

Overview of the *All of Us* Research Program

The *All of Us* Research Program

- ⦿ The cornerstone of the larger PMI – led by the NIH
- ⦿ One million or more volunteers, reflecting the broad diversity of the U.S.
- ⦿ Opportunities for volunteers to provide data on an ongoing basis
- ⦿ Data will inform a variety of research studies



All of Us Mission and Objectives

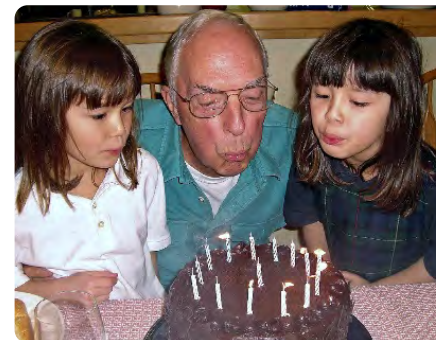
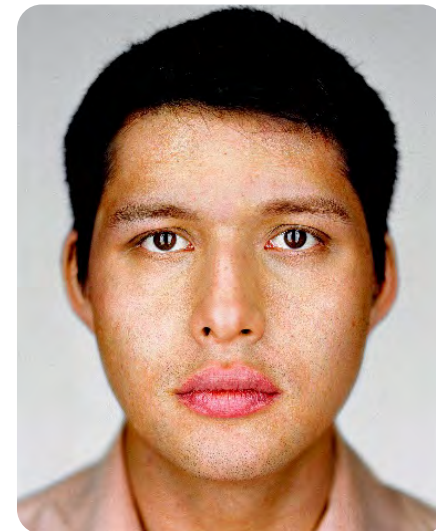


All of Us Values

- ⦿ 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.



Biomedical Research and Minority Communities

The New York Times

U.S.

WORLD

U.S.

N.Y. / REGION

BUSINESS

TECHNOLOGY

SCIENCE

HEALTH

SPORTS

OPINION

POLITICS

EDUCATION

BAY AREA

CHICAGO

Indian Tribe Wins Fight to Limit Research



Edmond Tilousi, 56, who can climb the eight miles to the rim of the Grand Canyon in three hours. [More Photos »](#)

By AMY HARMON
Published: April 21, 2010

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](#) disease — was commonly taken without their consent, stored and used by scientists.

The New York Times

Syphilis Victims in U.S. Study Went Untreated for 40 Years

JEAN HELLER
Associated Press

For public health officials, who have serious doubts about the morality of the study, also say that it is too late to treat the syphilis in any surviving participants.

Doctors in the service say they are now rendering whatever other medical services they can give to the survivors while the study of the disease's effects continues.

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The Boston Globe

Wellesley professor unearths a horror: Syphilis experiments in Guatemala

US apologizes for performing unethical study in 1940s

By Stephen Smith
Globe Staff / October 2, 2010

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.

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CONFRONTING INJUSTICE



Engaging new communities
in research is starting at
less than zero.

The value proposition won't sell itself – FOR GOOD REASON.

ENGAGING PEOPLE

At its heart, the *All of Us* Research Program is about engaging *ALL* people.



Success will be defined by **AUTHENTIC** engagement.

Minorities make up
38%
of the US population.

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

Minority enrollment in clinical trials?
>10%

VALUE TO PARTICIPANTS

African American population = 13.3% 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

***UBR populations include ethnic minorities, as well as age, sex, gender, orientation, income, education, geography, access to care and disability.**

POTENTIAL IMPROVEMENT IN MINORITY HEALTH

Health disparities are well known – NOT well understood.

- Why do African-Americans have a higher mortality rate from chronic diseases, including Alzheimer's, diabetes, and heart disease?
- Why is stroke more common among rural communities?
- Why is Hepatitis B more common in the Asian and Pacific Islander population?

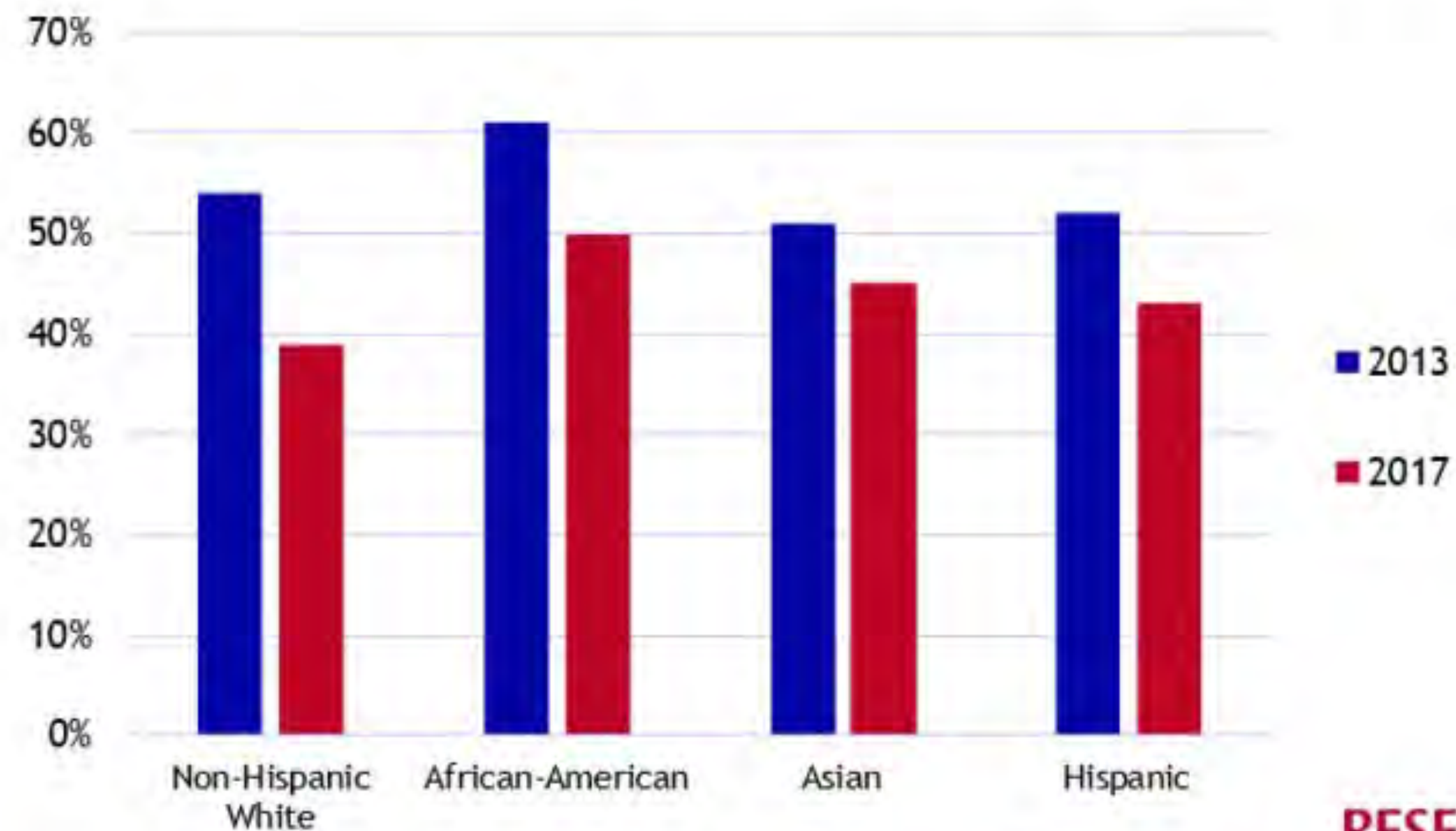
Precision medicine asks us to look even beyond racial or ethnic group and into unique biological information to determine likelihood of developing and dying from disease.

But we can only determine these genetic variations if we increase minority participation in research—then, we will be able to speed treatments and cures for the conditions and diseases that afflict minority populations the most.

Barriers are Decreasing

Lack of Trust Less of a Barrier to Clinical Trial Participation

Fewer than 10% of Americans participate in clinical trials. Which of the following do you think is a reason that individuals don't participate in clinical trials? (percentage saying lack of trust)



The Value of Participating in *All of Us*

- ⦿ **An opportunity to learn** some of your own health indicators and get your own data
- ⦿ An opportunity to **fight disease** and improve the health of future generations
- ⦿ The opportunity to **ensure that your community is included** in the studies that may lead to new understanding and new treatments
- ⦿ The opportunity to **be part of a movement** to make our health care more precise, more personal, and more effective



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.

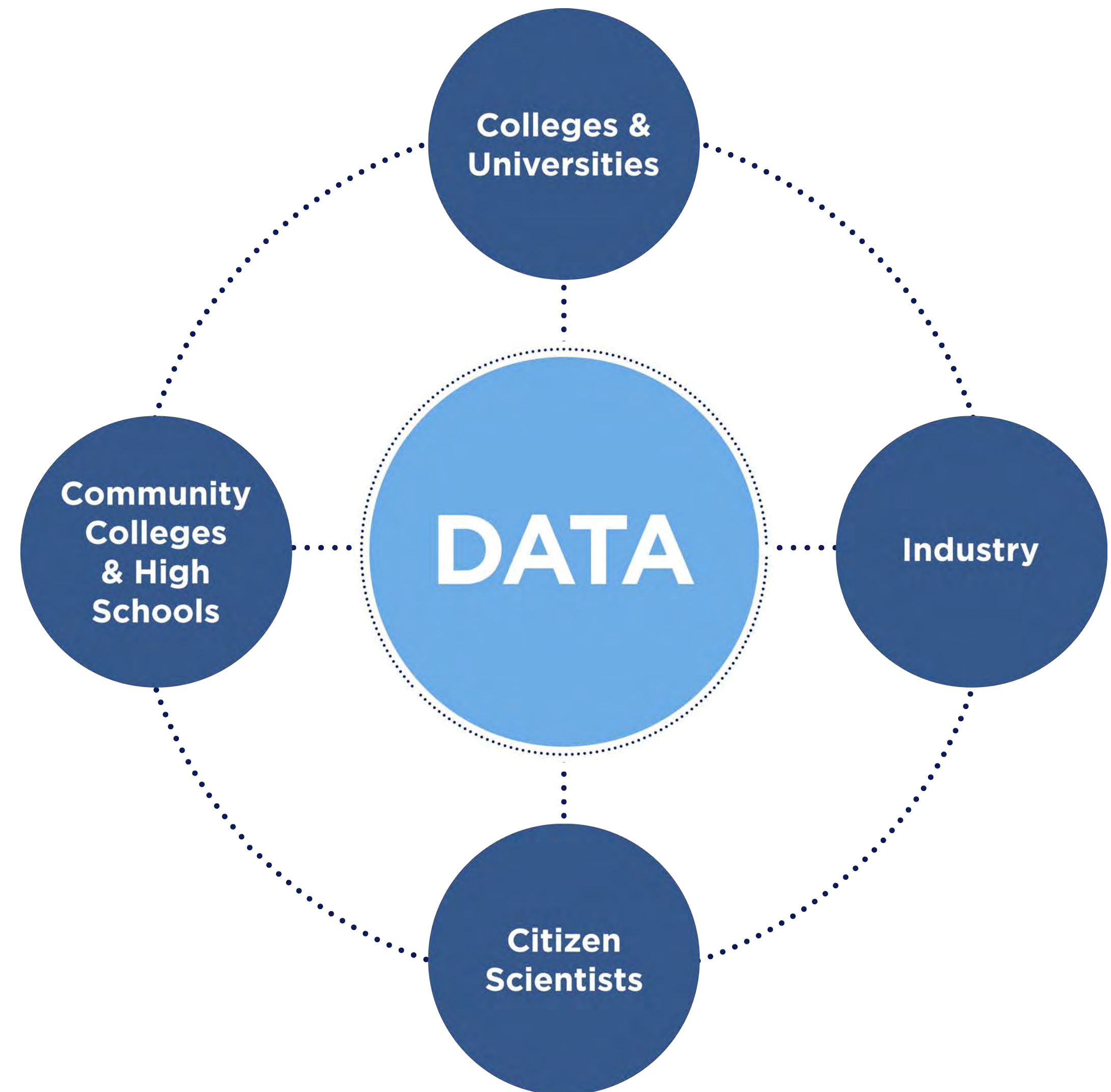
Involved in every step of program development:

- 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



All of Us Research Program Data

The program will start by collecting a limited set of standardized data from sources that will include:

- Participant surveys
- Electronic health records
- Physical measurements
- Biosamples (blood and urine samples)
- Mobile/wearable technologies
- Geospatial/environmental data

Data types will grow and evolve with science, technology, and trust.



Survey Shows Broad Support

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



Selected Scientific Opportunities

- ⦿ Develop quantitative **estimates of risk** for a range of diseases by integrating environmental exposures and genetic factors
- ⦿ Identify the causes of individual variation in response to commonly used therapeutics = **pharmacogenomics**
- ⦿ Discover **biological markers** that signal increased or decreased risk of developing common diseases
- ⦿ Develop **solutions to health disparities**
- ⦿ Use **mobile health technologies** to correlate activity, physiological measures, and environmental exposures with health outcomes
- ⦿ **Empower study participants** with data and information to improve their own health
- ⦿ Create a platform to enable **trials of targeted therapies**



Two Methods of Enrollment



DIRECT VOLUNTEERS



**HEALTH CARE PROVIDER
ORGANIZATIONS**