

# The *All of Us* Research Program

# The Potential of a Million

TCAC  
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# Core Values

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- Participation in the *All of Us* Research Program will be **open** to interested individuals.
- The Program will reflect the rich **diversity** of America.
- Participants will be **partners** in the Program.
- Trust will be earned through robust **engagement** and full **transparency**.
- Participants will have **access** to information and data about themselves.
- Data from the Program will be broadly **accessible** to **empower research**.
- The Program will adhere to the PMI **Privacy** and **Trust** Principles and the PMI **Data Security** Policy Principles and Framework.
- The Program will be a catalyst for **innovative research** programs and policies.

# Program Overview

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# Overview: *All of Us* Research Program

- Mission: To **accelerate scientific discovery** & breakthroughs in precision medicine
- How: Deliver a **national resource** of deep clinical, environmental, lifestyle, & genetic data from **one million participants** who are consented & engaged to provide data on an ongoing, **longitudinal basis** (60+ years!)
- Priority: Reflect the **broad diversity** of the U.S.—all ages, races/ ethnicities, gender, SES, geo, & health status—by over-recruiting those **underrepresented in biomedical research**
- Priority: Build the **tools & capabilities** that make it easy for researchers from citizen scientists to premier university labs to make discoveries using the **data & biosamples** and through **ancillary studies** w/ the cohort



# Major Building Blocks of the Research Program

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## DATA AND RESEARCH CENTER (DRC)

Vanderbilt University Medical Center  
with the Broad Institute and Verily

## BIOBANK

Mayo Clinic

## PARTICIPANT CENTER

Scripps Research Institute

## PARTICIPANT TECHNOLOGY SYSTEMS CENTER

Vibrent Health

## HEALTH CARE PROVIDER ORGANIZATIONS (HPOs)

Regional Medical Centers,  
Health Centers (including Federally  
Qualified Health Center pilots),  
VA Medical Centers

## COMMUNITY & ENGAGEMENT PARTNERS

Funding Opportunity  
Currently Open

# Program Status/Update

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# Major Building Blocks are on Target

- Built **awardee network** (50+); collaborating well
- **Protocol** submitted to IRB for approval; feedback expected this week or next
- Delivered & tested **new name, content, & brand**
- Development almost complete of **enrollment website, 1-800#, smartphone apps, data center**
- Testing **IT interfaces** for data/sample transfer and testing/documenting **security systems** for ATO
- Started build out of **biobank capacity** (35M+ vials)
- Got “**beta**” **feedback** on content & interfaces; identified **participant segments** for targeting



# National Network of Partners for Launch

**Building  
Block  
Partners**

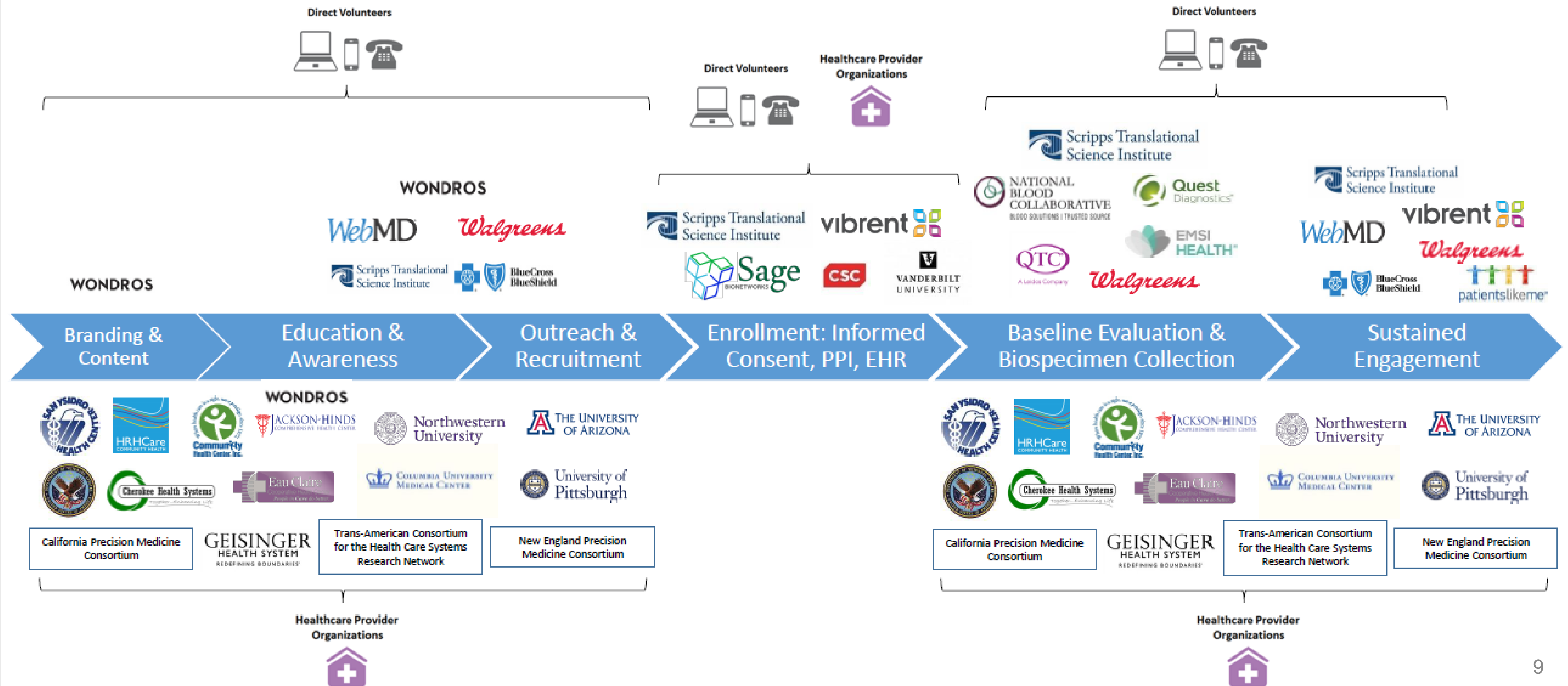
**RMCS**  
regional med centers

**FQHCs**





Participants can join as a Direct Volunteer or through a Health Provider Organization (HPO):  
Regional Medical Centers (RMC) / Federally Qualified Health Center (FQHC) / Veterans Affairs Medical Center (VAMC)



# Engagement with American Indian and Alaska Native Individuals and Communities

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# Engagement Goals

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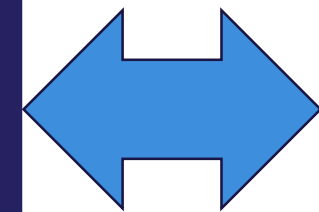
- ◎ Work collaboratively with American Indians and Alaska Natives (AI/AN) to ensure that the concerns of Tribal Nations are addressed, thereby facilitating participation in *All of US*.
  - Share information with the AI/AN community about *All of Us* including highlighting the potential value of participation.
  - Understand AI/AN concerns about biomedical research in general and *All of Us* in particular.
  - Identify strategies to ensure benefits from this project and to return value to the AI/AN community.
  - Collaborate to identify opportunities and understand best practices for conducting AI/AN health research, which may result in amendments to the research protocol for this community.



# Engagement Plans

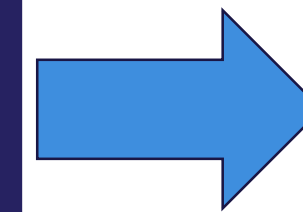
## Advisory Panel Task Force Provides Insight and Feedback

- Task Force will include Tribal leaders (or designees), researchers and providers
- Will be charged with providing insight and feedback about AI/AN engagement and inclusion



## Gather Feedback from Community; Request Consultation with Tribal Leaders

- Host listening sessions at AI/AN conferences, TCAC or HRAC meeting
- HPO partners may host additional input sessions with their local Tribal nations
- When ready, will request Consultation for additional input



## Consider Input and Develop Implementation Strategy

- Review input and determine next steps, which may include protocol amendments
- Consider opportunities to partner with Tribal Nations, IHS clinics, community health centers, researchers

# Potential Areas for Task Force Input

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- ⦿ Consent
- ⦿ Identification of AI/AN
- ⦿ IRB review
- ⦿ Biospecimen management, ownership, and access/sharing
- ⦿ Researcher access to data
- ⦿ Role of industry
- ⦿ Genomic sequencing
- ⦿ Return of information
- ⦿ Research topics
- ⦿ Conflict resolution

# Feedback / Questions?

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# Thank You!

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National Institutes  
of Health

**All** *of* **US**

**THE FUTURE OF HEALTH BEGINS WITH YOU**

The  
Precision  
Medicine  
Initiative