The *All of Us* Research Program

PGRN
February 2, 2018

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Deputy Director, *All of Us* Research Program
National Institutes of Health
All of Us Mission and Objectives

Nurture relationships
with one million or more
participant partners, from all
walks of life, for decades

Our mission
To accelerate health research
and medical breakthroughs,
enabling individualized
prevention, treatment,
and care for all of us

Deliver the
largest, richest
biomedical
dataset ever
that is easy, safe,
and free to access

Catalyze the
robust ecosystem
of researchers and funders
hungry to use and support it
21st Century Cures Act

- Broad bi-partisan support
- Provisions relevant to All of Us:
  - Provides the Precision Medicine Initiative with $1.455 billion over 10 years
  - Provides flexible funding mechanism, Other Transaction Authority
  - Language on diversity, data sharing, privacy
  - Provides important privacy protections critical for engendering trust
- Senate hearing tomorrow on implementation
Major Building Blocks of the Research Program

DATA AND RESEARCH CENTER (DRC)
Big data capture, cleaning, curation, & sharing in secure environment
Vanderbilt, Verily, Broad Institute

BIOBANK
Repository for processing, storing, & sharing biosamples
Mayo Clinic

PARTICIPANT CENTER
Direct volunteer participant enrollment, digital engagement innovation, & consumer health technologies
Scripps Research Institute (with multiple partners)

PARTICIPANT TECHNOLOGY SYSTEMS CENTER
Web & phone-based platforms for participants
Vibrent Health

HEALTH CARE PROVIDER ORGS (HPOs)
Clinical & scientific expertise network, enrollment & retention of participants
20+ regional med centers, FQHCs, VA, future awards to grow network

COMMUNICATIONS & ENGAGEMENT
Comms, marketing, & design expertise; Engagement coordination & community partners network
Wondros, HCM, future awards to grow network of community partners
All of Us Research Program Data

The Program will start by collecting a limited set of standardized data from sources that will include:

- Participant questionnaires
- Electronic health records
- A baseline physical evaluation
- Biospecimens (blood and urine samples)
- Mobile/wearable technologies
- Geospatial/environmental data

Data types will grow and evolve with science, technology, and trust.

| V1 platform | V2 platform | V3 platform | Vx platform...
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<td>Samples</td>
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All of Us Research Program Participant Activities

1. Learn
2. Discuss
3. Enroll & Consent
4. Questionnaires
5. Physical Measures
6. Bio-Samples
7. Lifestyle & Health Data Contributions
8. Research Projects & Publications
9. Return of Information
10. Duration
Two Methods of Engagement

DIRECT VOLUNTEERS

HEALTH CARE PROVIDER ORGANIZATIONS
**Vision:** Make it possible for anyone, anywhere in the country to participate in biomedical research.

**Where we are:**
- Built a network of partners
- Reach of 37,000 facilities or providers covering 97% of US…but we cannot fully staff all at once.

**Question:**
- How can this approach become a national resource independent of *All of Us*?
- What decisions or choices do we need to make now to facilitate this over time?
Consent / e-Consent

- Recruit 18+ years old initially; kids plan in Q1
- eConsent or paper long-form
- 6th grade reading level; English & Spanish initially
- eConsent process includes modules on:
  - Participant Provided Info (PPI) + Linkage + Re-contact
  - Physical Measurements (PM) + Biospecimen
  - Sensors or wearable devices
  - EHR
  - Genetic information
- Videos expand on key concepts
- Separate opt-in & signature for some modules, including EHR and genetics (state laws)
PPI/Survey Modules for Launch

PPI Enrollment Surveys
1. The Basics
2. Overall Health
3. Lifestyle

In Development (++)
4. Personal Health History
5. Medications
6. Family History
7. Health Care Access and Utilization
8. Sleep
9. Environment/exposures
Physical Measurements

- Blood pressure
- BMI
- Heart rate
- Height
- Hip circumference
- Waist circumference
- Weight

Biospecimen Collection
- Blood (or saliva)
- Urine

Participants will have access to their physical measurements through:
- The Participant Portal
- In Writing
Building capacity for the entire research community:

- EHR data from disparate sources: Sync 4 Science, data aggregators
- Claims data: CMS-NIH collaboration (PCORTF): Medicare Beneficiary Claims Data to Research Studies
- Medications: directly from pharmacies
- Genetic testing reports: Sync 4 Genes, Sync for Genes has been created to leverage HL7 FHIR infrastructure for communicating information from clinical genomic labs in a format for universal use across medicine.
Participants will be asked to authorize linkage of their EHR information.

<table>
<thead>
<tr>
<th>Initial Data Types</th>
<th>Expanded Data Types (May Include)</th>
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<tbody>
<tr>
<td>• Demographics</td>
<td>• Clinical Notes</td>
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<tr>
<td>• Visits</td>
<td>• Radiology, cardiology, and other reports</td>
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<tr>
<td>• Diagnoses</td>
<td>• Mental Health Reports</td>
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<tr>
<td>• Procedures</td>
<td>• Substance Abuse, Alcohol use, and Tobacco use</td>
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<tr>
<td>• Medications</td>
<td>• More laboratory results, potentially including genomics</td>
</tr>
<tr>
<td>• Laboratory Visits</td>
<td></td>
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<tr>
<td>• Vital Signs</td>
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Sync-4-Science Pilot Sites
Return of Information

Participants may receive, depending on their preferences:

- Individual health information
- Survey data (comparative)
- EHR data, claims data
- Research results
- Ongoing study updates
- Aggregated results
- Scientific findings
- Opportunities to be contacted for other research opportunities
Data Access
Researcher Based Access

- No data removal
- Tiered access approval
- Data passport model
- Broad access, researchers from all sectors, citizen scientists, etc

**Data Passport:**
All of Us data is consented for general research use; no specific data use restrictions.

Access to All of Us data resources will be researcher-based, not project-based, manner.

Researchers will be granted “data passports” to access Registered-and/or Controlled-access datasets.

All research uses will be posted publicly (provision in Cures)
**Data Tiers**

**Public** - Data that poses minimal risks to the privacy of research participants. Fully open without login. 
anyone, anywhere, anytime

**Registered** - Data that has some risk of identifying research participants and therefore poses some privacy risk to participants. 
requires data use agreement, identity verification, ethics training, approval

**Controlled** - Data that poses more risk to the privacy of research participants. 
requirements for registered access + institutional signing official
Currently we have >13,500 participants enrolled at >100 sites

Through the winter and spring, will enroll ~25,000 participants

Test the initial protocol, call center, online tools & interfaces, language of consent & questionnaires, workflow for staff at each location, biobank shipments, etc.

National launch in Spring 2018

Welcome!

You are one of the very first people to experience the All of Us Research Program.

Ultimately, All of Us will include at least one million people who will share information about themselves for this groundbreaking research program. Developing a research program of this size is not easy. We want to be sure we get it right.

We’re still in the early stages of creating the features, tools, and resources we want to have available for all participants. Before we open the program widely, we are enrolling a limited number of people as beta testers. In the meantime, please take a look around the site.

Is there anything you’d like to see that isn’t there? Anything that you found confusing or hard to use? Or that you particularly liked?

The website you are about to visit will be updated throughout the beta phase. Please come back to visit again if you get the chance.

Thank you for your help, and welcome to the All of Us Research Program!

Eric Dishman
Director, All of Us Research Program
National Institutes of Health | U.S. Department of Health and Human Services

Click “We're in beta” at top of https://www.joinallofus.org/
Scientific Priorities
The All of Us Research Priorities Workshop

- **Date and Location:** March 21-23, 2018, in Bethesda, MD
- **Purpose:** Identify key research priorities that will capitalize on the All of Us Research Program’s one million or more participants to help ensure optimal value for advancing precision medicine.
- **Planning Committee:** Senior leaders across NIH’s Institutes and Centers.
- **Workshop Participants:** A broad array of stakeholders (e.g., researchers, participants, professional societies, advocacy groups); by invitation.
- **Outreach Plans:** Obtain substantial input on research questions and requirements prior to the workshop.
- **Updates:** You can subscribe at https://www.joinallofus.org/news-and-events

### Three Big Questions for the workshop

1. **Near Term**
   - What are low-hanging fruit questions/measures for which the scale of All of Us could help accelerate knowledge & breakthroughs in precision medicine?

2. **Mid-Term**
   - What kinds of questions might this Program answer where additional work selecting among measures/instruments is needed?

3. **Long Term**
   - What kinds of questions are ripe for a program of this size but for which we need fundamental science & tech to develop the instruments and methods?
Need research communities to walk through a winnowing down process from research areas to specific elements we can consider for the next protocol.
All of Us Wants Your Ideas!

Are you interested in helping researchers understand more about why people get sick or stay healthy? If so, we need your ideas to help make the All of Us Research Program the best resource it can be to support future research.
Crowdsourcing Use Cases-- Demonstration

https://allofusresearchpriorities.ideascale.com/

- Register (easy to do)
- Log in
- Submit use cases
- Read use cases
- Comment on use cases
- Vote on use cases
All of Us Research Program Seeks Input on Research Priorities

December 19, 2017

We need your help!

The All of Us Research Program aims to build one of the largest, most diverse datasets of its kind for health research, with one million or more volunteers nationwide, who will sign up to share their information over time. Researchers will be able to access participants' de-identified information for a variety of studies to learn more about the biological, behavioral, and environmental factors that influence health and
Questions?

Sign up for updates: joinallofus.org
@AllofUsResearch   #JoinAllofUs
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<th>All of Us Consortium Members</th>
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### DV Network (Direct Volunteers)

- Scripps Translational Science Institute
- DXC.technology
- Walgreens
- BlueCross BlueShield
- WONDROS
- HMG

### HPO Network (Health Care Provider Organizations)

#### RMCs
- California Precision Medicine Consortium
- Illinois Precision Medicine Consortium
- New England Consortium for the Health Care Systems Research Network
- Trans-American Consortium for the Health Care Systems Research Network
- New York City Precision Medicine Consortium
- Southern All of Us Network
- SouthEast Enrollment Center

#### All of Us, Wisconsin
- UC San Diego Health
- UC Irvine Health
- UC HEALTH
- University of Arizona
- University of Pittsburgh
- SPECTRUM HEALTH
- Banner Health
- University of Chicago
- Northwestern University
- Keck Medical Center of USC
- Rush University Medical Center
- Northwestern University Feinberg School of Medicine
- University of Illinois at Chicago
- Duke University
- Emory University
- Morehouse School of Medicine
- University of Florida
- University of Miami
- University of Minnesota
- New York Presbyterian
- Well's Cornell Medicine
- Columbia University Medical Center
- University of Alabama
- University of Texas Medical Branch
- University of Wisconsin
- University of Pittsburgh
- VA Medical Centers
- US Department of Veterans Affairs

#### Community Partners

- All of Us, Wisconsin
- University of Arizona
- University of Pittsburgh
- Commonwealth Health Center Inc.
- Jackson Health Services
- Baylands Health Services
- University of Miami
- University of Florida
- University of Alabama
- University of Minnesota
- New York Presbyterian
- Well's Cornell Medicine
- Columbia University Medical Center
- University of Alabama
- University of Texas Medical Branch
- University of Wisconsin
- VA Medical Centers
- US Department of Veterans Affairs

#### Communication & Engagement

- WONDROS
- HMG
- Wondros
- HMG

#### Platform Development

- Scripps Translational Science Institute
- Sage
- Vanderbilt University
- WONDROS
- Wondros
- vibrant