All of Us
RESEARCH PROGRAM

The future of health begins with you

Pre-Launch Webinar
May 2, 2018
Agenda

- Overview of the *All of Us* Research Program
- National Launch of *All of Us*
- Get Involved with *All of Us*
What Is Precision Medicine?

**Precision medicine** is an emerging approach for disease treatment and prevention that takes into account individual variability in lifestyle, environment, and biological makeup.

It is a radical shift in how each of us can receive the best care possible based on our unique characteristics.
Precision Medicine in Real Life

Right treatment for the right person --

- Prescription Eyeglasses
- Insulin Pump
- Blood Transfusions
- Hearing Aid
Why now?

We have technologies that can collect and crunch huge amounts of data.

More people are engaged in their health, and can track and share their data — like steps and sleep.

We have a greater understanding of human genes.

The time is right.
The All of Us Research Program is a historic, longitudinal effort to **gather data from one million or more people** living in the United States to **accelerate research and improve health**. By taking into account individual differences in **lifestyle, socioeconomics, environment, and biology**, researchers will uncover paths toward delivering **precision medicine** – or **individualized prevention, treatment, and care** – for all of us.

“All of Us is among the most ambitious research efforts that our nation has undertaken!”

*NIH Director Francis Collins, M.D., Ph.D.*
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
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
What is the promise for participants?

- An opportunity to help **fight disease** and improve the health of future generations.
- A chance to **learn about your own health**, including personalized risk factors or exposures.
- The ability and choice to **access your own data**, including increasingly rich health records.
- An opportunity to **ensure that your community is included** in the studies that lead to new understanding and new treatments.
- A chance to **learn about additional research opportunities** that may interest you.
- The choice to **meet others like you**, perhaps even joining some of them to propose & do research.

This is a long-term relationship and the value to participants (and researchers) will grow over time.
What is the promise for researchers?

- 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.
What is the promise for providers?

- Over time, increased scientific evidence and improved guidelines to enable precision medicine opportunities for more people and conditions:
  - Better understanding of the impact of environment and lifestyle factors on health.
  - Increased knowledge of differences in risk factors and response to treatments among diverse populations.
  - More information on the development of conditions that will allow for earlier detection.
  - Deeper understanding of different conditions that may allow for better stratification.
- Innovations that may make it easier to share electronic health records with other providers and patients.
- New knowledge to help address health disparities, increase patient engagement, and understand the usefulness of consumer health devices and apps.

Help accelerate medical breakthroughs by sharing information about All of Us with your patients!
<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
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<tbody>
<tr>
<td>How can we prevent the chronic pain that affects more than 100 million people across the U.S. each year?</td>
<td>Or develop better pain medicines that aren’t addictive? Or develop better treatments for diabetes, which affects almost 10% of Americans—or prevent diabetes altogether?</td>
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<tr>
<td>Or slow or even stop different kinds of dementia?</td>
<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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Transformational Approaches
A Transformational Approach to Diversity

Reflecting the country’s rich diversity to produce meaningful health outcomes for communities historically underrepresented in biomedical research.
UNDERREPRESENTED IN BIOMEDICAL RESEARCH

Build Trust

Create Value
A Transformational Approach to Participation

Participants in the All of Us Research Program will be true partners—not patients, not subjects—in the research process.

Involved in program development:

- What data we collect
- What lab analyses we do
- What research is conducted
- How data gets returned
A Transformational Approach to Data Access

- Data sharing will be a priority to both researchers and participants.
- Participants will have access to study information and data about themselves.
- Data collection will start small and will grow over time.
- Privacy and security will adhere to the highest standards.
- NIH will invest to level the playing field so diverse researchers can play.
How will *All of Us* lead to discoveries?

**Participants Share Data**
Participants share health data online. This data includes health surveys and electronic health records. Participants also may be asked to share physical measurements and blood and urine samples.

**Data Is Protected**
Personal information, like your name, address, and other things that easily identify participants will be removed from all data. Samples—also without any names on them—are stored in a secure biobank.

**Researchers Study Data**
In the future, approved researchers will use this data to conduct studies. By finding patterns in the data, they may make the next big medical breakthroughs.

**Participants Get Information**
Participants will get information back about the data they provide, which may help them learn more about their health.

**Researchers Share Discoveries**
Research may help in many ways. It may help find the best ways for people to stay healthy. It may also help create better tests and find the treatments that will work best for different people.
The Importance of Diversity
Program Infrastructure
Enrolling in *All of Us*
### All of Us Research Program Infrastructure

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
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<tr>
<td><strong>DATA AND RESEARCH CENTER</strong></td>
<td>Big data capture, cleaning, curation, &amp; sharing in secure environment</td>
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<td></td>
<td><em>Vanderbilt, Verily, Broad Institute</em></td>
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<td><strong>BIOBANK</strong></td>
<td>Repository for processing, storing, and sharing biosamples (35+M vials)</td>
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<td><em>Mayo Clinic</em></td>
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<td><strong>PARTICIPANT TECHNOLOGY SYSTEMS CENTER</strong></td>
<td>Web and phone-based platforms for participants</td>
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<td><em>Vibrent Health</em></td>
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<tr>
<td><strong>PARTICIPANT CENTER / DV NETWORK</strong></td>
<td>Direct volunteer participant enrollment, digital engagement innovation, and consumer health technologies</td>
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<td><em>Scripps Research Institute</em> (with multiple partners)*</td>
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<tr>
<td><strong>HEALTHCARE PROVIDER ORGS NETWORK</strong></td>
<td>HPOs with clinical &amp; scientific expertise, enrollment &amp; retention of participants</td>
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<td><em>30+ regional medical centers, FQHCs, VA, and future awards to grow network</em></td>
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<tr>
<td><strong>COMMUNICATIONS &amp; COMMUNITY NETWORK</strong></td>
<td>Communications, marketing, and design expertise; engagement coordination and community partners network</td>
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<td><em>Wondros, HCM, 29 community partner organizations, and future awards to grow network</em></td>
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All of Us Consortium Members

DV Network
(Direct Volunteers)

HPO Network
(Health Care Provider Organizations)

RMCs
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

All of Us, Wisconsin

University of Arizona

University of Pittsburgh

FQHCs (Federally Qualified Health Centers)

VA Medical Centers

Communication & Engagement

Platform Development
Potential Activities Asked of Participants (Protocol V1)

- Enroll, Consent & 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

*Based on diverse sampling and capacity

Pilots under development: richer EHR data, health apps, fitness wearables, and return of genetic info
Approach to Privacy and Security

- Guided by privacy, trust, and data security principles developed by experts with input from the public.
- Data warehouse is built with the most advanced security available.
- Experts have done and will continue to do rigorous security testing.
- Data is encrypted and direct identifiers are removed.
- Researchers must agree to a code of conduct before accessing the data.
- Participants’ preferences will be respected.
- Protected by a Certificate of Confidentiality.
- Committed to transparency in the event of a data breach.

Safeguarding your identity and data to the best of anyone’s abilities is our most important responsibility.
Next Steps for *All of Us*
Since July 2016…

- Developed and updated protocol
- Completed a successful beta test with real participants, tools, and data
- Built robust network of 100+ academic, provider, technology, and community partners
- Launched 125+ clinics to enroll participants, with plans to expand to additional states and locations
- Developed participant-friendly and bilingual (English/Spanish) enrollment website, participant portal, app, and call center
- Built biobank and 24-hour shipping process with capacity for 35M+ vials
- Developed data warehouse with infrastructure to collect, clean, curate, de-identify, and eventually share the data
- Completed end-to-end security and usability testing
- Developed innovative pilots for testing electronic health record and wearables strategies
- Created interactive mobile exhibit that travels the country
- Development of the Research Portal is underway; expected to be open with initial public dataset in 2019
Invited a broad array of stakeholders, including researchers, participants, professional societies, & advocacy groups to the Workshop in Bethesda, MD on March 21-23, 2018

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

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

All of Us team is currently reviewing & synthesizing the data we gathered

Will have additional opportunities to submit use cases & requirements
National Launch: May 6, 2018

THE FUTURE OF HEALTH IS COMING. JOIN US.

Join us for the official launch of the *All of Us* Research Program. Help us advance precision medicine.

Watch live on Sunday, May 6, 2018.

SPEAKERS INCLUDE

Francis Collins, M.D., Ph.D.
Dara Richardson-Heron, M.D.
Eric Dishman

WATCH OUR WELCOME VIDEO

Community Artwork for All Of Us by Ariel Wilson, San Diego, CA

How Can You Take Part in the Event?
Get Involved with *All of Us*
Learn More about All of Us

JoinAllofUs.org

@AllofUsResearch
#JoinAllofUs
The future of health begins with you.

The All of Us Research Program has a simple mission. We want to speed up health research breakthroughs. To do this, we’re asking one million people to share health information. In the future, researchers can use this to conduct thousands of health studies.

JOIN NOW
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National Launch: May 6, 2018

Seven sites host half-day, simulcasted events that include:

- **Speakers program:**
  - One-hour livestreamed program at all sites
  - Representative of local community – participants, cultural performances, luminaries
  - Dr. Francis Collins, Eric Dishman, Dr. Dara Richardson-Heron at two sites, remarks simulcasted live

- **Community educational fair:**
  - Interactive AOU booth - engage with program staff, begin digital enrollment, branded giveaways
  - Local vendors: farmer’s market, cooking demonstration, health screenings

- **Art activation:**
  - One local artist at each site creates interactive, collaborative community portrait

The simulcasted events will be supported by:

- **Facebook Live speakers program:** produced like broadcast television, to occur before streaming of simulcasted sites
- **Community events:** organized by many NIH champions, AOU consortium members, advocates, etc.
- **National & local print, broadcast, and social media strategy**
Engaging at Launch and Beyond

- Post program information on your organization’s social media channels
- Follow *All of Us* on social media (Twitter, Facebook, YouTube and Instagram) and share program content; use the hashtag #JoinAllOfUs
- Include information about *All of Us* in a weekly or monthly digital newsletter
- Write and post a blog about the importance and value of *All of Us*
- Host an in-person community event or conference call/webinar with network or partners
- Distribute *All of Us* info flyers, posters, etc. at a meeting, conference, or event
- Promote the national launch online experience including the live webcast
- Share a recap about the national launch in digital or print newsletters
Twitter Accounts to Follow

We suggest following the below accounts, in addition to other *All of Us* consortium member accounts, to keep you in the know on the *All of Us* Research Program.

<table>
<thead>
<tr>
<th>Person/Organization</th>
<th>Twitter Handle</th>
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<tbody>
<tr>
<td><em>All of Us</em> Research Program</td>
<td>@AllofUsResearch</td>
</tr>
<tr>
<td>Eric Dishman</td>
<td>@EricDishman</td>
</tr>
<tr>
<td>Francis Collins</td>
<td>@NIHDirector</td>
</tr>
<tr>
<td>NIH</td>
<td>@NIH</td>
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Community Resources (JoinAllofUs.org)

Community Resources

The All of Us Research Program offers free downloadable materials to help community members spread the word about the program.

For questions about these resources or how to use them, please contact AllofUsEngagement@nih.gov.

Downloadable PDFs

Videos

How All of Us Helps Research (1:54)
What is All of Us? (1:56)
Spanish language version available
THANK YOU!

Questions/Share Ideas:
Lydia_Kuykendal@hcmstrategists.com