

*Improving the Evidence Base to
Advance Health Equity*

All of Us Research Program

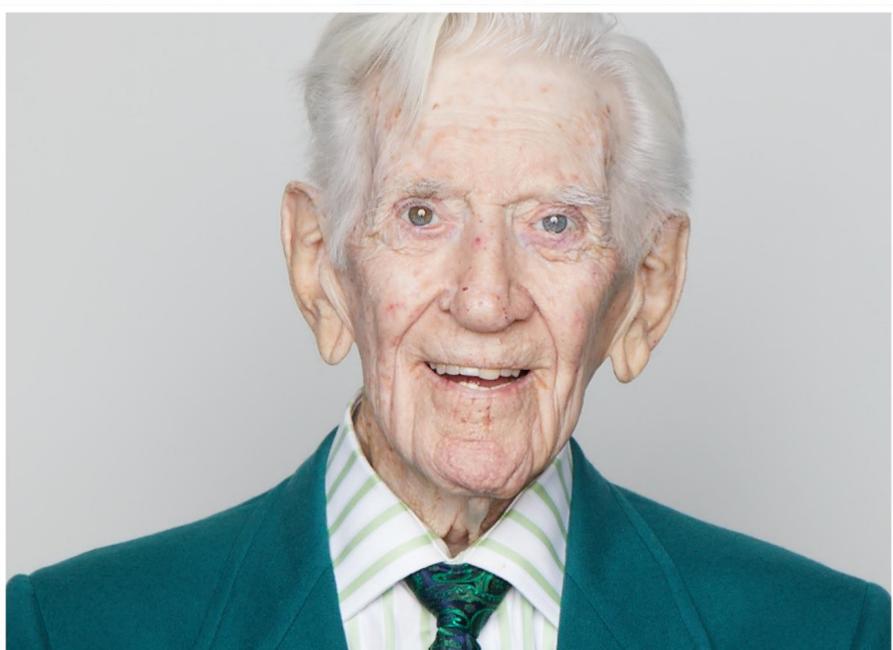


National Institutes
of Health

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All of Us
RESEARCH PROGRAM



**precision medicine:
the right treatment
for the right person
at the right time**

The *All of Us* Research Program

- The cornerstone of the larger Precision Medicine Initiative – 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

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 Research Program Core 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.

What is the promise for participants?

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



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

**the program will reflect the rich diversity of
the United States.**

Minorities make up
38%
of the US population.

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

Minority enrollment in clinical trials
<10%

underrepresentation in biomedical research populations includes dimensions of race and ethnicity, as well as age, sex, gender, orientation, income, education, geography, access to care, and disability.

History of 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 of Its DNA



Jim Wilson/The New York Times

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
The Associated Press

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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

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

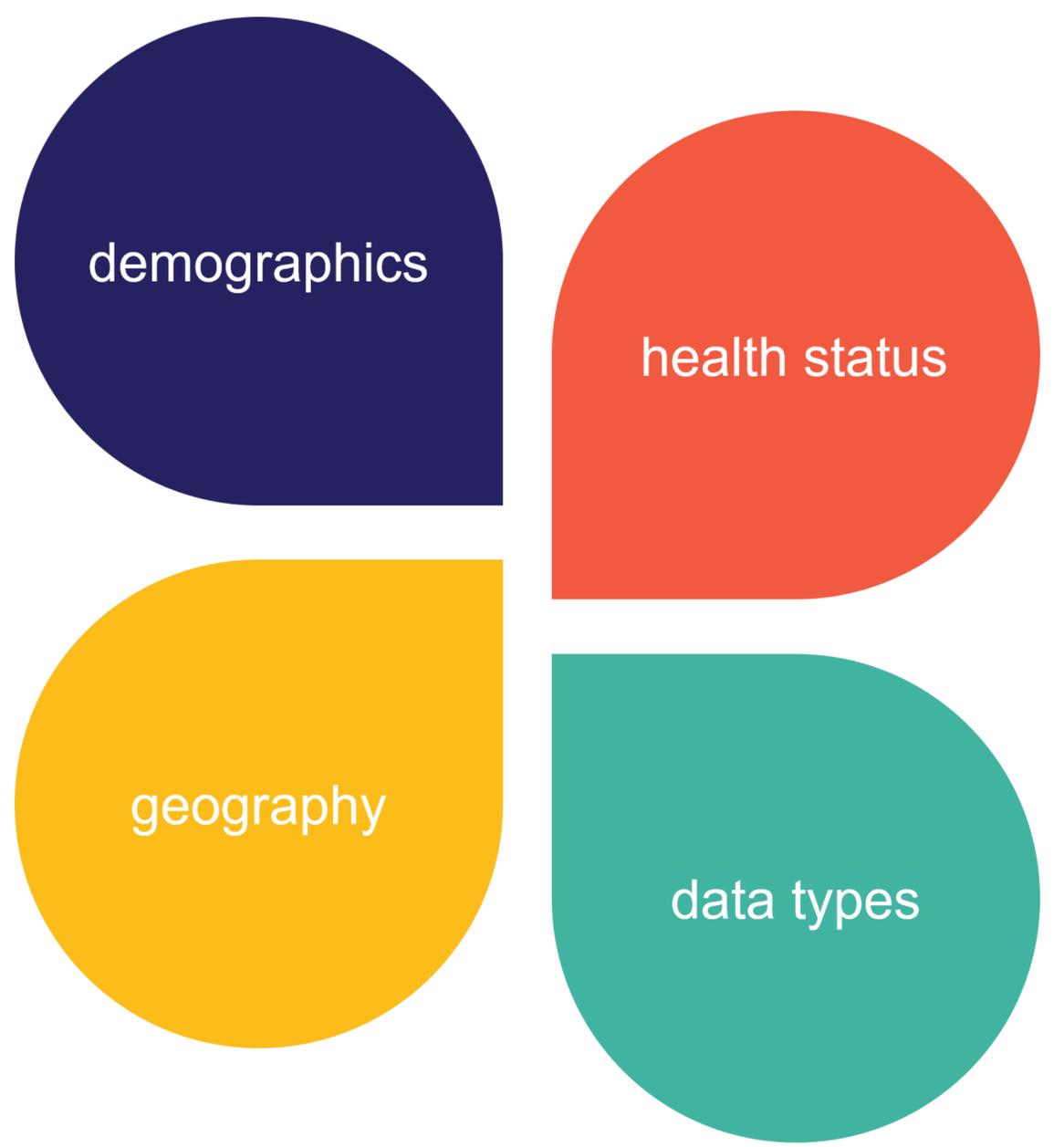
Picking through musty files in a Pennsylvania archive, a Wellesley College professor made a heart-stopping discovery: US government scientists in the 1940s deliberately infected hundreds of Guatemalans with syphilis and gonorrhea in experiments conducted without the subjects' permission.

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The *All of Us* Approach to Diversity

Reflecting the country's rich diversity to produce meaningful health outcomes for communities historically underrepresented in biomedical research.

- Develop a **national network of Health Care Provider Organizations (HPOs)** with incentives & methods to reach most diverse people & places
- Create **an innovative network of Direct Volunteer partners** to reach 90%+ where all people live, within 20-45 minutes
- Build a **network of national & local Community Partners** to help build lifelong, trusted relationships with key communities & areas in the country
- Drive programs that **ease the way** for diverse communities to participate



demographics

health status

geography

data types

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 are fibroids more prevalent in African American women?
- 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.

All of Us Participant Partners



**Registered
participants**
165,000+



**Core
participants**
95,000+



**% participants
underrepresented
in biomedical research**
75%

build trust • create value



participants are partners in the program.

The *All of Us* Approach to Participation

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



Landmark NIH Study Hopes to Enroll 1 Million Americans



MIRIAM GUZMAN: "I have a long family history of diabetes, and I thought that maybe there's information in my genes that could be relevant."



US Seeking 1 Million for Massive Study of DNA, Health Habits

U.S. researchers are seeking 1 million volunteers to share their DNA and health habits for science.

MICHELLE McNEELY: "If they can use my genes and someone's genes in California and someone's genes in New York to find some common ground, to help discover some cure – they can use my genes all day long."

**trust will be earned through
robust engagement and full transparency.**

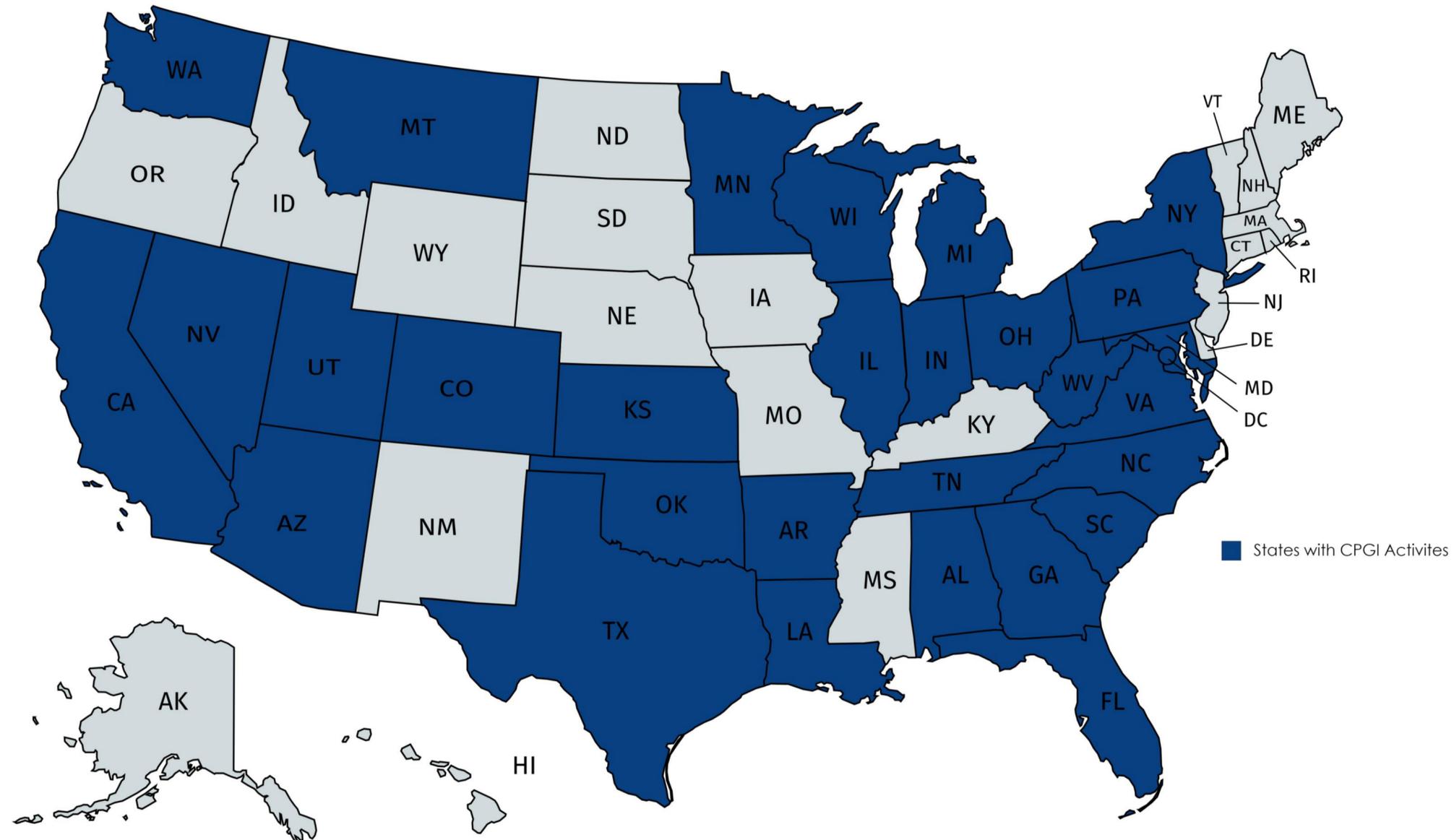
Leveraging trusted intermediaries to both speak for and relay information to diverse communities

Community and Provider Partner Network



Community Partner Engagement Activities

Community and provider partners have conducted a total of **273 activities** across **30 states** reaching **more than 2.6 million*** potential participants.



* Estimate is low as in early stages of collecting Phase 2 metrics.

Community Partners In Action



**trust will be earned through
robust engagement and full transparency.**

Meeting people where they are

The *All of Us* Journey



- A hands-on experience to build awareness and excitement
- Opportunity to enroll
- Supported by trained staff
- Since August 2017, visited 32 states (and DC), over 80 cities, and has been to over 230 events
- Since October 2018, a 2nd Journey bus equipped with a waiting area and private rooms for physical measurement and biospecimen collection



**trust will be earned through
robust engagement and full transparency.**

Providing clear, comprehensive, and convenient resources

Landmark Effort to Advance Precision Medicine

National Library of Medicine



**trust will be earned through
robust engagement and full transparency.**

Listening and being responsive to input

**participants will have access to
their information.**

Return of Information

● Individual and Comparative Information

- Survey data
- EHR data, claims data
- Assays, including genomics

● Study Results

- Aggregated results
- Scientific findings

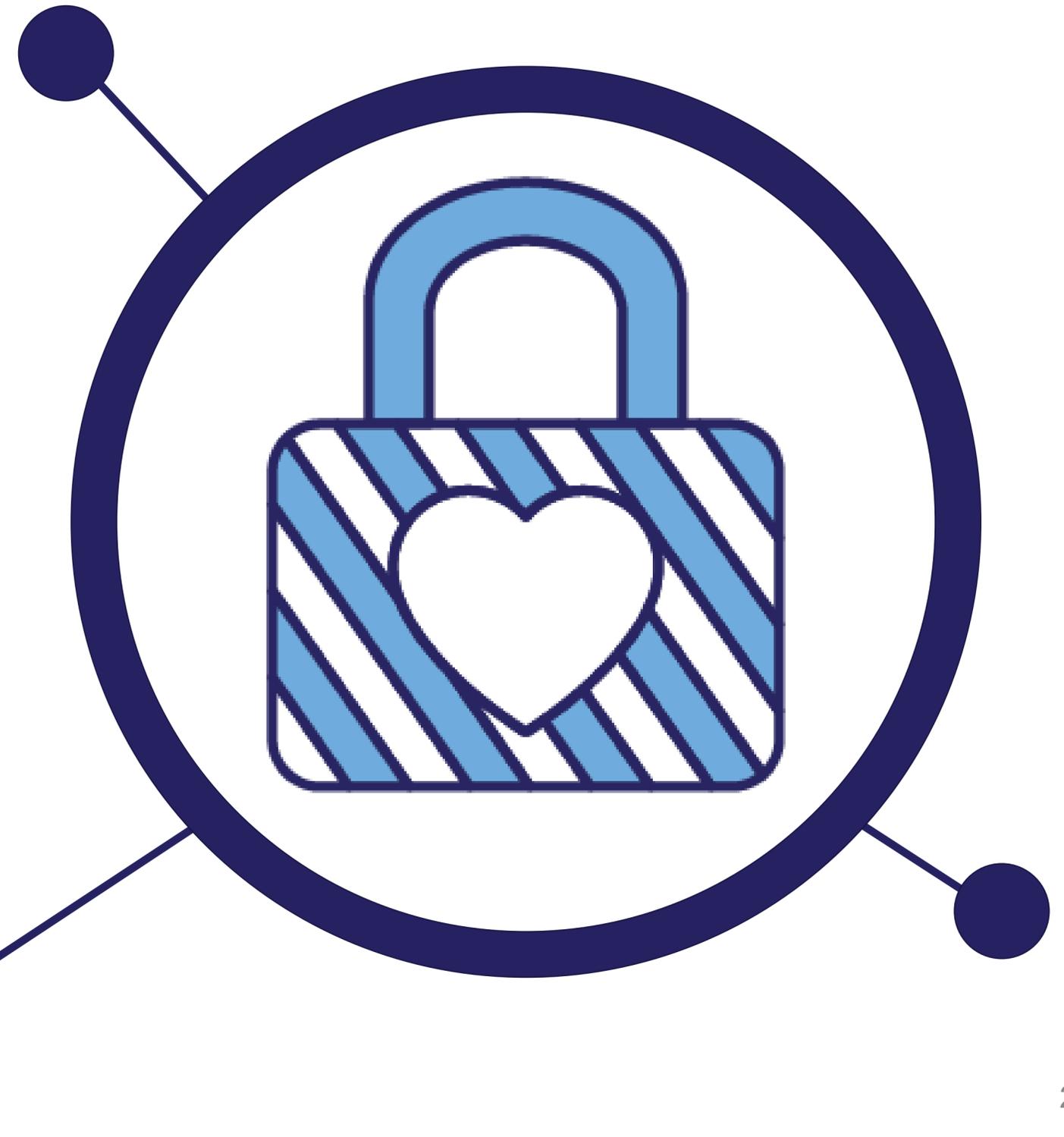
● Program and Research Information

- Ongoing study updates
- 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.





where
are we headed?

The future of *All of Us*

- **Broadening inclusion** to additional demographics
- **Provider outreach** to engage with and educate clinical stakeholders
- Expanding **linguistic support** for non-English or non-Spanish speakers
- **Increasing number of facilities** across the country to collect physical measurements and biospecimens

All of Us | The
RESEARCH PROGRAM | Precision
Medicine
Initiative



@AllofUsResearch
#JoinAllofUs
allofus.nih.gov
Joinallofus.org