The All of Us Research Program

American Medical Association’s Federation of Medicine
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Grand opportunities to scale research discoveries for precision medicine

- Taming Wild New Data Types: which are meaningful to research? Standards & comparability? Roadmap of future?
- Diverse, Longitudinal Engagement at Scale: how to achieve, especially in times of increasing social division?
- Opportunities for evidence-based policy to support the science and translation of precision medicine: what are the gaps? Roadblocks?
- Expanding the Researcher Pool: from citizen science to community colleges? New incentives to data/knowledge share?
- Researching New Business Models: what do insurers, pharma, providers look & act like in precision health era?
**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

**Catalyze the robust ecosystem**
of researchers and funders hungry to use and support it

** Deliver the largest, richest biomedical dataset ever**
that is easy, safe, and free to access
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
Important Privacy Protections/Policies

Certificates of Confidentiality
- All of Us Research Program data is currently covered by Certificates of Confidentiality
- The new provision in Cures:
  - Requires issuance of a certificate to all investigators “engaged in biomedical, behavioral, clinical, or other research in which identifiable, sensitive information is collected”
  - Prohibits disclosure (except in limited circumstances), and is inadmissible in court
  - Allows for disclosure with the participant’s consent

Freedom of Information Act
- Section 2013 of the Cures Act implements similar privacy protections on data held by the federal government.

PMI Privacy and Trust Principles
- Articulate a core set of values and responsible strategies for engendering public trust to serve as a foundation for PMI.
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.
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
Build direct volunteer capacity

- **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

### 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
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
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.
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>
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<tr>
<td>Laboratory Visits</td>
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<td>Vital Signs</td>
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Sync 4 Science Vendor Partners

Epic

RUSH
MyChart

eClinicalWorks

Cerner

Authorization Needed

I, ZTEST, MONIQUE, (not you Sign on) request that University of Missouri Health Care (UMHC, MO - PO1) share the following health information with Pilot Prep Demo Research App.

University of Missouri Health Care (UMHC, MO - PO1) will share this information for 20 minutes.

- personal information
- intervention records
- conditions
- allergies and intolerances
- procedures

I am the authorized representative, am allowing access to the records of:

ZTEST, MONIQUE (ID 125)

Expecting different people?

Please email me a copy of this authorization.

Allscripts

FollowMyHealth™

You have given permission to TestApp to access your FollowMyHealth Account:

- Allergies
- Demographics
- Immunizations
- Results
- Medications
- Social History
- Conditions

TestApp will be allowed to view and download the following data in your FollowMyHealth account:

- Data I entered myself
Sync-4-Science Pilot Sites
Currently we have >13,000 participants enrolled at >100 sites

Through the fall and winter, will enroll ~15,000-25,000 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

Beta Phase, Leading to National Launch 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/
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
Engagement Strategy
UNDERREPRESENTED IN BIOMEDICAL RESEARCH

Building Trust

Creating Value within Communities
The Challenges Before Us

- We must **build trust** with participants and providers by being open and honest partners.

- We must **address concerns** and **seek expert advice** on issues such as:
  - Privacy and security
  - How data will be used
  - How vulnerable populations will be protected (e.g. children)
Historical Transgressions in Research

Indian Tribe Wins Fight to Limit Research

SUPAI, Ariz. — Seven years ago, the Havasupai Indians, who live amid the turquoise waterfalls and red cliffs miles deep in the Grand Canyon, issued a “banishment order” to keep Arizona State University employees from setting foot on their reservation — an ancient punishment for what they regarded as a genetic-era betrayal.

'The Baltimore Sun'

'Immortal' cells, moral issues

Case of Henrietta Lacks shows need for ethical component in health care reform

February 12, 2010 | By Ruth R. Faden

Much has been written and discussed recently about Henrietta Lacks, the African-American woman from Virginia whose cancer cells, collected for research 60 years ago — as she was being treated for the cervical cancer that took her life — inexplicably but astoundingly grew in the laboratory without end. The cells, named HeLa, have contributed to cancer therapies, the polio vaccine and a myriad of other biomedical advances.

Sadly, in 1951, tissue from patients destined exclusively for biomedical research — and not, for example, to diagnose or treat of disease — was commonly taken without their consent, stored and used by scientists.

Wellesley professor unearths a horror: Syphilis experiments in Guatemala

US apologizes for performing unethical study in 1940s

By Stephen Smith

Picking through musty files in a Pennsylvania archive, a Wellesley College professor made a heart-stopping discovery: US government scientists in the 1940s deliberately infected hundreds of Guatemalans with syphilis and gonorrhea in experiments conducted without the subjects' permission.
All of Us Research Program: Triple Engagement Strategy

Health Care Provider Organizations
- Regional medical centers
- Federally Qualified Health Center pilot sites
- Veterans Affairs medical centers

Participant Center
Scripps Research Institute leads “direct volunteer” outreach with many partners, e.g.:
- Walgreens
- Blue Cross Blue Shield Association
- National Blood Collaborative
- WebMD

NIH Engagement Partners
- Community and faith-based organizations
- Patient advocacy groups
- Provider associations
- NIH Institutes and Centers
Snapshot of Engagement Activities & Investments

Core Value
“Participants will be Partners in the Program”.

Assess, Learn and Build Engagement Capacity and Impact within a Strong Network

Activate and Integrate Trusted and Impactful Community and Provider Partners across the Nation

Optimize All of US Mobile Engagement Asset “All of Us Journey”

Elevate Participant Voices!

Develop Specific Plans for Special Population Engagement

Evaluate, Iterate and Enhance – Learn as we go!

Core Value
“Trust will be earned through robust engagement and full transparency”.

Meeting People in Their Communities
Providers Are Valued Partners

How You Can Help

- Serve as a resource to patients when they ask you about *All of Us*; help them understand the value of research and what it means for them, their families, and future generations

- Support the *All of Us* Research Program by proactively speaking with patients and with other providers about the program, its value, and goals

- Help patients who enroll to understand the data and information that the program shares with them over time

- Learn more about the program; Become a program Ambassador; Enroll
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](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.
Crowdsourcing Use Cases -- IdeaScale Webpage

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.

https://allofusresearchpriorities.ideascale.com/
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
# All of Us Consortium Members

## DV Network
(Direct Volunteers)
- Scripps Translational Science Institute
- Walgreens
- BlueCross BlueShield
- WONDROS
- DXC.technology
- patientslikeme
- WebMD
- HCM

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

### RMCs
- University of Arizona
- University of Pittsburgh
- FQHCs (Federally Qualified Health Centers)
- VA Medical Centers

### Community Partners
- Delta
- National Alliance for Hispanic Health
- Mission Health
- San Francisco General Hospital Foundation

### Communication & Engagement
- WONDROS
- HCM

### Platform Development
- Scripps Translational Science Institute
- VANDERBILT UNIVERSITY
- WONDROS
- vibrent