Self-Reported (In-Portal)	By Collection Partner

Protocol Option Remote: Self Collected

Location	Collection Kit Order	Appointment Scheduling	Verify Identity	Collect Biosamples	Collect Physical Measures	Biosamples Returned
At Home Saliva Kit	In-Portal / Phone	NA	Remote (via ID.me)	Saliva	Self-Reported (In-Portal)	By Participant (Via USPS)

All of Us Participant Data Authorization & Sharing

All of Us **protocol supports data authorization and sharing from select external data sources**

Participants can authorize access and share data from

- EHR / Patient Portals
  - Connect to health provider organization nationally
- Digital Health Accounts & Apps
  - Including linked devices and app data from
    - Fitbit
    - Apple Health
    - Google Fit

Example: *All of Us* Participant EHR Data Authorization and Sharing

All of Us Participant Return of Information

All of Us strives to support return of collected data to program participants by:

- Providing access and data visualization for participant authorized EHR information

- Integrating informational content for participants associated with elements of their EHR including Medline Plus details.

- Sharing survey responses and aggregate summaries of survey data

Example: *All of Us* Participant EHR Data Visualization & Informational Content

All of Us Genetic Return of Results Provided via Integration w/ Program Partners

***All of Us* is committed to responsibly returning genetic information and results to program participants**

Engagement Genetics

Genetic Ancestry

Traits
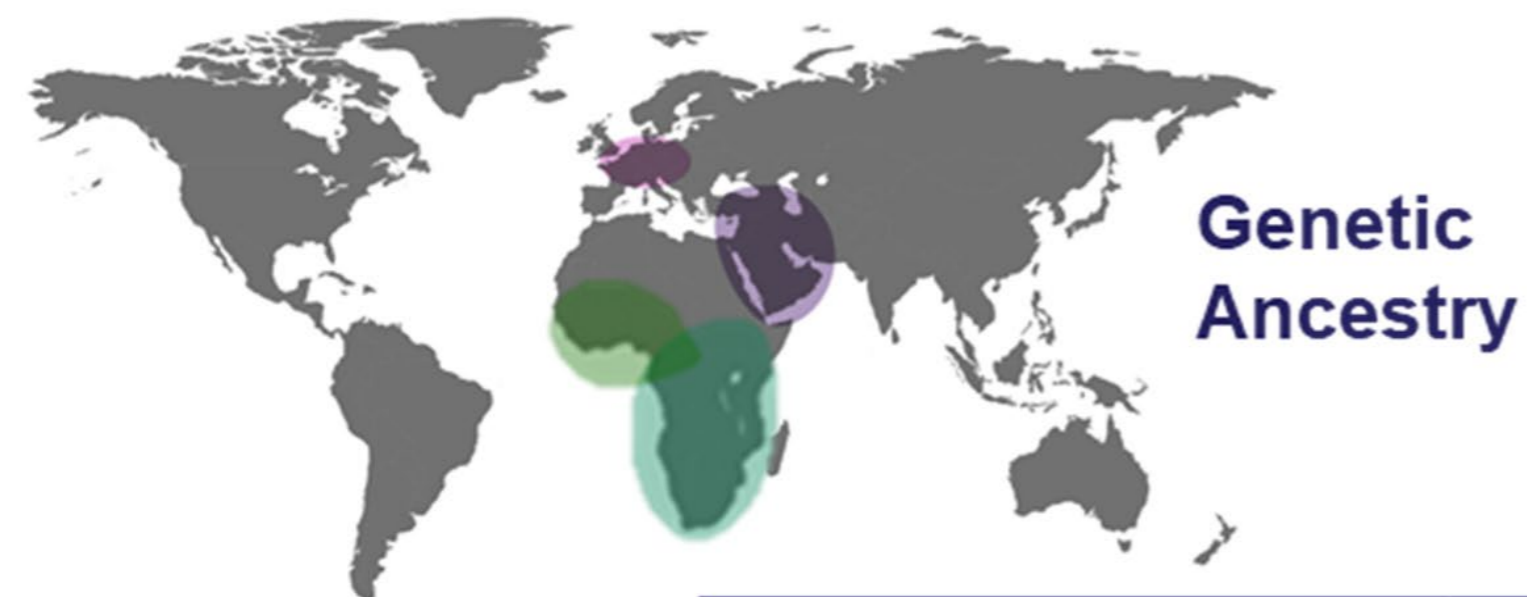
- Genetics Engagement Module (GEM)
- Genotyping
- Shared UI with Color Health

color

Health-Related Genetics

Hereditary Disease Risk

- ACMG v2.0
- Genome sequencing

Medicine and your DNA

- Pharmacogenetics
- Genome sequencing
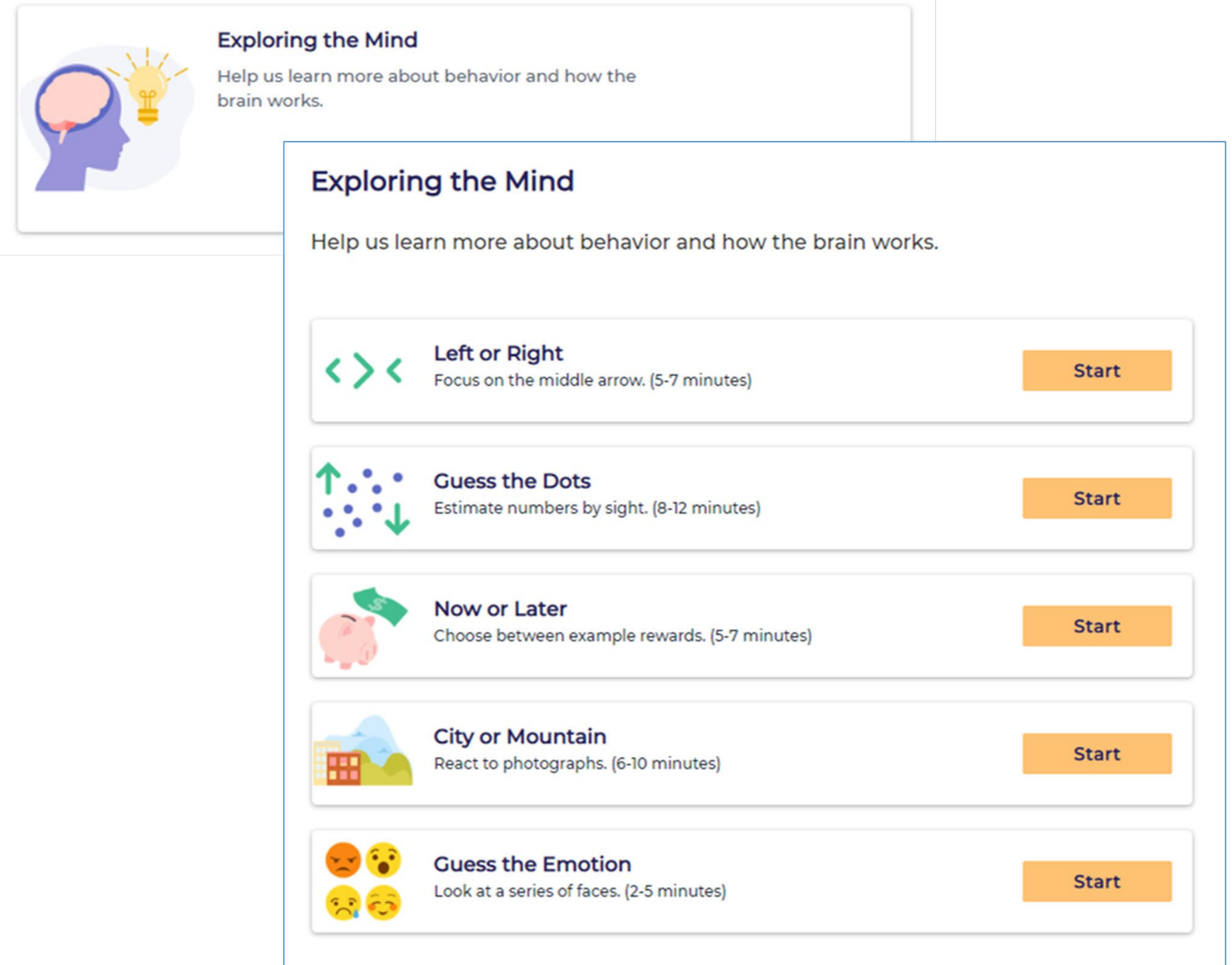
FDA Investigational Device Exemption (IDE) issued July 9, 2020

All of Us Ancillary Studies Integration & Support

An "ancillary study" expands the *All of Us* dataset by:

- **Adding new data for all or a subset of participants by:**
  - Collecting new information directly from participants
  - Generating new data from existing or new biospecimens

- **Program will enable ancillary studies by:**
  - Configuring, embedding or integrating approved data collection methods and tools into the platform.
  - Providing approved study teams access to PPSC platforms and tools
    - Allowing set-up, configuration, testing, deployment, and self-service management of ancillary studies

Example: *All of Us* ancillary study collecting objective task-based behavioral data

Exploring the Mind
Help us learn more about behavior and how the brain works.

Exploring the Mind
Help us learn more about behavior and how the brain works.

Left or Right
Focus on the middle arrow. (5-7 minutes)
Start

Guess the Dots
Estimate numbers by sight. (8-12 minutes)
Start

Now or Later
Choose between example rewards. (5-7 minutes)
Start

City or Mountain
React to photographs. (6-10 minutes)
Start

Guess the Emotion
Look at a series of faces. (2-5 minutes)
Start

ROA Purpose & Overview of the PPSC Structure

Purpose of the ROA

The purpose of this announcement is to solicit and review proposals, evaluate potential partners, and ultimately fund the future *All of Us* Participant and Partner Services Center (PPSC).

- The PPSC will **provide technology systems** and both **direct and indirect research services**.

- Through PPSC, the program aims **to enable support for** a continuously evolving set of **engagement, enrollment and retention partnerships**, participant **audiences** (including children), assessment **methods**, research **services**, ancillary study **protocols**, and **return of information** to participants.

- The program seeks partners that can **provide these capabilities quickly and accurately** using existing platforms and processes, and do so **in a way that precisely meets participants' needs** across a variety of participation journeys.

Relationship between Existing PTSC & TPC w/ Anticipated PPSC Awards

- The structure of the planned PPSC award overlaps with the *All of Us* Participant Technology Systems Center (PTSC) and the Participant Center (TPC) awards, but significantly extends the expectations for future participant experience capabilities and research support services that will be necessary for the program's continued growth.
  - We are initiating the process to establish the PPSC award at this time to ensure a timely and seamless process to compete, select, and transition program support from the existing PTSC and TPC awards to the future PPSC award.
    - The transition of award mechanism will be executed programmatically, regardless of the ultimate outcome of the PPSC competition.

PPSC Award Base Period (15 months)

- The base period of this award will facilitate a transition from the program's current participant and study staff services to the PPSC award team and their resultant services.

  - Current *All of Us* platforms are supported by multiple awards, including the PTSC and TPC

- Proposed technology systems and research services must be capable of integrating with *All of Us* platform partners, configuring to the protocol, providing cross platform testing and training staff, and coordinating production launch within 8-12 months from the time of the award.

  - The PPSC award team will be expected to integrate with partners including, but not limited to, the Data and Research Center (DRC) and Genetic Counseling Resource (GCR)

- Following successful production launch, the PPSC will transition existing participant user accounts from any legacy systems.

All of Us Partner Audiences Served by the PPSC Award

PPSC platforms and teams will provide technology and services that support multiple participant and program partner audiences including:

- **Prospective, New, and Existing Participants**
  - Engaging with the program in a variety of modes and settings, as well as stages of program progression based on date of consent and individual interest or barriers to longitudinal program participation
- **Study Staff / Managers**
  - Facilitating and managing the engagement, enrollment, and retention activities of regional partners
- **Program Administrators**
  - Monitoring and evaluating progress and performance of individual staff, partner organizations, participant segments, etc., based on program-defined key performance indicators
- **(Ancillary Studies Team) Researchers**
  - Establishing, configuring, pre-testing, deploying, and managing program-approved ancillary studies using the PPSC platforms and tools

Participant & Partner Services Center (PPSC) Award Structure

- **The PPSC award will consist of two cores supporting delivery of 1) program technology and 2) research support services that leverage a core technology platform to support program delivery.**
  - Research Technology Systems Core (RTS)
  - Program Management and Delivery Core (PMD)
- **Offerors are encouraged to partner within their proposal to provide research services and technology expertise capable of supporting both the RTS and PMD cores within a single award.**
  - NIH may also select recipients to support individual PPSC cores.
- **Selected partners accepting an award are required to collaborate to achieve the PPSC and program objectives.**
  - In the event that multiple awards are issued under this announcement, the PMD Core will serve as the administrative coordinating center for the PPSC, managing cross-core coordination and project delivery.

Research Technology Systems Core (RTS): Overview

The Research Technology Systems (RTS) core must provide scalable and secure enterprise technology capable of supporting both central program and regional partner-implemented research protocols and participant support, providing extensible tools to

1) **Meet the needs of the national program**, including the NIH, program partners integrating with PPSC systems and services, and communications and engagement award partners, and

2) **Simultaneously support hundreds of regional organizations and thousands of individual sites'** abilities to leverage central platforms to support marketing, community outreach and engagement, participant enrollment and retention, study operations, and program monitoring and analytics.

- **Integration of commercial and/or research platforms solutions are encouraged in order to best support delivery** of the *All of Us* Research Program.

- **Staffing for the RTS core must support the ability to deploy, secure, maintain, enhance, and integrate RTS platforms**, in collaboration with program partners and third-party systems required to implement the *All of Us* Research Program.

Program Management and Delivery Core (PMD): Overview

- **The PMD Core provides indirect and direct research support services supporting protocol operations for *All of Us*.**

- **Indirect Research Support Team**

  - **The indirect research support team will engage and collaborate directly with NIH and program partners** providing scientific, program operations, and technical expertise necessary to leverage the RTS Core platform(s) and facilitate program and protocol development, implementation, compliance, delivery, and change management.

    - The team will **manage and support products and services including, but not limited to, public, participant, and staff-facing software tools, content management system(s), standard operating procedures, staff training, and *All of Us* partner collaborations.**

- **Direct Research Support Team**

  - **The direct research support team will provide methodological expertise, professional services, research equipment and supplies, systems for integration, and contracts or licensing agreements,** as necessary.

    - The team will **conceptualize, implement, and manage scalable multimodal study delivery and innovation methods for participant enrollment, engagement, and retention** across the *All of Us* Research Program's Core Protocol, sub-, and ancillary studies.

PPSC Systems, Services & User Audiences Overview (Not Comprehensive)

PPSC FISMA Privacy & Security Controls Implementation, Management, Continuous Monitoring & Auditing

All of Us NIH Program Staff

All of Us Trained Staff & Partners

All of Us Ancillary Studies Teams & Partners

ID & Access Management

CMS / Web Tools, Data & Mgmt.

Marketing, analytics & content publication tools, data & testing capabilities

Program Communications Services, Configuration & Mgmt

Campaign, workflow & communications content configuration, testing & analytics tools

Supporting communications via email, SMS, letter mail & phone

Participant Platform(s) Protocol Configuration & Mgmt.

Digital program & protocol experience configuration & testing

Preference-based experience mgmt & design

Protocol experimentation & piloting

Analytic reporting & self-service data analytics tools

Study Mgmt. Platforms & Services for Partners

Enrollment location configuration, details & calendar mgmt

Audience & workflow mgmt for prospective & existing participants

Individual user support, profile & case mgmt

Ancillary Study Support

Data analytics & reporting tools - standard/self-service

Program Partner & Third-Party Data & Experience Integration Services

Program platform integrations, implementation, configuration & maintenance

Participant protocol data collection tools & innovation testing

Participant engagement & information return

Ancillary Study Support

Data transfer to DRC

Non-Digital Participant Engagement, Support & Program Delivery

Develop / integrate protocols, methods, services & tools to facilitate non-digital support & program participation

Central documentation of non-digital engagements

Data transfer to DRC

Participant protocols & data collection tools

Participant engagement & information return

All of Us Prospective & Participant Community

Awareness, information & engagement content

Prospective & participant audiences

General & targeted marketing & engagement w/ prospective participants

Preference-based comms for participants

ID & Access Mgmt.

Participant Portal Digital Participation & Engagement Platform

Including

Registration, consents, surveys, biosample donation scheduling / mgmt, data authorizations & connections, engagement & educational content, return of information & results, technology access distribution or support, ancillary study participation

Non-Digital Participation

Including

Survey admin. / processing via CATI & PAPI, letter mail & phone-based engagement & retention tasks, etc.

PPSC-Centered Overview of Awardee Relationships (Not Comprehensive)

Engagement, Enrollment & Comm. Partners

HPO — 1, 2, N
Engage. — 1, 2, N
Comm. — 1, 2, N

All of Us Prospective & Participant Community

Support & Genetic Counseling Partners

Support Center

Genetic Counseling Resource

Participant & Partner Services Center

CMS / Web Tools, Management, & Data

Program Communications Services, Configuration & Management

Participant Platform(s) Protocol Configuration & Management

Study Management Platforms & Services for Partners

Program Partner & Third-Party Data & Experience Integration Services

Non-Digital Participant Engagement, Support & Program Delivery

Enterprise Management, Systems Security & Privacy Support

DRC

Biosample Collection Systems

Data Repositories

Data Exchange & Mngt Tools

Biosample Management & Data Generation Partners

Biobank

Genome Centers — 1, 2, 3

Passive Data Transfer & Linkage Partners

HPO EHR Data Transfer

CLAD

Linkage 1
Linkage 2
Linkage 3
Linkage n

Researchers & Program Stakeholders

All of Us Research Hub

All of Us Researcher Workbench

Submission Requirements & Timeline

Award Information

- **Award(s) Type: Other Transactions (OT)**

- **OT Authority: Public Health Service Act (PHSA) sec. 402(n), 42 U.S.C. sec. 282(n)**

- **Budget: $37.5 million total costs (Base Period)**

  - RTS Core: $17.5 million total cost

  - PMD Core: $20 million total cost

- **Period of Performance: 15-month base period; up to four 12-month optional period**

Competition Process

- **This Other Transactions Award Competition Process will include five Phases:**
  - **Phase I - Submission and Evaluation of White Papers**
  - Phase II - Submission and Evaluation of Full Technical Proposals (Invite Only)
  - Phase III - Capabilities Demonstration and Evaluation (Invite Only)
  - Phase IV - Submission and Evaluation of Full Budget/Cost Proposal (Invite Only)
  - Phase V - Notification of Other Transactions (OT) Award
- **For selected proposals invited to the next Phase, further instructions will be provided.**

Note: To be eligible for invitation to subsequent Phases and award, offerors must submit a White Paper.

White Paper Submission Requirements

- **White Paper Intent Response Form (Amendment 1)**
  - Due February 24, 2023, at 3pm ET
- **White Paper Submission Requirements**
  - Due March 20, 2023, at 3pm ET
  - Email to AOU-ROA@nih.gov
  - One White Paper submission per offeror
  - Format: MS Word or Adobe PDF
    - Less than 100MB
    - No hard copies, facsimiles, zip files, or password protected files

White Paper Content Requirements

- **White Paper Content**
  - Cover Page (1 page maximum)
  - Table of Contents (1 page maximum)
  - RTS Core Summary (10 pages maximum)
    - Provide a summary for key elements of the offeror's 1) technology capabilities, research methods, and services; 2) team structure and partnerships; and 3) relevant past experience.
  - PMD Core Summary (10 pages maximum)
    - Provide a summary for key elements of the offeror's 1) technology capabilities, research methods, and services; 2) team structure and partnerships; and 3) relevant past experience.
  - Resumes (1 page per PD/PI)
  - Bibliography (no page limit)
- **White Papers that do not comply with the submission requirements may result in the White Paper being rejected without evaluation.**

White Paper Evaluation and Invitation to Phase II

- **White Papers will be scored on a scale from 1 to 9 for *each* Core proposed based on the following evaluation criteria:**
  - Programmatic Alignment
  - Scientific Merit
  - Technical Merit
- **The program anticipates that 6 to 12 offerors will be invited to participate in Phase II.**

Tentative Offeror Invite Milestone Schedule (Phase II - Phase V)

- **Phase I - Submission of White Papers: 3/20/23**
- Phase II - Invitation to submit Full Proposals: 5/10/23
- Phase III - Invitation to submit Capabilities Demonstrations: 8/1/23
- Phase IV - Invitation to submit Full Budget/Cost Proposal(s): 9/26/23
- Phase V - Execution of Other Transactions (OT) Award(s): 12/22/23
- OT Award(s) Start: 1/1/24

Note: To be eligible for invitation to subsequent Phases and award, offerors must submit a White Paper.

Questions & Answers

PPSC FAQs: Overview

- **Questions and answers about the *All of Us* Participant and Partner Services Center (PPSC) Research Opportunity Announcement are posted on [sam.gov](sam.gov).**

- **Additional questions can be submitted to AOU-ROA@nih.gov.**

  - Direct responses will be provided to the question submitter.

  - In addition, the public FAQ document will be updated to reflect the general question content and NIH response.

  - Questions must be submitted at least 14 calendar days prior to the White Paper due date to ensure a response.

Questions & Answers

- **(James) Are applicants expected or required to apply for both cores of the Participant and Partner Services Center (PPSC) Research Opportunity Announcement?**

  - Offerors may apply to support one or both cores, depending on their organizations' specific capabilities. An organization is limited to a single submission but may be included as a collaborating partner on more than one application.

  - Offerors are encouraged to propose partnerships within their proposal to provide research services and technology expertise across cores within a single award. NIH may also select separate offerors to support individual PPSC cores.

  - All selected partners accepting an award must work collaboratively to achieve the program's goals and the PPSC milestones and objectives.

    - In the event that multiple awards are issued under this announcement, the Program Management and Delivery (PMD) core will serve as the administrative coordinating center for PPSC, managing cross-core coordination and project delivery.

Questions & Answers (Cont.)

- **(LaMeshia) Are for-profit entities and small businesses eligible for the Participant and Partner Services Center (PPSC) award?**
  - The award is open to all entities listed in the ROA Section 6: Eligibility Information, including for-profit organizations and small businesses. There is no specific set-aside for small businesses in this award.
- **(LaMeshia) Will the program provide potential collaborating partners for applicants?**
  - No. Applicants are encouraged to seek out collaborating partners that they are confident they can work with well. Offerors may apply to support one or both cores, depending on their organizations' specific capabilities.
- **(Chris) Does the NIH stipulate either the reuse or replacement of current *All of Us* technology systems for the Participant and Partner Services Center?**
  - No. The Program is competing the Participant and Partner Services Center ROA as an open competition in order to identify and select the technology platforms and services that best align with and support the future requirements of the program.
  - Offerors should propose the technology solutions they feel best meet the capabilities requested for the Research Technology Systems (RTS) and Program Management and Delivery (PMD) Cores.

Questions & Answers (Cont.)

- **(Chris) Are the *All of Us* Research Program Participant and Partner Services Center (PPSC) and the Center for Linkage and Acquisition of Data (CLAD) opportunities linked in any way?**

  - The PPSC and CLAD are independent program opportunities.

  - Please see NOT-PM-23-002 for more details on CLAD.

- **(Chris) Will the Participant and Partner Services Center (PPSC) award be expected to aggregate and deliver participant data to researchers?**

  - No, the responsibility for developing, supporting and maintaining researcher platforms, data, and access is managed by the Data and Research Center (DRC).

Questions & Answers (Cont.)

- **(James) Is the awardee expected to interact with the program's IRB for permission to provide experiences for participants?**

  - Yes, in some cases the awardee may need to work with the *All of Us* Research Program IRB.

  - The *All of Us* Research Program also has a Research Compliance Team that supports primary interactions with the IRB.

    - The PPSC award should anticipate a close working relationship with the *All of Us* Research Compliance Team and program partners when supporting requested capabilities including, but not limited to:

      - Coordinating and administering research methods, and supporting program planning and protocol development associated with PPSC objectives and deliverables

      - Facilitating implementation of approved program protocols through configuration based on program requirements and style guides, best practices, and accessibility requirements

      - Monitoring and auditing compliance of approved program protocols.

Questions & Answers (Cont.)

- **(James) The ROA indicates the PPSC will provide support for integration of additional platforms or services for data collection or return to augment the PPSC platform capabilities. Can you share any information about the integrations, or the timing and scope of these requirements?**
  - The PPSC will support the *All of Us* Research Program within a network of systems requiring integration and either bidirectional or unidirectional data exchange.
  - Integrations will support functions ranging from research data collection (from the program or a third-party system), data transfer to the Data and Research Center for storage and researcher access, and information return such as genetic information and results.
  - More specific details about timing and scope will be provided in a later phase of the competition process.

Questions & Answers (Cont.)

- **(LaMeshia) Is being an existing awardee or participant partner in the *All of Us* consortium considered a conflict of interest for this award?**
    - Being an *All of Us* Program Consortium member does not itself cause an organizational conflict of interest (OCI).
    - If you believe there may be an actual, potential, or perceived conflict of interest as described in the PPSC ROA Section 9.5, please submit the following information to AOU-ROA@nih.gov with subject line "OTA-23-002 - Participant and Partner Services Center OCI Concern":
        - Name
        - Company name
        - Description of work being performed related to work being requested in the PPSC ROA
            - Identify all relevant facts concerning any past, present or anticipated interests (family member, financial, contractual, organizational, or otherwise, as contractor, subcontractor, or consultant) relating to the work requested in the PPSC ROA. Such interests may have a bearing on whether you or your company has an actual or apparent conflict of interest with respect to being able to render impartial, technically sound, and objective assistance or advice, and without being given an unfair competitive advantage.
        - The NIH will then review the information and confirm whether an actual, potential, or perceived OCI exists and if a mitigation plan is needed or if future participation is not possible due to the OCI found.

Questions & Answers (Cont.)

- **(Chris) Does the NIH expect that the existing participant portal platforms (supported by the PTSC and TPC awards) will both be replaced by one new system implemented by the PPSC? Or will / must the PPSC inherit aspects of the original portal systems to build upon?**
  - The Program is competing the Participant and Partner Services Center ROA as an open competition in order to identify and select the technology platforms and services that best align with and support the future requirements of the program.
    - Offerors should propose the technology solutions they feel best meet the capabilities requested for the Research Technology Systems (RTS) and Program Management and Delivery (PMD) cores.
  - NIH does not stipulate either the reuse or replacement of current *All of Us* technology systems for the Participant and Partner Services Center.
  - The program does anticipate a single participant portal platform and a central study management platform will result from the PPSC award, consistent with the capabilities requested within the ROA.

Questions & Answers (Cont.)

- **(James) How does the NIH envision the PPSC awardee interacting and functioning among the *All of Us* NIH teams (e.g., Communications) and other program awardees?**

  - The PPSC award will coordinate directly with the NIH PPSC Program Officer and their designee(s) regarding milestone delivery, strategic planning, and project oversight.

  - *All of Us* awardees function as a consortium.

    - Program management meetings and standard operating procedures will be established between functional teams in order to support the operational and coordination needs between partners.

- **(LaMeshia) If a White Paper proposes both RTS and PMD cores and is selected, will NIH specify which core(s) are invite to Phase II?**

  - Cores will be reviewed and scored individually.

  - Offerors who propose to support both the RTS and PMD cores, and are invited to Phase II, will be informed if both or a single core was invited to proceed to Phase II.

  - The submitting organization for White Papers that is invited to subsequent phases must continue to lead the submission process.

- **(LaMeshia) Does NIH plan to publicize the names of offerors who pass Phase I?**

  - No, NIH does not plan to release publicly a list of offerors that proceed to Phase II.

Questions & Answers (Cont.)

- **(Chris) How many researchers are currently conducting program-approved ancillary studies?**
  - Initial ancillary studies for the *All of Us* Research Program are being conducted in collaboration with NIH Institutes and Centers.
  - The program envisions that many ancillary studies will be supported in the future, and is actively working to establish processes for proposal, evaluation and approval of future ancillary studies.
- **(James) Capability request: "Technology, methods, and services to enable digital access and sustainable participation."**
  Is the goal of this capability to address digital access or all inequities involved in sustaining participation?
  - The priority for technology, methods, and services to enable digital access and sustainable participation is anticipated to focus on
    1) access to technology and/or broadband service; and,
    2) training and support to enable technology and service utilization to support program participation.
  - The program acknowledges that no initiatives supported by the PPSC will be capable of addressing all inequities involved in sustaining participation.

Questions & Answers (Cont.)

- **(James) Regarding ROA requested capabilities for: "Enterprise analytics data systems and tools to be used for marketing purposes, participant engagement, experience sampling, and program reporting."**
What is the Program's vision for these tools and their implementation? Who are the consumers of these data? Will PPSC data scientists be working with or possibly integrated with the NIH *All of Us* Office of Data and Analytics?

  - Collectively, the RTS Core Tools and PMD Core Services supported by PPSC must support a wide range of program partners and use-cases. Audiences will include 1) study staff and managers, 2) program administrators, and 3) ancillary studies teams.

  - NIH *All of Us* Program Officers, as well as staff and leadership from Program offices and divisions work closely and collaboratively with partners to coordinate the oversight, goals, and successful delivery of program objectives.

  - Analytics data systems and tools will be leveraged to support a mix of workflow-based processes, audience characterization, segmentation and experience tailoring; program monitoring & evaluation, etc.

Questions & Answers (Cont.)

- **(Chris) In regards to "Supporting program and platform requirements for data quality monitoring, assurance, and control". Could the Program please share existing data quality standards that have been set by the program?**
  - Offeror should address their capabilities and process for data quality monitoring, assurance, and control. More specific details will be provided in a later phase of the competition process.
- **(James) In regards to "facilitating partner collaborations", Could the Program please further break down the categories of work for the PPSC that fall within this area?**
  - In addition to deployment, configuration and use of PPSC systems, the PPSC team must provide training and support for study staff on all relevant PPSC software, systems, and tools.
    - Study staff and managers from program partners are a key audience of support for the PPSC and deployed technology must support their engagement, enrollment and retention efforts.
  - *All of Us* awardees function as a consortium.
    - Program management meetings and standard operating procedures will be established between functional teams in order to support the operational and coordination needs between partners.

Closing

1. ROA Informational Webinar slides and Questions and Answers will be posted as an amendment on **Sam.gov**

2. Follow this opportunity on **Sam.gov** to get notifications to amendments

3. Email any inquires to **AOU-ROA@nih.gov**

Thank You!

https://www.joinallofus.org/

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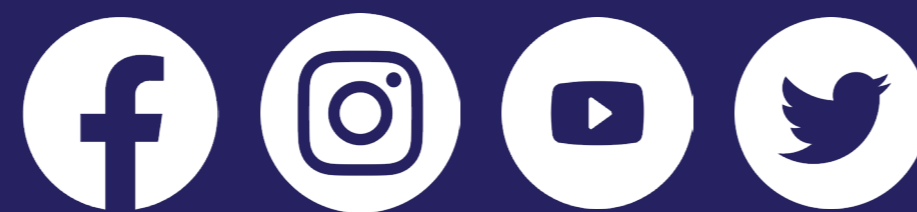
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