

An Introduction to the

# *All of Us* Research Program



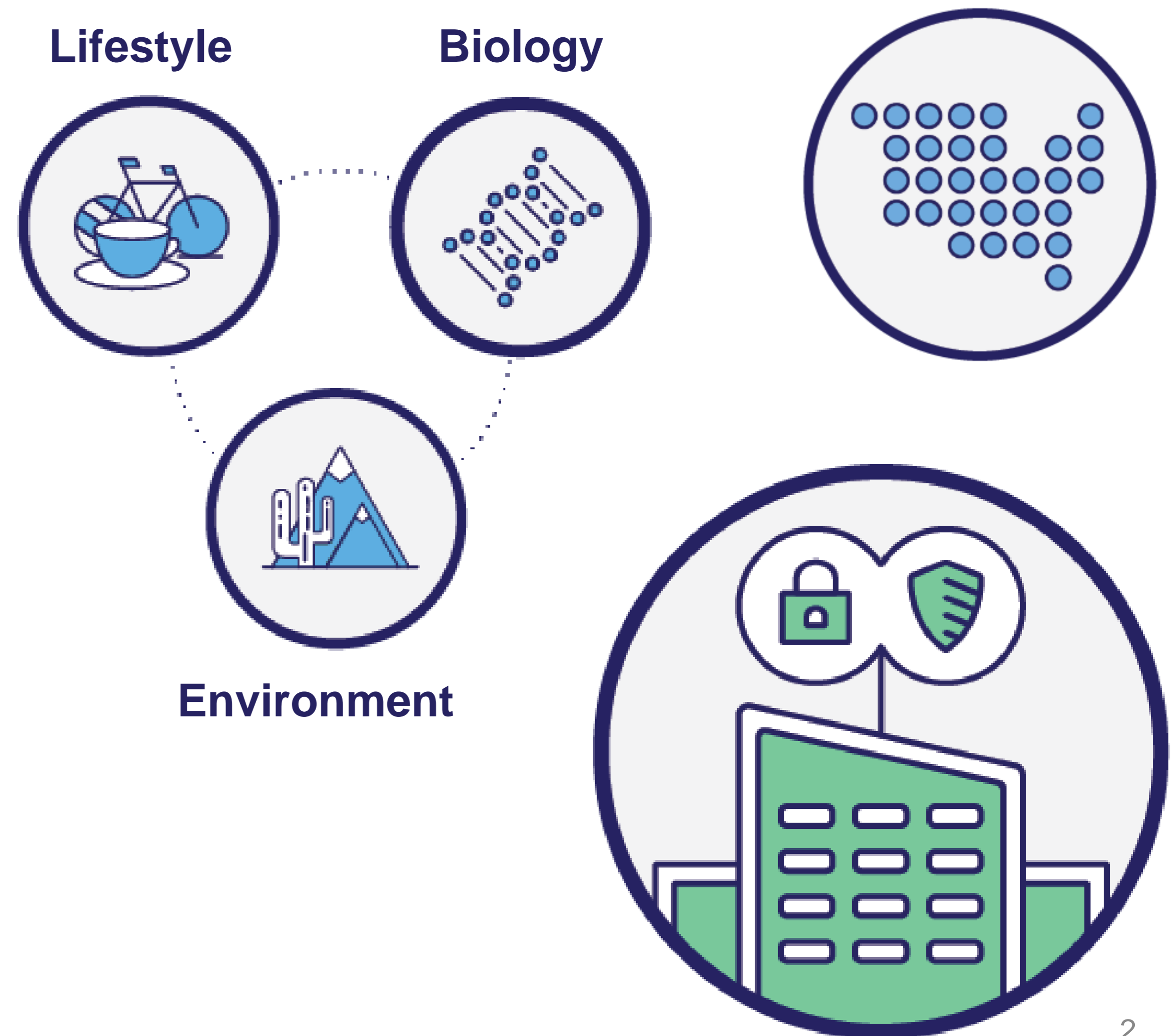
National Institutes  
of Health

Presented on March 18, 2018

# What is precision medicine?

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

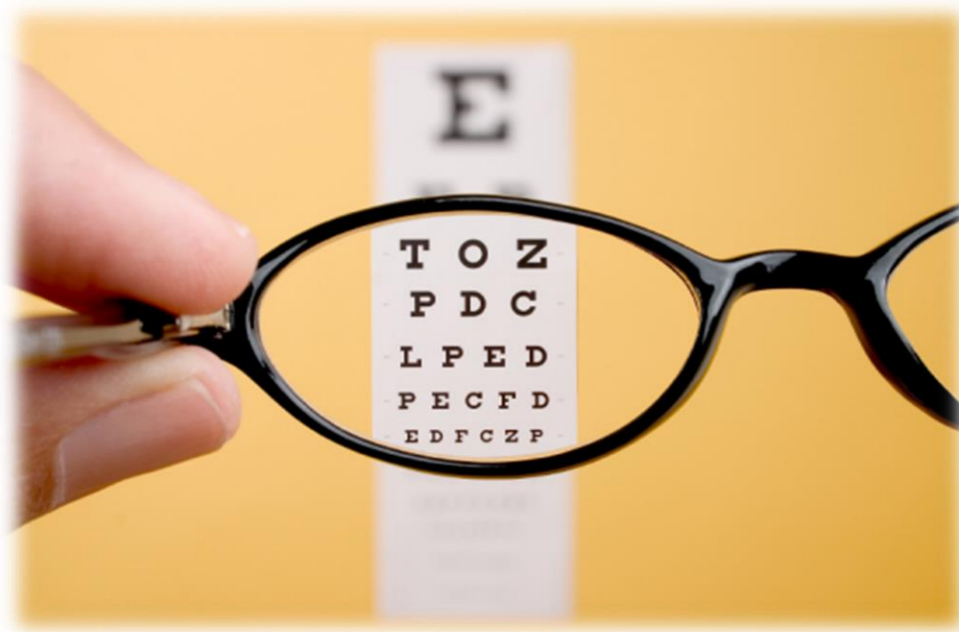
It is a radical shift in how each of us can receive the best care possible based on our unique makeup.



# Examples of Precision Medicine

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Right treatment for the right person --



Prescription  
Eyeglasses



Insulin Pump



Blood  
Transfusions



Hearing Aid

# The Cost of Imprecise Medicine

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## 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

**All of Us**  
RESEARCH PROGRAM

**The future  
of health  
begins  
with you**



# What is the NIH *All of Us* Research Program?

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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.***

# All of Us Mission and Objectives

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## 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 a robust ecosystem

of researchers and funders hungry to use and support it



# *All of Us Values*

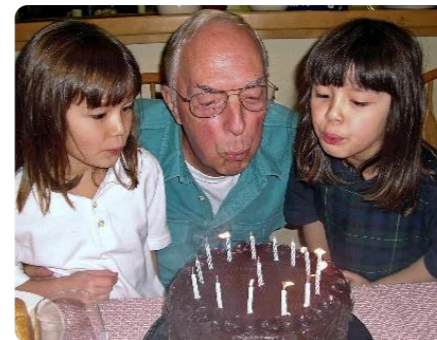
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- Participation in the *All of Us* Research Program will be **open** to interested individuals
- The program will reflect the rich **diversity** of America
- Participants will be **partners** in the program
- Trust will be earned through robust **engagement** 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



# 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

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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:

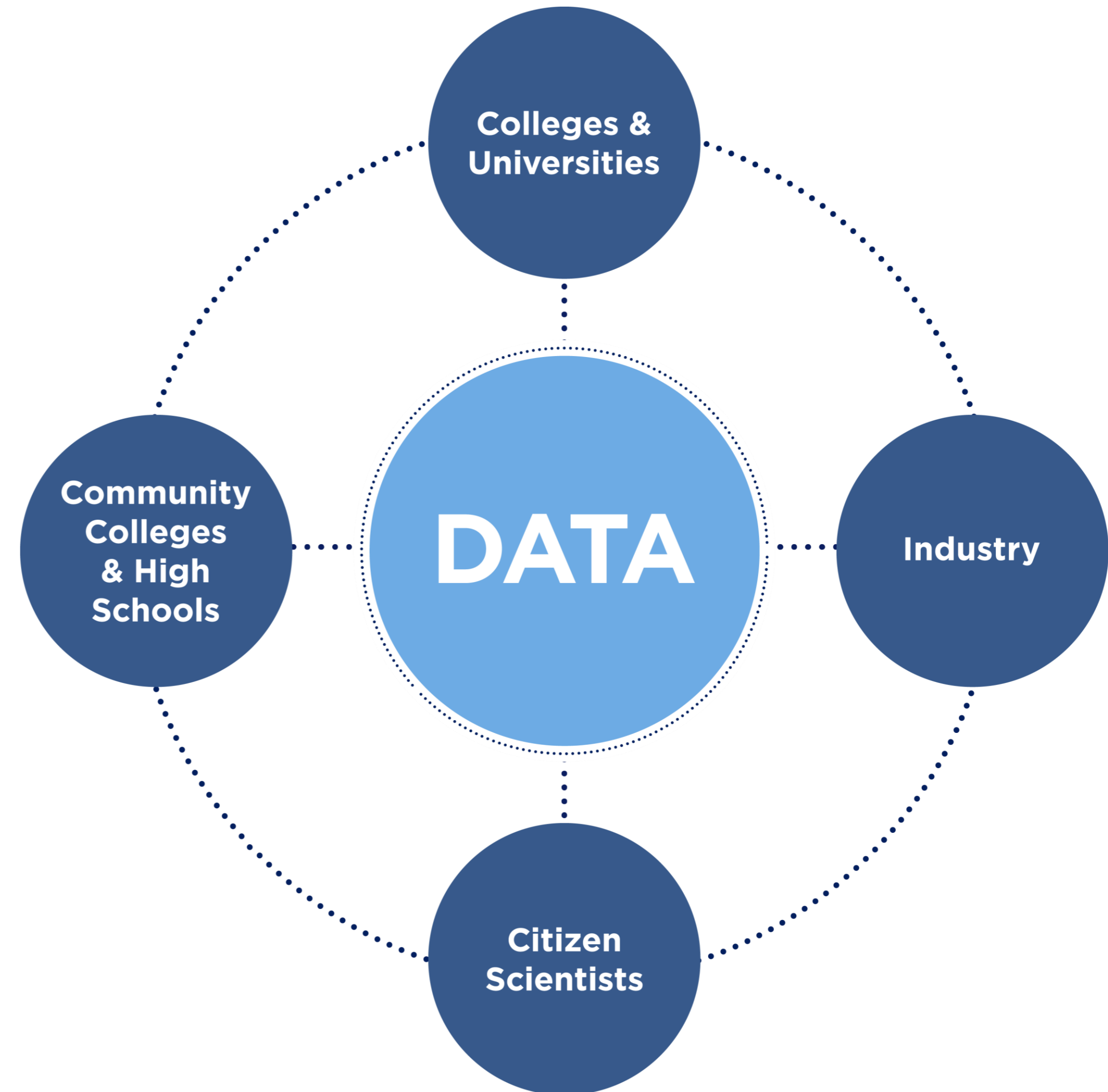
- What data we collect
- What lab analyses we do
- What research is conducted
- How data gets returned



# A Transformational Approach to **Data Access**

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- ⦿ 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

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# UNDERREPRESENTED IN BIOMEDICAL RESEARCH

## Build Trust

## Create Value within Communities



# What is the promise for participants?

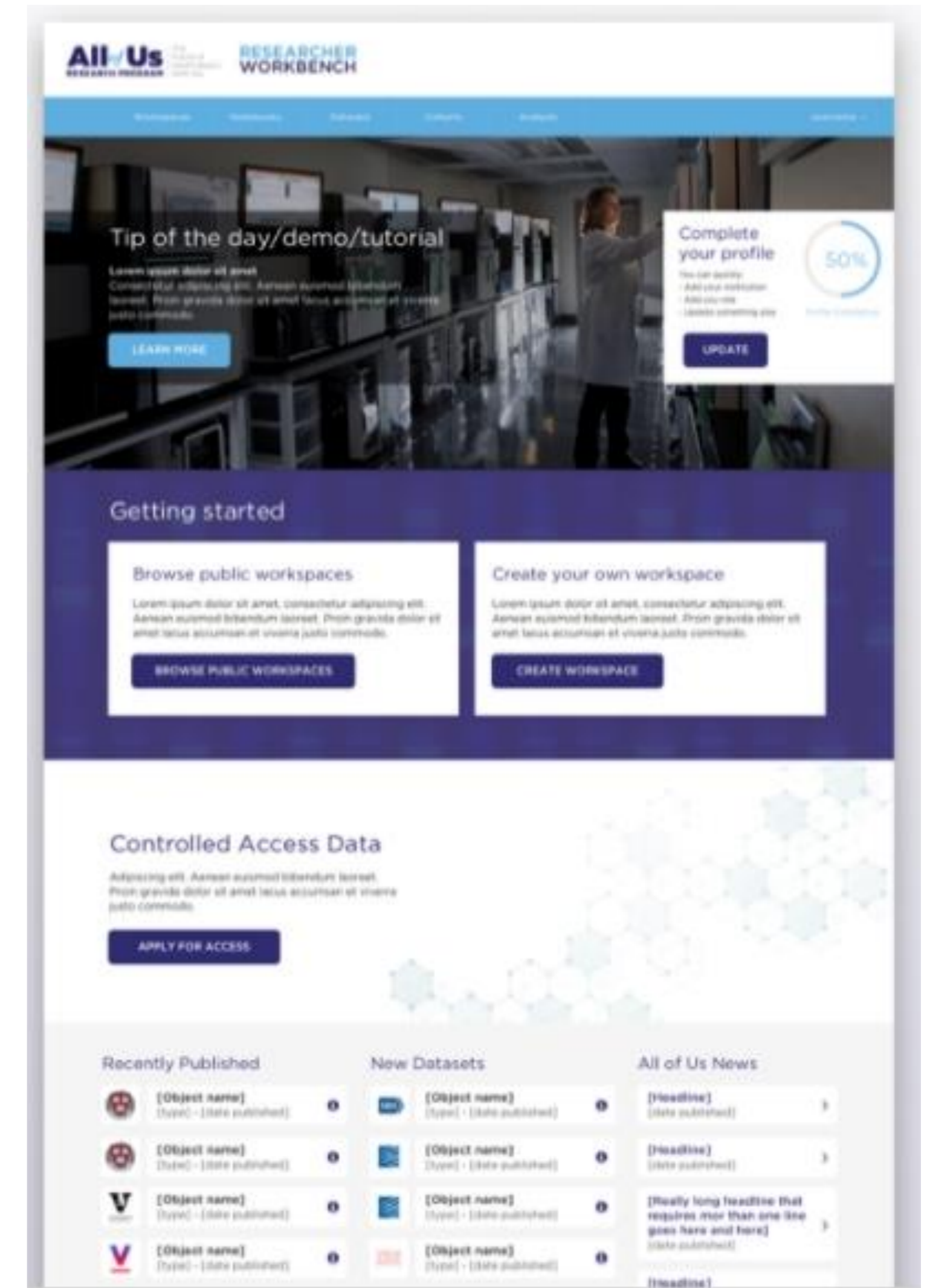
- An opportunity to help **fight disease** and improve the health of future generations.
- A chance to **learn about your own health**, including personalized risk factors or exposures.
- The ability and choice to **access your own data**, including increasingly rich health records.
- An opportunity 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?

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- ◎ 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!



# Program Building Blocks & Enrolling in *All of Us*

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# The *All of Us* Research Program Consortium

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## 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*

# National Network of Inaugural Partners

**National Partners**

**Regional Medical Centers**

**FQHCs**



# All of Us Consortium Members

## DV Network (Direct Volunteers)



Biobank



## 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

UC San Diego Health



All of Us, Wisconsin

University of Arizona

University of Pittsburgh

FQHCs (Federally Qualified Health Centers)

VA Medical Centers



## Communication & Engagement

WONDROS



## Platform Development



WONDROS



# Community and Provider Partner Network



# Enrolling in *All of Us*

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**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

▶ WATCH INTRODUCTION



EXPLORE OUR TOUR ACROSS AMERICA ▶



ATTEND LAUNCH EVENTS IN PERSON OR ONLINE ▶



WATCH DIRECTOR ERIC DISHMAN SHARE PROGRAM UPDATES ▶

Have Feedback?

# 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

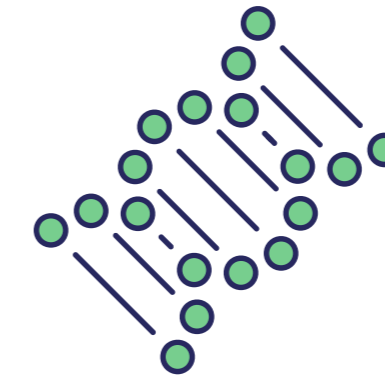
- Three initial surveys: The Basics, Overall Health, & Personal Habits
- Additional surveys will be released on an ongoing basis.



## Physical Measurements\*

- Blood pressure
- BMI
- Heart rate
- Height
- Hip circumference
- Waist circumference
- Weight

*\*Based on diverse sampling and capacity*



## Provide Biosamples\*

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

*\*Based on diverse sampling and capacity*



## 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

*Coming soon*



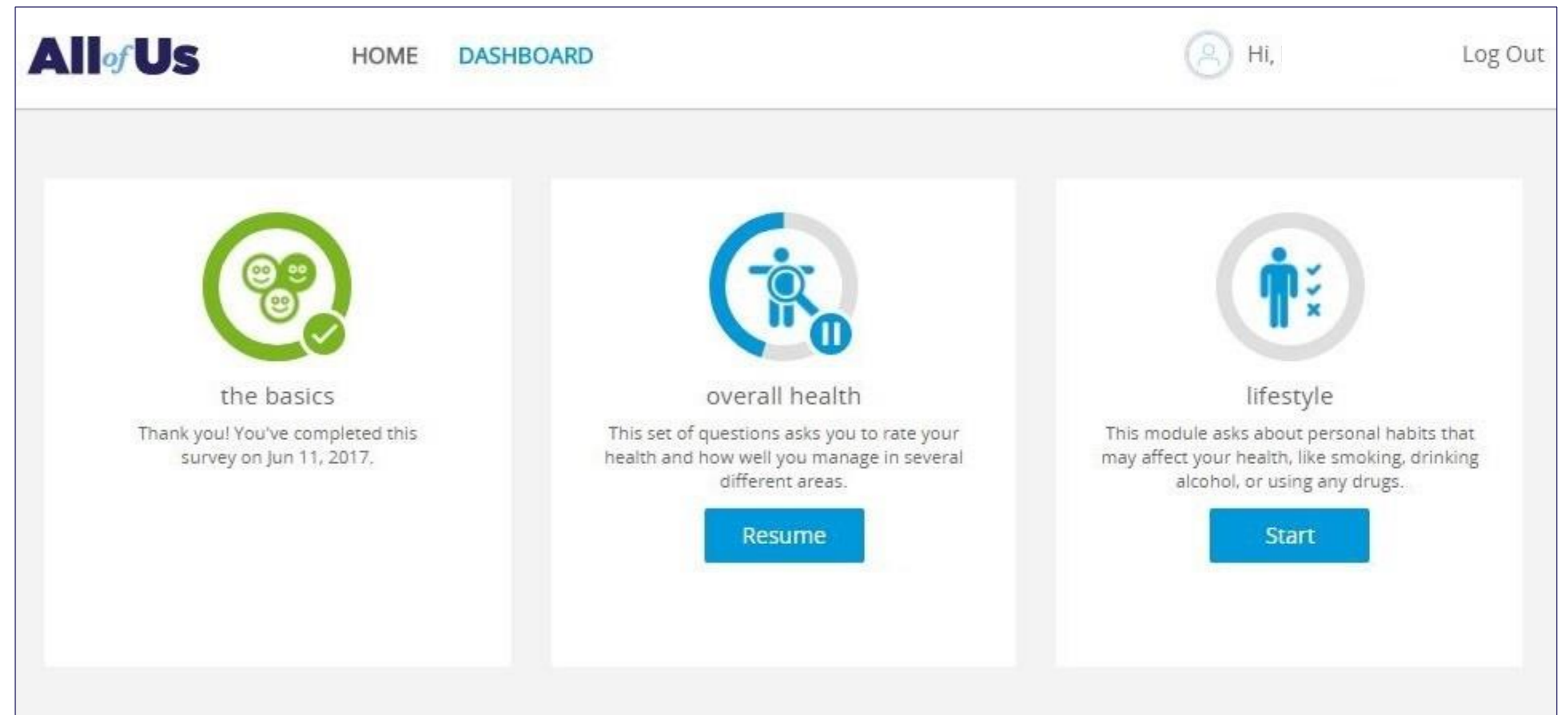
# Current Survey Modules

## Enrollment Surveys

1. The Basics
2. Overall Health
3. Lifestyle

## Coming Soon

4. Personal Health History
5. Family History
6. Health Care Access and Utilization



# Program activities of interest to the Disability community

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## 1. Data Collection

### *Participant Provided Information (PPI) Committee:*

- Tasked with developing surveys for participants to complete
- Disability Task Force recently created for new survey module
- Staffed by consortium members but ability for outside experts to provide information

## 2. Enrollment/Consent

### *Special Populations Committee:*

- Tasked with developing a plan and recommendations for enrollment of decisionally impaired individuals
- Will begin work after plan for enrollment of children complete and protocol approved by IRB (2019)

# Approach to Privacy and Security

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- 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.**

## Learn More

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[JoinAllofUs.org](https://JoinAllofUs.org)



**@AllofUsResearch**  
**#JoinAllofUs**

# Questions?

Ronnie Tepp

[ronnie\\_tepp@hcmstrategists.com](mailto:ronnie_tepp@hcmstrategists.com)



National Institutes  
of Health