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
TO DATE…

>75,000 Participants have consented

74.7% are under-represented in biomedical research

125+ sites now enrolling in 18 states

Biobank > 860K tubes (capacity for 35M)

34+ Community & provider partners ready for outreach

Developed participant-friendly and bilingual website, portal, app, call center

Developed data warehouse to collect, clean, curate, de-identify the data

Research Portal to be open with initial public dataset in 2019

Begin enrolling children within one year of launch

Genomics to begin in late 2018/early 2019
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*

**PARTICIPANT CENTER / DV NETWORK**
Direct volunteer participant enrollment, digital engagement innovation, and consumer health technologies
*Scripps Research Institute (with multiple partners)*

**HEALTHCARE 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, 18 community partner organizations, and future awards to grow network*
What are the potential activities asked of participants in the current protocol?

**Enroll, Consent and Authorize EHR**
- Recruiting 18+ years old initially; plan to include children in 2019
- Online, interactive consent
- Includes authorization to share Electronic Health Record (EHR) data

**Answering Surveys**
- Three initial surveys: The Basics, Overall Health, & Personal Habits
- Additional surveys will be released on an ongoing basis.

**Physical Measurements***
- Blood pressure
- BMI
- Heart rate
- Height
- Hip circumference
- Waist circumference
- Weight

**Provide Biosamples***
- Blood (or saliva, if blood draw is unsuccessful)
- Urine specimen
- Biosamples will be stored at the program’s biobank

**Wearables and Digital Apps**
- Share data from wearable fitness devices, starting with FitBit
- Share data about mood & cardio-respiratory fitness through integrated apps
- More integrations to come

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*Based on diverse sampling and capacity
Coming soon
Discussion of Genomics Plans & Aspirations

- Genotyping & whole genome sequencing for all 1M people as fast as funding/capacity buildout allow

- Just released Funding Opportunity for Genome Centers
  - Start genotyping & WGS fall 2018 w/ 2-3 genome centers

- Responsible Return of Information (RROI) pilot of 20k diverse people w/ genetic counseling resource to launch in late 2018/early 2019

- Begin sharing de-identified genomic data (and EHR, survey, etc.) at Research Portal launch, first half 2019
Technology to Support Integration of Health Data

- 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.
  - Other data types: Imaging, payor data, Specialty EHR (dental, etc.)
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>
</tr>
<tr>
<td>• Visits</td>
<td>• Radiology, cardiology, and other reports</td>
</tr>
<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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Scientific Planning
The opportunity to save time and resources and accelerate your research breakthroughs by leveraging:

- A rich resource of data, including biospecimens and increasingly robust electronic health records.
- A longitudinal dataset that will follow participants as they move, age, develop relationships, get sick, and try treatments.
- A diverse cohort of participants, including people both healthy and sick, from all walks of life and all parts of the country.
- Both raw data and data that is already cleaned and curated.
- Robust computing and analytic tools to support complex data analyses in a secure data environment.
- A group of engaged participants who may be eager to participate in ancillary studies.

The ability to easily share workspaces and analyses with research partners and reviewers.

The chance to learn from the program’s pilots and experiments and leverage innovations for other studies and cohorts.

As with most studies, we are collecting, evaluating, and curating initial datasets; availability in 2019.
Strategy: provide diverse data types for participants as a national resource

Environmental
- Highway proximity
- Chemical exposures
- Air pollution
- Water quality
- Weather
- Occupational hazards
- Zip code
- Occupational hazards
- Zip code

Biological/Clinical
- Metabolomics
- Mental health
- Meds
- Electronic health records
- Proteomics
- Genomics
- Microbiomics
- Exercise
- Eating
- Drinking
- Self-report
- Drug usage
- ADLS
- Smoking history
- Routines

Social
- Upbringing
- Education level
- Family structure
- Stress
- Literacy level
- Access to care
- Financial means
- Size of social network
- Religion

Behavioral
- Exercise
- Eating
- Drinking
- Self-report
- Drug usage
- ADLS
- Smoking history
- Routines

My needs
My mind
My means
My body
My goals

My body
My mind
My means
My goals

My needs
All of Us is building a Resource for others to drive their science

SECONDARY DATA ANALYSES

Vx platform...

V1 platform
- Data
- Samples
- Analyses
- Tools
- Cohort

V2 platform
- Data
- Samples
- Analyses
- Tools
- Cohort

V3 platform
- Data
- Samples
- Analyses
- Tools
- Cohort

ANCILLARY/SUB STUDIES

PILOT
- environmental risk study

PILOT
- a disparities study

PILOT
- a new survey instrument

PILOT
- whole genome seq

PILOT
- a biomarker study

PILOT
- utility of phone/GIS data

SECONDARY DATA ANALYSES

ANCILLARY/SUB STUDIES
**Kinds of Questions this Resource May Help Answer**

<table>
<thead>
<tr>
<th><strong>How can we prevent the chronic pain that affects more than 100 million people across the U.S. each year?</strong></th>
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<tr>
<td>Or develop better pain medicines that aren’t addictive?</td>
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<tr>
<td>Or develop better treatments for diabetes, which affects almost 10% of Americans—or prevent diabetes altogether?</td>
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<tr>
<td>Or drive local disparities interventions that work sustainably?</td>
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<tr>
<td>Or slow or even stop different kinds of dementia?</td>
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<tr>
<td>Or develop more cancer cures that will work the first time, so we can skip painful trial-and-error chemotherapy?</td>
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March 2018 Research Priorities Workshop

• March 21-23, 2018, in Bethesda, MD

• Participants: 347 Researchers, All of Us Participants, Professional Societies, Advocacy Group Industry/Tech, Federal Agencies; by invitation

• Purpose: Identify key research priorities to help ensure optimal value for advancing precision medicine.

• Collected use cases & requirements
  
  800+ in advance from the stakeholder community through IdeaScale crowdsourcing platform
  
  500+ at the workshop

• Next Steps: These data will be prioritized and synthesized into a scientific requirements document to help inform protocol development and scientific priorities for the next 10 years.
All of Us Protocol Development Lifecycle

- Needs and Opportunities
  - Scientific Discoveries
  - Research Questions
  - New Technologies

**All of Us Responsibilities**

- Integrate set of compiled data types, derived from use cases into list of requirements
- Set priorities – All of Us Consortium; NIH Institutes and Centers; All of Us Advisory Panel
- Iteratively seek and review additional input for potential incorporation into the All of Us protocol

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**All of Us Protocol Development Lifecycle**

- Describe Use Cases
- Elicit Protocol Requirements
- Implement All of Us Protocol
- Plan All of Us Protocol
- Prioritize Protocol Requirements
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)
Return of Results
Research Participants Want Information Back

PLOS ONE published a public opinion survey conducted by the Foundation for the NIH.

2,601 responses were analyzed.

79% supported the program after reading a short description.

54% said they would definitely or probably participate if asked—not predictive of enrollment numbers, but encouraging.

- Little variability among demographic groups
- Most important incentive for participation: learning about one’s health information

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
Return of Genetic Results in the *All of Us* Research Program

Workshop March 6-7, 2017

**WORKSHOP GOALS:**

- Assess the state-of-the-field for the return of genomic information.
- Establish guidelines for return of genetic results considering the distinctive features and core principles of the *All of Us* Research Program.