An Introduction to the

All of Us Research Program

Presented on 4/25/2019

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Precision medicine is an emerging approach for disease treatment and prevention that takes into account individual variability in lifestyle, socioeconomics, environment, and biology. It is a radical shift in how each of us can receive the best care possible based on our unique makeup.
Precision Medicine in Real Life

Right treatment for the right person --

- Prescription Eyeglasses
- Insulin Pump
- Blood Transfusions
- Hearing Aid
The Cost of Imprecise Medicine

Patients
- Health care is often targeted to the average patient, not the individual
- Health problems can take years to unravel, with significant trial and error

Providers
- Not enough research to draw on for clinical evidence, especially in diverse populations
- Medical records scattered in different places
- Not enough time for analysis one patient at a time

Researchers
- Enormous time and cost spent building IT systems vs. doing research
- Siloed data resources and funding opportunities
- Challenges acquiring large sample sizes
- Slow translation of data into knowledge
The future of health begins with you.
What is *All of Us*?
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.*
Kinds of Questions this Resource May Help Answer

How can we prevent the chronic pain that affects more than 100 million people across the U.S. each year?

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?

Or slow or even stop different kinds of dementia?

Or develop more cancer cures that will work the first time, so we can skip painful trial-and-error chemotherapy?
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,
ensuring individualized
prevention, treatment,
and care for all of us

Catalyze a 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
All of Us Research Program Values

1. Participation is open to all.
2. Participants reflect the rich diversity of the U.S.
3. Participants are partners
4. Trust will be earned through transparency.
5. Participants will have access to their information.
6. Data will be accessed broadly for research purposes.
7. Security and privacy will be of highest importance.
8. The program will be a catalyst for positive change in research.
A Transformational Approach to Diversity

Reflecting the country’s rich diversity to produce meaningful health outcomes for communities historically underrepresented in biomedical research.
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 every step of 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
Approaching Value and Building Trust
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!
Minorities make up **38%** of the US population.

Minority populations to rise to over **56%** of overall population.

Underrepresented in biomedical research populations include ethnic minorities, as well as age, sex, gender, orientation, income, education, geography, access to care and disability.

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**African American population = 13.2% of US population**
- 5% of clinical trial participants nationwide

**Hispanic population = 17% of US population**
- 7.6% of NIH clinical trial participants
- 1% of clinical trial participants nationwide

**Asian American, Native Hawaiian, & Pacific Islander population = 5.6% of US population**
- One of the most understudied of all racial/ethnic groups
UNDERREPRESENTED IN BIOMEDICAL RESEARCH

Build Trust

Create Value within Communities
Coming Together

[Video Insert: Importance of Diversity]

[https://www.youtube.com/watch?v=XyJ6r4ZhGII]
These are my children Paul, Anne, and Daniel.
Program Building Blocks & Enrolling in *All of Us*
# 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, 29 community partner organizations, and future awards to grow network
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

DV Network

HPO Network
Community and Provider Partner Network
Enrolling in *All of Us*

DIRECT VOLUNTEERS

HEALTH CARE PROVIDER ORGANIZATIONS
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
Potential Activities Asked of Participants

**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

**Pilots under development:** richer EHR data, health apps, fitness wearables, and return of genetic info
Survey Modules

Enrollment Surveys

• The Basics
• Overall Health
• Lifestyle
• Family History
• Health Care Access and Utilization

Coming Soon

• Personal Health History
• Disability
• Pain
• Medications
• Diet
• Social Determinants of Health
• Physical activity
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
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

As of March 2019:
- 190,000 individuals have signed up
- 115,000 have completed the enrollment process
835,000. # Samples Biobank
490,000 # on online surveys
    - 75 percent are from groups often underrepresented in modern medical research, and 50 percent are from racial and ethnic minorities

We need All of Us to reach the goal of One Million! JoinAllofUs.org/together
Learn More

JoinAllofUs.org/together

@AllofUsResearch
#JoinAllofUs

Precision Medicine Initiative, PMI, All of Us, the All of Us logo, and “The Future of Health Begins with You” are service marks of the U.S. Department of Health and Human Services.
Questions

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