Participant Technology Systems Center

Informational Webinar

December 16, 2019

@AllofUsResearch  #JoinAllofUs
AGENDA

- Introduction to the *All of Us* Research Program
- Timeline for the funding announcement
- Application components and process
- Objectives of the funding announcement
- OT award background
- Q & A session
Introduction to the *All of Us* Research Program
**All of Us Mission and Objectives**

**Nurture relationships**
with one million or more participants, 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 data set ever**
that is easy, safe, and free to access

**Catalyze a robust ecosystem**
of researchers and funders hungry to use and support it
Major building blocks of the *All of Us* Research Program consortium

**DATA AND RESEARCH CENTER**
Big data capture, cleaning, curation, & sharing in secure environment

*Vanderbilt, Verily, Broad Institute*

**BIOBANK**
Repository for processing, storing, and sharing biosamples (35+M vials)

*Mayo Clinic*

**PARTICIPANT TECHNOLOGY SYSTEMS CENTER**
Web and phone-based platforms for participants

*Vibrent Health*

**GENOMICS PARTNERS**
Genotyping and whole genome sequencing of biosamples; counseling and educational resources for participants

*Baylor College of Medicine, Broad Institute, University of Washington (with multiple partners), and Color*

**PARTICIPANT CENTER / DV NETWORK**
Direct volunteer participant enrollment, digital engagement innovation, and consumer health technologies

*Scripps Research Institute (with multiple partners)*

**HEALTH CARE PROVIDER ORGS NETWORK**
HPOs with clinical & scientific expertise, enrollment & retention of participants

*30+ regional medical centers, FQHCs, VA, and future awards to grow network*

**COMMUNICATIONS & COMMUNITY NETWORK**
Communications, marketing, and design expertise; engagement coordination and community partners network

*Wondros, HCM, University of Utah, and many community engagement partner organizations*
### All of Us Consortium Members (beyond community partners)

<table>
<thead>
<tr>
<th>HPO Network (Health Care Provider Organizations)</th>
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<tbody>
<tr>
<td><strong>All of Us California</strong></td>
</tr>
<tr>
<td>UC San Diego Health</td>
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<td>CEBARS SINAL</td>
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<td>USC University of Southern California</td>
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<td>San Diego Blood Bank</td>
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<td>FCRMC</td>
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<td><strong>All of Us Wisconsin</strong></td>
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<td>Wisconsin Healthcare System</td>
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<td>UW Health</td>
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<td>Advocate Health</td>
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<td><strong>All of Us Pennsylvania</strong></td>
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<tr>
<td>University of Pittsburgh</td>
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<tr>
<td>Temple University</td>
</tr>
<tr>
<td><strong>All of Us New England</strong></td>
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<td>Brigham Health Women’s Hospital</td>
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<td>Partners HealthCare</td>
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<td>UMass Memorial Health</td>
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<td>Spectrum Health</td>
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<td>Reliant Health</td>
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<td>McLean Hospital</td>
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<tr>
<td><strong>All of Us Pennsylvania</strong></td>
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<td>University of Arizona and Banner Health</td>
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<td><strong>Trans America Consortium</strong></td>
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<td>Columbia University Medical Center</td>
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<tr>
<td>New York Presbyterian Hospital</td>
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<tr>
<td>Well Cornell Medicine</td>
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<td><strong>All of Us New England</strong></td>
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<td><strong>All of Us Southern Network</strong></td>
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<td><strong>All of Us SouthEast Enrollment Center</strong></td>
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<tr>
<td><strong>Communications &amp; Engagement</strong></td>
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<tr>
<td>WONDROS</td>
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<td><strong>Participant Technology Systems Center (PTSC)</strong></td>
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<td><strong>Biobank</strong></td>
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<td><strong>Data &amp; Research Center (DRC)</strong></td>
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<td><strong>Genomics Partners</strong></td>
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<td>EHR Health Services</td>
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<tr>
<td>Mayo Clinic</td>
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<tr>
<td>Columbia University Medical Center</td>
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<tr>
<td><strong>Vanderbilt University Medical Center</strong></td>
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<td><strong>Broad Institute</strong></td>
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<td><strong>Verily</strong></td>
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<td>UTHSC San Antonio</td>
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<td>University of Tennessee Health Science Center</td>
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<td><strong>VA Medical Centers</strong></td>
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<td>U.S. Department of Veterans Affairs</td>
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All of Us Community Engagement Partners (as of October 2019)
How to become one in a million

Create account
Complete consent and surveys
Have measurements taken
Provide blood and urine sample
You are now one in a million!

Registered participants
350,000+

Core participants
235,000+

% participants underrepresented in biomedical research
75%
Timeline for the funding announcement
Important dates

- Dec. 6, 2019: FO posted
- Dec. 16, 2019: Informational webinar
- Feb. 14, 2020: Application due date
- Feb. 2020: Application review begins
- July, 2020: Award notices sent out
- June, 2020: (estimated) Orientation
Application components and process
Application components ("Required Application Instructions", pg. 2-3)

Page limit = 40 (excluding an optional cover letter)
Submission process (“Instructions for Application Submission”, pg. 3-4)

Applications must be submitted via NIH eRA ASSIST System

Applicant must be registered in eRA Commons

Review “Instructions for Application Submission” section of FO
• Use OTA-20-001 in the field requesting Funding Opportunity Announcement

Instructions for Application Submission

Applications must be submitted via the NIH eRA ASSIST System by February 14, 2020 (5:00 p.m. local time). To submit an application via ASSIST, the applicant organization must be registered in eRA Commons (see instructions). Organizations already registered in eRA Commons do not need to reregister.

Once the organization is registered, the individual(s) with the role of Signing Official (SO) and Program Director/Principal Investigator (PD/PI) must be affiliated with the organization and have eRA Commons credentials to complete the submission process.

Use OTA-20-001 in the field requesting Funding Opportunity Announcement.
1. **Evaluate**: Applications will be evaluated for responsiveness to the Funding Opportunity requirements and merit by an appropriate review group convened by the NIH.

2. **Select**: Top applications will be selected.
Objectives of the funding announcement
The PTSC has multiple areas of responsibility for the *All of Us* Research Program, including:

- Platform operations and maintenance
- Systems integration and support
- Participant services development
- Partner services development and support
- Operational analytics and reporting.

Provide technology systems to support program participation from individuals across a broad spectrum of age, cultural background, digital access, educational attainment, health status, socioeconomic status, and technical expertise.
Component 1: Platform Operations and Maintenance

- Demonstrate awareness of and capabilities to operate, maintain, monitor, and assess a cost-efficient, privacy- and security-compliant cloud environment for All of Us systems development and operations
  - Supporting platform operations and maintenance (O&M,) including security operations, privacy and security compliance (see Data Security and Privacy Management)
  - Supporting development operations and managing commercial cloud platform and software
  - Implementing quality assurance systems and processes to manage the software development life cycle.
  - Support O&M services for partners, to leverage shared resources among integrated systems.
Component 2: Systems Integration and Support

- Demonstrate awareness of and capabilities to support system integrations and accelerate assessment, onboarding, and operational integration for technology or research service partners for the All of Us Research Program.

- The vision of the All of Us Research Program is to ultimately open application development opportunities to broader research and software development communities by leveraging an innovation ecosystem to
  - Expand research data collection methods
  - Enhance engagement and return of information to participants
  - Support customized user experiences for specific populations or research protocols
Component 3: Participant Services Development

- Propose solutions to support participation from diverse populations and settings. A few key items highlighted below.
  - Implement current and future protocols for the *All of Us* Research Program, including informed consent materials, surveys, educational content, return/visualization of participant information, customization of content or experience based on participant profile or preferences, and user authorizations management for data sharing.
  - Consider user experience optimization and innovation for both facilitated and unassisted participant interactions in order to improve efficiency and effectiveness of enrollment, engagement, and long-term retention of participants.
  - Support a testbed for rapid user testing and piloting of tools not yet deployed but in development or consideration for use.
  - Consider the needs of the program to support additional user populations (e.g., children and adolescents), protocol-based substudies, and ancillary studies.
Component 4: Partner Services Development and Program Support

- Propose solutions to support engagement, enrollment, and retention of diverse participants within a variety of settings. Tools should support program staff for protocol implementation, facilitation, and management, including
  - Appointment scheduling and management.
  - Multi-channel (e.g., email, SMS, push notifications, direct mail, phone) participant communications and communications workflows.
  - Case management, including cohort, sub-cohort, and individual analytics data access associated with participant status/demographics/region/etc.
  - Participant account management and user support.

- Provide support for or coordinate implementation of essential services necessary for PTSC or partner/integrated systems including
  - UI/UX testing for iOS, Android, and web applications.
  - Section 508 compliance auditing and mitigation for PTSC-provided tools.
  - Training and support resources for all PTSC-managed software/services.
Component 5: Operational Analytics and Reporting

- Propose approaches and solutions to support and enhance capability for the All of Us Research Program to leverage rapid and iterative data science methods to increase the performance and efficiency of program components, including strategies for awareness, education, and recruitment, and participant communications for engagement and retention.
  - Analytics tools and services to support real-time visibility for study staff into cohort, sub-cohort, and individual participant status, activity, and engagement with the All of Us protocol(s).
  - Curated web and/or mobile platform analytics to optimize the program’s ability to monitor and iteratively enhance content and experience to improve enrollment, engagement, progression, and retention of participants.
Design and implement technical and policy safeguards necessary to ensure data security including compliance with NIST standards to a Federal Information Security Management Act (FISMA) Moderate requirement.

- The NIH *All of Us* may require additional security measures not included in the FISMA moderate standards.

Prior to system use in *All of Us*, an Authority to Operate (ATO) from NIH will be required along with documentation describing the current security monitoring/practices in place in accordance with FISMA review standards.

The NIH *All of Us* ISSO will request an annual independent review of security controls, in addition to continual review and testing, to ensure overall effectiveness against evolving threats and consistent implementation as a requirement of renewal of the ATO.
OT award background
Other Transactions Authority

- The Other Transactions (OT) award mechanism is not a grant, cooperative agreement, or contract.
- For *All of Us*, the National Center for Advancing Translational Sciences (NCATS) manages the OT awards.
- All applicants should read and be familiar with the Other Transaction Award Policy Guide for NIH Precision Medicine Initiative Research Programs. (The NIH Grants Policy Statement does not apply to OT awards.)
- OT allows NIH the flexibility to alter the course of projects in real time to meet the overarching programmatic goal. This means awarded activity can be expanded, modified, partnered, not supported, or later discontinued based on program needs.
- If selected for award, applicants should expect significant ongoing NIH involvement.
Submission Process

- All applicants must submit their application via the NIH eRA ASSIST System.
- To complete the application process, you must complete the NIH Commons Registration first. If you already have a Commons Registration, you do not need to reregister.
- The deadline for application submission is February 14, 2020 by 5pm local time.

Please start the registration and application submission process early to avoid a late application submission due to technical issues.

Late applications will NOT be accepted!
Next steps

1. Submit additional questions to AllofUsFOAInquiries@nih.gov

2. Release slide deck, questions, and answers

3. Application due date: February 14th, 2020

4. Review applications: March 2020

5. Send out award notices: June 2020

6. Hold orientation event (estimated): July-August
Q & A session
Please use the **Q&A box** to submit additional questions.
Thank You!