Supporting Data-Powered Health for Researchers Participants, and Communities

All of Us Research Program

Amanda J. Wilson

Head, National Network Coordinating Office

National Library of Medicine, *All of Us* Research Program partner

Dara Richardson Heron, M.D.
Chief Engagement Officer, *All of Us* Research Program

Katherine D. Blizinsky, Ph.D.
Policy Director, *All of Us* Research Program

With Thanks

Learn More

JoinAllofUs.org
ResearchAllofUs.org

@AllofUsResearch
#JoinAllofUs

Precision Medicine Initiative

All of Us
RESEARCH PROGRAM

The future of health begins with you

precision medicine:

the right treatment for the right person at the right time

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 to analyze 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

what is *All of Us*?

- 2015: White House announced the Precision Medicine Initiative

what is *All of Us*?

- 2015: White House announced the Precision Medicine Initiative

MISSION: To enable a new era of medicine through research, technology, and policies that empower patients, researchers, and providers to work together toward development of individualized care

what is *All of Us*?

- 2015: White House announced the Precision Medicine Initiative

MISSION: To enable a new era of medicine through research, technology, and policies that empower patients, researchers, and providers to work together toward development of individualized care

- Privacy and Trust Principles
- Data Security Policy Principles

what is *All of Us*?

- 2015: White House announced the Precision Medicine Initiative

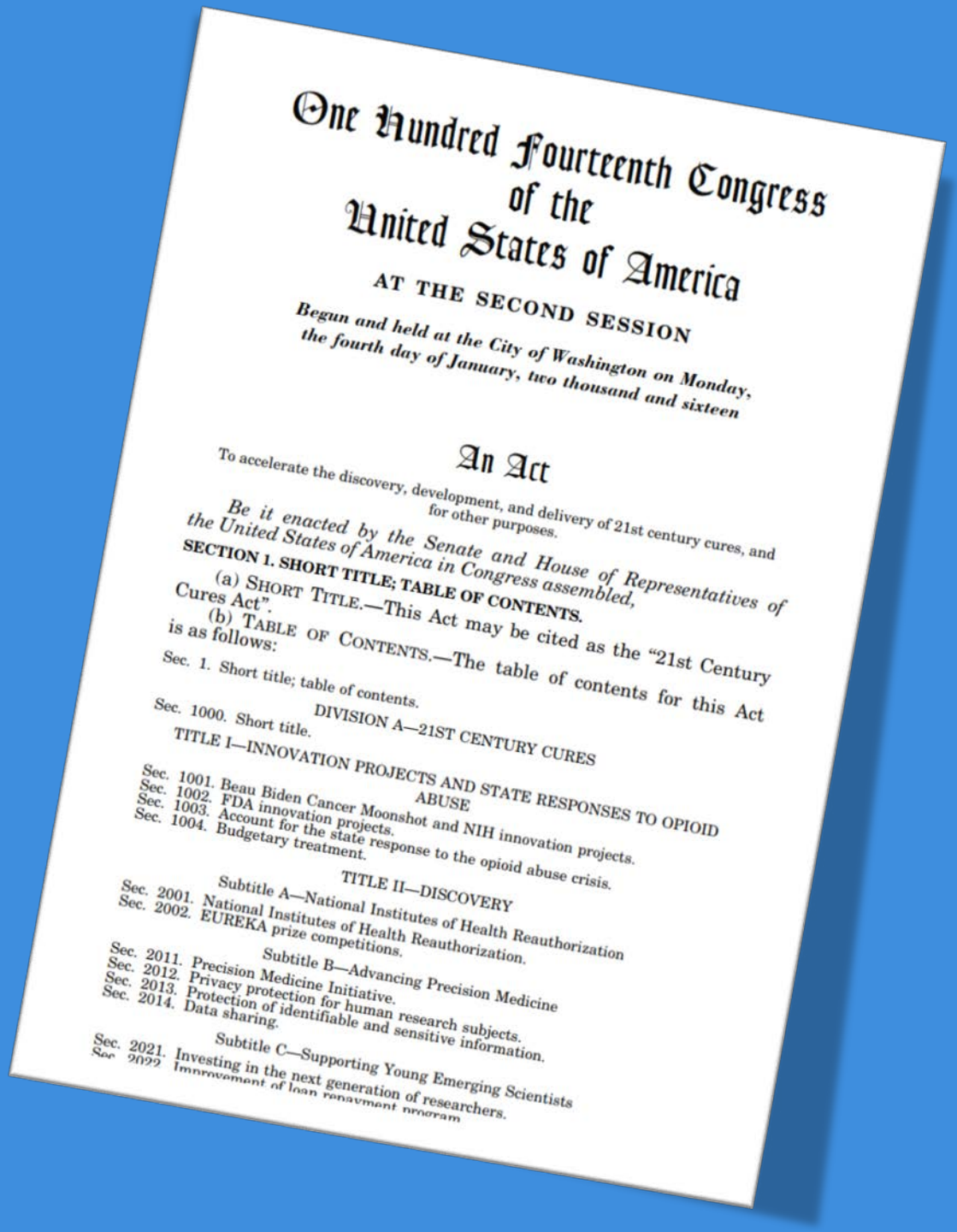
MISSION: To enable a new era of medicine through research, technology, and policies that empower patients, researchers, and providers to work together toward development of individualized care

  - Privacy and Trust Principles
  - Data Security Policy Principles

- 2016: Codified and Statutorily Mandated by the 21st Century Cures Act

21st Century Cures Act

- H.R.34. (Pub. L. 114-255) enacted December 13, 2016
- Provides the Precision Medicine Initiative with $1.455 billion over 10 years
- Language on:
  - Diversity
  - Data sharing
  - Privacy



One Hundred Fourteenth Congress
of the
United States of America

AT THE SECOND SESSION

Begun and held at the City of Washington on Monday, the fourth day of January, two thousand and sixteen

An Act

To accelerate the discovery, development, and delivery of 21st century cures, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "21st Century Cures Act".

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

Sec. 1. Short title; table of contents.

DIVISION A—21ST CENTURY CURES

Sec. 1000. Short title.

TITLE I—INNOVATION PROJECTS AND STATE RESPONSES TO OPIOID ABUSE

Sec. 1001. Beau Biden Cancer Moonshot and NIH innovation projects.
Sec. 1002. FDA innovation projects.
Sec. 1003. Account for the state response to the opioid abuse crisis.
Sec. 1004. Budgetary treatment.

TITLE II—DISCOVERY

Subtitle A—National Institutes of Health Reauthorization

Sec. 2001. National Institutes of Health Reauthorization.
Sec. 2002. EUREKA prize competitions.

Subtitle B—Advancing Precision Medicine

Sec. 2011. Precision Medicine Initiative.
Sec. 2012. Privacy protection for human research subjects.
Sec. 2013. Protection of identifiable and sensitive information.
Sec. 2014. Data sharing.

Subtitle C—Supporting Young Emerging Scientists

Sec. 2021. Investing in the next generation of researchers.
Sec. 2022. Improvement of loan repayment program

What is the *All of Us* Research Program?

- ***Rich, Longitudinal Resource***: Deliver a national resource of deep **clinical, environmental, lifestyle, & genetic data** from one million participants who are consented & engaged to provide data on an ongoing, longitudinal basis (60+ years!)

- ***Diversity of Participants***: Reflect the broad diversity of the U.S.—**all ages, races/ ethnicities, gender, SES, geographies, & health status**—by over-recruiting those underrepresented in biomedical research

- ***Diversity of Researchers***: Build the tools & capabilities that make it easy for researchers **from community scientists to premier university labs** to make discoveries using the data & biosamples and through ancillary studies w/ the cohort

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

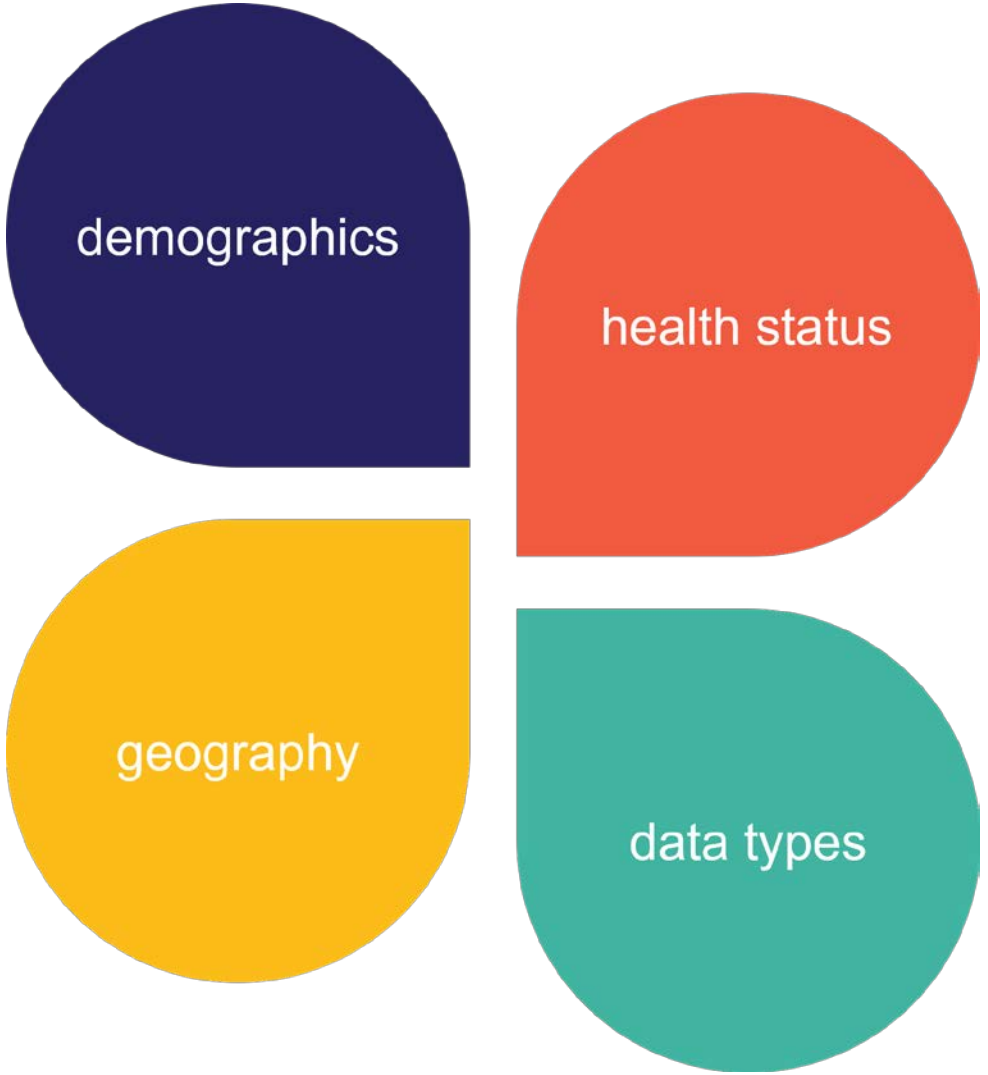
Catalyze a robust ecosystem
of researchers and funders hungry to use and support it

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.

A Transformational Approach to Diversity

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



A Transformational Approach to Participation

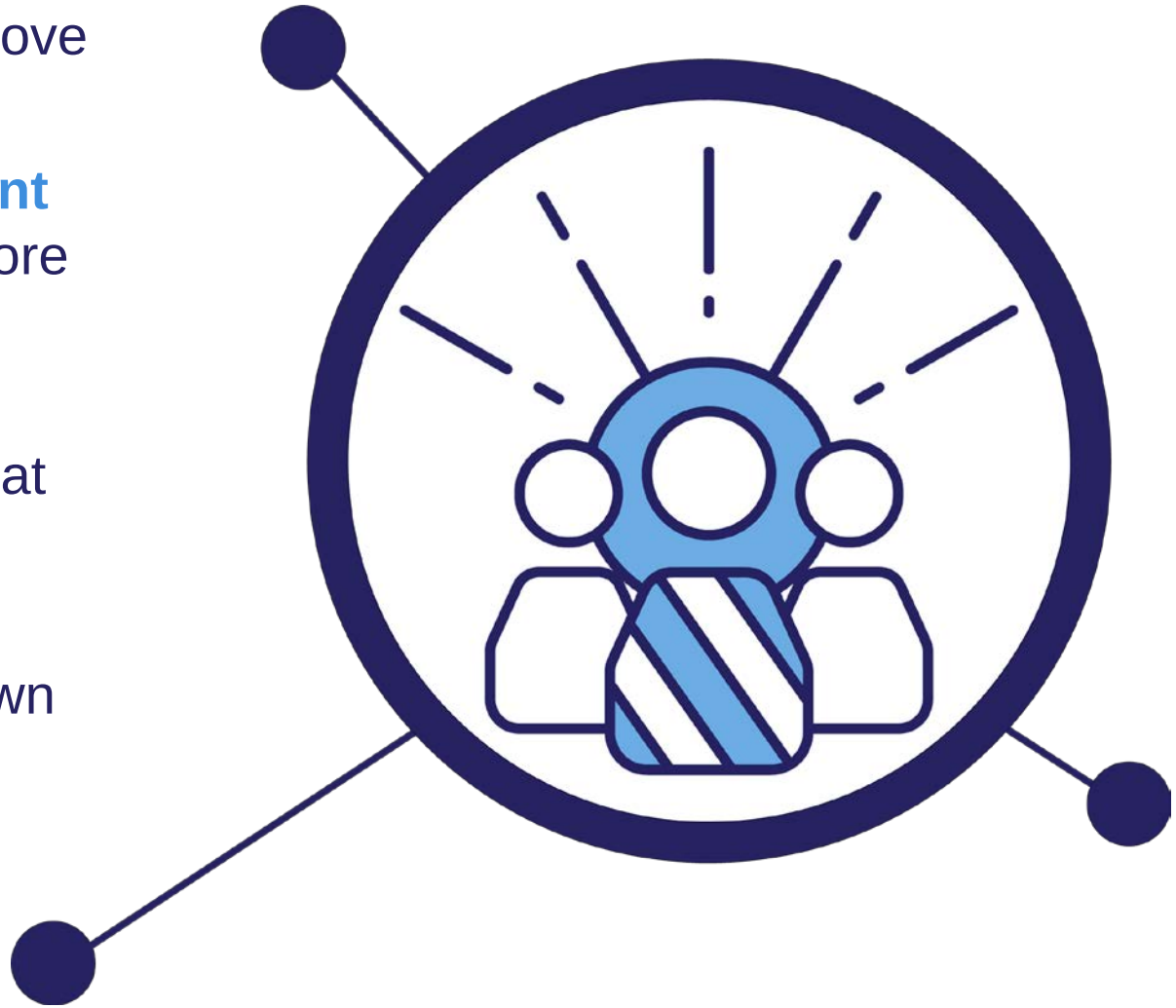
Participants are true partners - not patients, not subjects - in the research process.

They are involved in helping us think through:

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

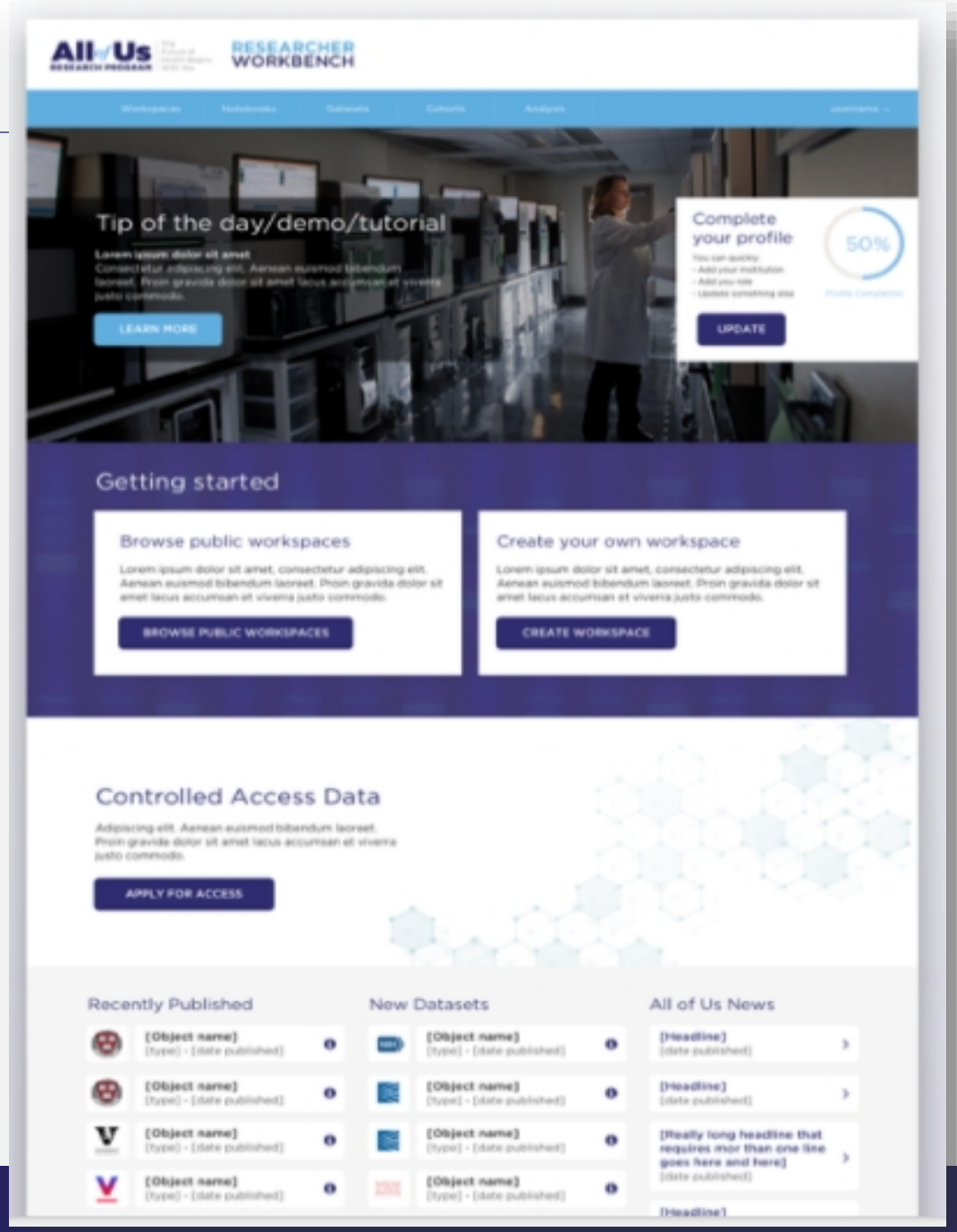
What is the Promise for Participants?

- 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



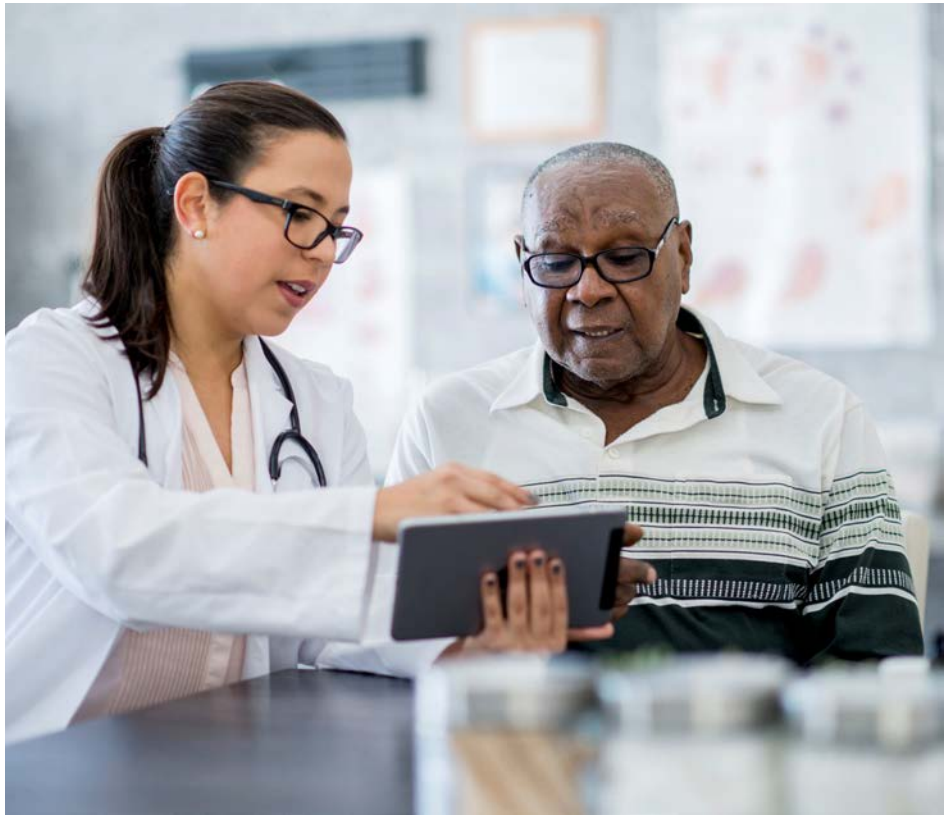
What is the Promise for Researchers?

- The opportunity to **save time and resources** and **accelerate your research breakthroughs**
- 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.



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**.



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 identity and data is our most important responsibility.

All of Us Research Program Building Blocks

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, community partners, and future awards to grow network

All of Us Consortium Members

DV Network

(Direct Volunteers)

Scripps Translational Science Institute
National Blood Collaborative
QTC — A Leidos Company
Walgreens
BlueCross BlueShield
DXC.technology
Quest Diagnostics
EMSI HEALTH
patientslikeme
WebMD

Biobank

Mayo Clinic

HPO Network

(Health Care Provider Organizations)

RMCs

California Precision Medicine Consortium

UC San Diego Health
UC Davis Health
Keck Medical Center of USC
UC Irvine Health
UC Health
UCSF — University of California San Francisco
San Diego Blood Bank — Saving lives today. Improving life tomorrow.
Cedars-Sinai

Illinois Precision Medicine Consortium

Northwestern University
The University of Chicago
NorthShore University HealthSystem
RUSH
The University of Illinois at Chicago

New England Precision Medicine Consortium

Partners HealthCare
Massachusetts General Hospital
Brigham Health — Brigham and Women's Hospital
Boston University School of Medicine
Boston Medical Center — Exceptional care. Without exception.
University of Massachusetts Medical School

Trans-American Consortium for the Health Care Systems Research Network

Henry Ford Health System
Essentia Health
BaylorScott&White Health
Spectrum Health

New York City Precision Medicine Consortium

Columbia University Medical Center
NYC Health+ Hospitals
NewYork-Presbyterian
Weill Cornell Medicine

Southern *All of Us* Network

UAB School of Medicine — Knowledge that will change your world
UAB The University of Alabama at Birmingham — Knowledge that will change your world
The University of Mississippi Medical Center
UAB Medicine — UAB Hospital
Tulane University
Tuskegee University
Cooper Green Mercy Health Services
Huntsville Hospital
University Medical Center
University of South Alabama Health System
LSU Health New Orleans

SouthEast Enrollment Center

UHealth — University of Miami Miller School of Medicine
Emory University
Morehouse School of Medicine
OneFlorida — Clinical Research Consortium

All of Us, Wisconsin

Marshfield Clinic
Clement J. Zablocki VA Medical Center
University of Wisconsin School of Medicine and Public Health
Medical College of Wisconsin
BloodCenter of Wisconsin — Part of Versiti

University of Arizona

The University of Arizona
Banner Health

University of Pittsburgh

University of Pittsburgh

FQHCs (Federally Qualified Health Centers)

Cherokee Health Systems
Jackson-Hinds Comprehensive Health Center
San Ysidro Health
HRHCare — Community Health
Community Health Center, Inc.
Eau Claire

VA Medical Centers

VA | U.S. Department of Veterans Affairs

Communication & Engagement

WONDROS
HCM Strategists

Platform Development

Scripps Translational Science Institute
Sage Bionetworks
Vanderbilt University
WONDROS
vibrent
Broad Institute
verily

Two Methods of Enrollment

DIRECT VOLUNTEERS

HEALTH CARE PROVIDER ORGANIZATIONS

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

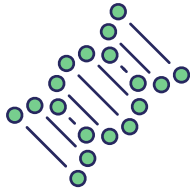
Answering Surveys

- Surveys: The Basics, Overall Health, Lifestyle, Family History, Health Care Access and Utilization
- 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

All of Us Today and into the Future

Present

- **> 200,000** participants registered
- **> 100,000** core participants
- **~ 75%** of current participants self-identify as belonging to one or more population that has been historically underrepresented in biomedical research

Future

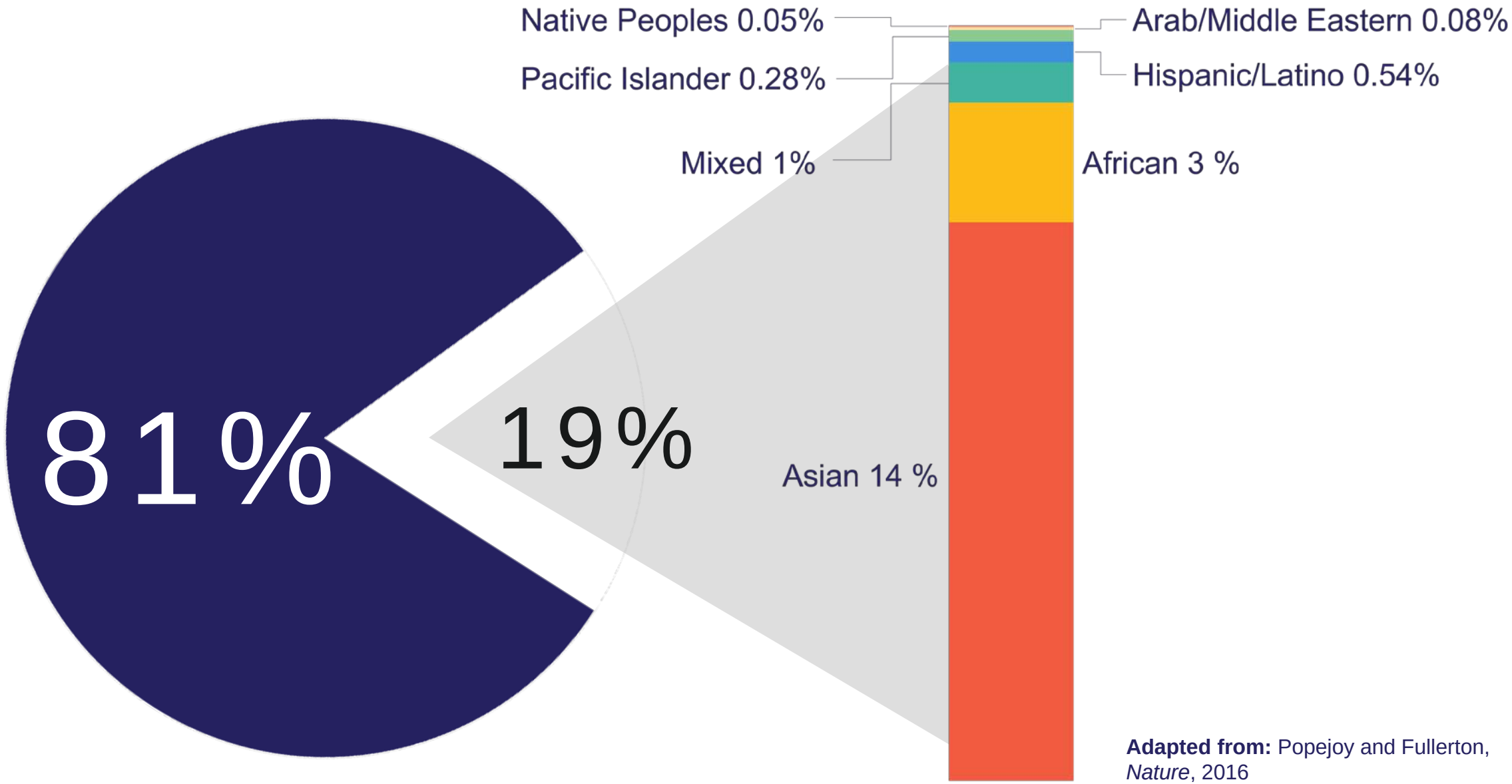
- **Broaden inclusion** to additional demographics
- **Provider outreach** to engage with and educate clinical stakeholders
- Expand **linguistic support** for non-English or Spanish speakers
- Launch the **researcher portal**

Importance of Historically Underrepresented Populations

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.

Persistent Racial and Ethnic Bias in GWA Studies



Adapted from: Popejoy and Fullerton, *Nature*, 2016

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, sexual orientation, income, education, geography, access to care, and disability.

Potential Improvements in Minority Health

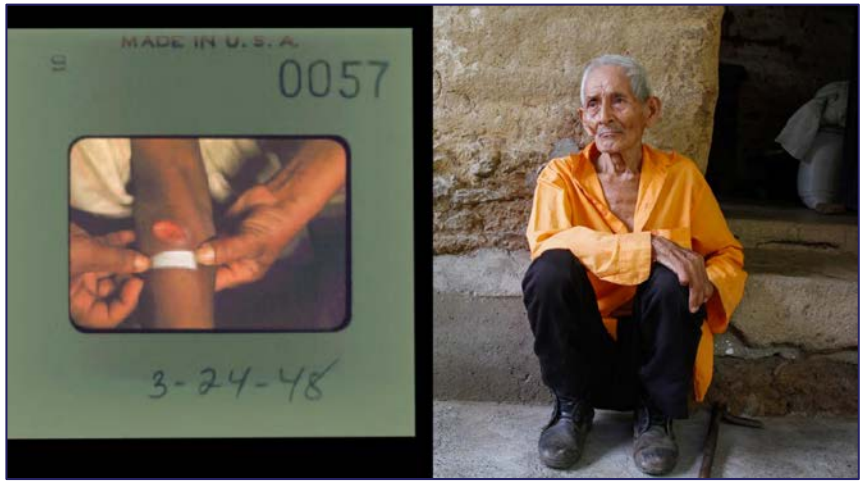
Health disparities are well known but NOT well understood.

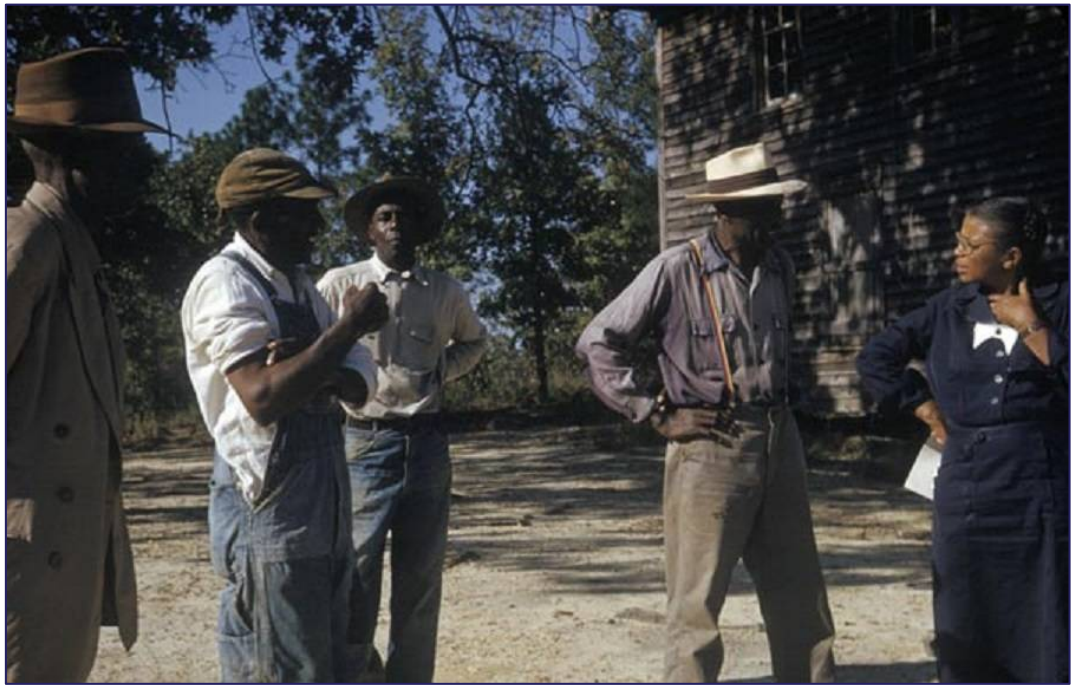
- Why do African-Americans have a higher mortality rate from chronic diseases, including cancer, Alzheimer's, diabetes, and heart disease?
- Why is stroke more common among rural communities?
- Why is Hepatitis B more common in the Asian and Pacific Islander population?

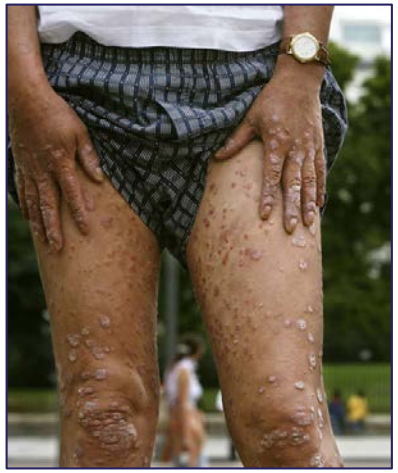
Precision medicine asks us to look even beyond racial or ethnic group and into unique biological information to determine likelihood of developing and dying from disease.

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.

Disenfranchisement and Historical Abuses







UNDERREPRESENTED IN BIOMEDICAL RESEARCH

Build Trust & Create Value

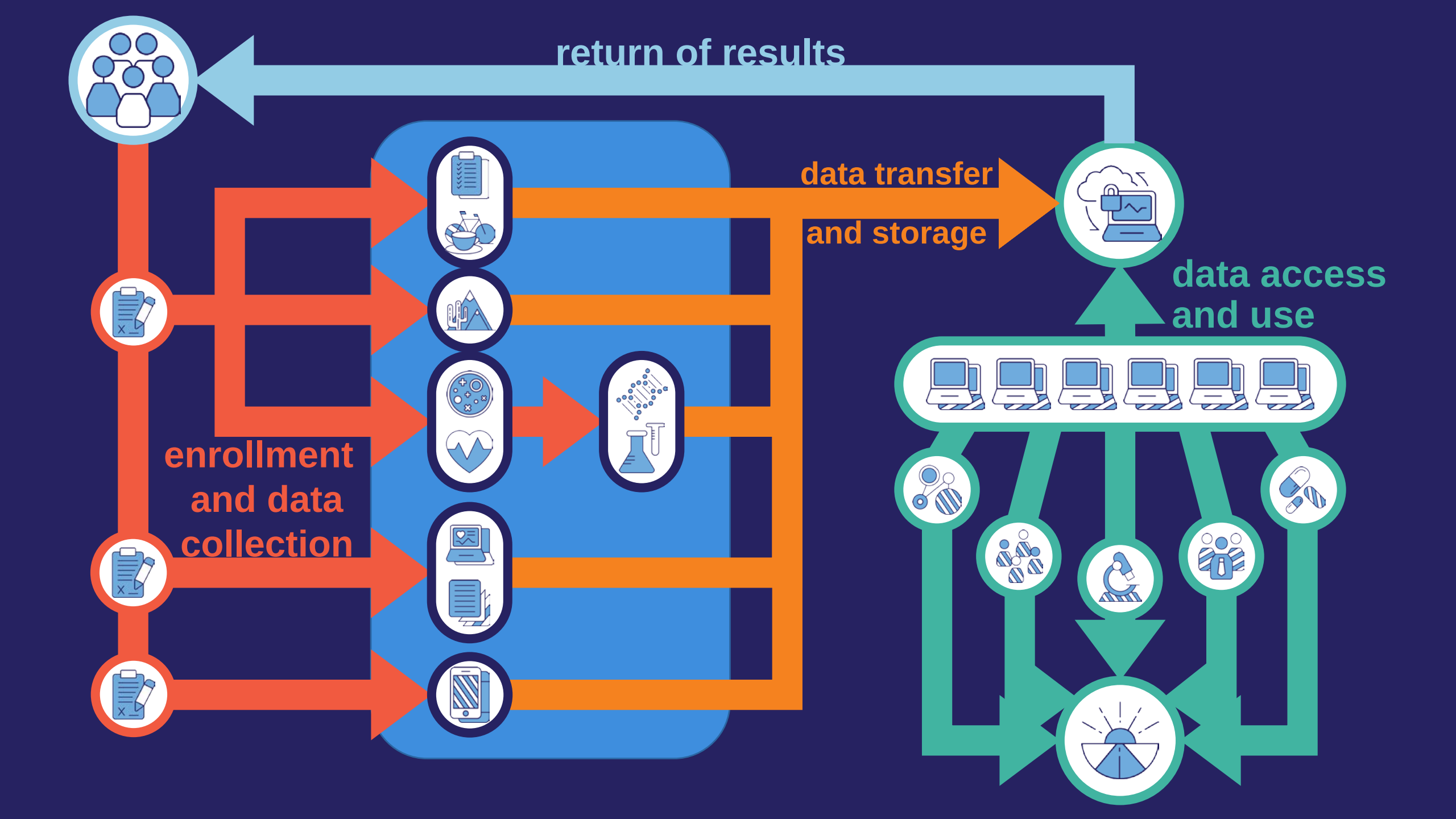
trust will be earned through
robust engagement and full transparency.

All of Us Community and Provider Partner Network

All of Us Data Access

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.


return of results
data transfer
and storage
data access
and use
enrollment
and data
collection

All of Us Research Program Data

- Participant Surveys
- Electronic Health Records
- Physical Measurements
- Biospecimens and Assays
- Mobile/Wearable Tech
- Geospatial/Environmental Data

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

considerations

Sharing Data with Researchers

- Data ownership and control
- Participant privacy and identifiability
- Rules for appropriate access and use
- Prevention and penalizing misuse

Balancing openness and oversight

Balancing paternalism and autonomy

- Ethical, legal, and regulatory obligations
- Potential benefits and harms
- Content and context of data return
- Feasibility

Sharing Data with Participants

sharing data with

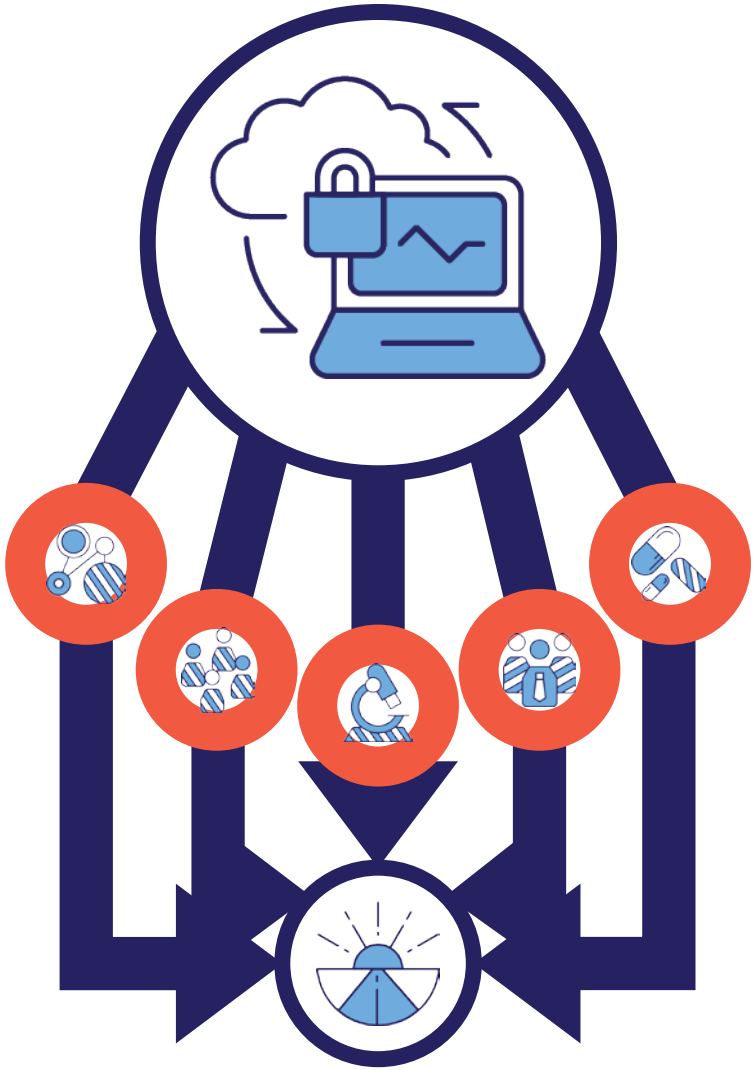
researchers

Balancing Openness with Oversight

- What is an appropriate standard of deidentification?
- What privacy and security provisions (should) apply?
- Who should get access to the data, and how much should they be trusted?
- What responsibilities are borne by the data user?
- What are the potential avenues and harms of data misuse?
- What can be done to dissuade and/or punish bad actors?

"They're harmless when they're alone, but get a bunch of them together with a research grant and watch out."

The *All of Us* Approach to Data Access



NIH will invest to level the playing field so diverse researchers can play

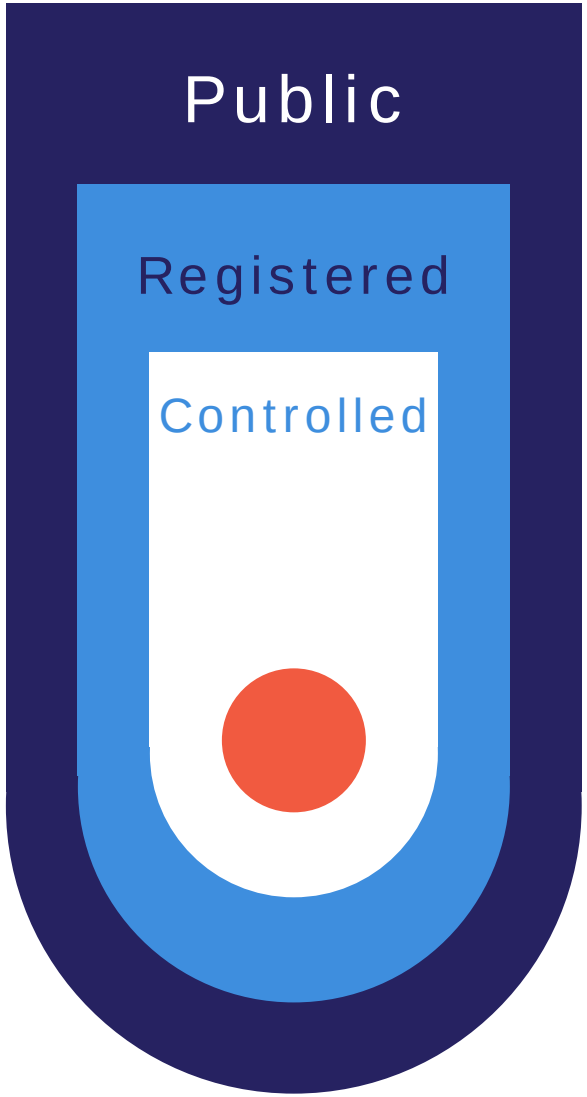
- *All of Us* data will be available to **all types of users**

The *All of Us* Approach to Data Access

NIH will invest to level the playing field so diverse researchers can play

- *All of Us* data will be available to **all types of users**
- The *All of Us* Data Resource will employ a **cloud-based analysis platform**

The *All of Us* Approach to Data Access



NIH will invest to level the playing field so diverse researchers can play

- *All of Us* data will be available to **all types of users**
- The *All of Us* Data Resource will employ a **cloud-based analysis platform**
- Access will be **tiered**

The *All of Us* Data Resource Code of Conduct (examples)

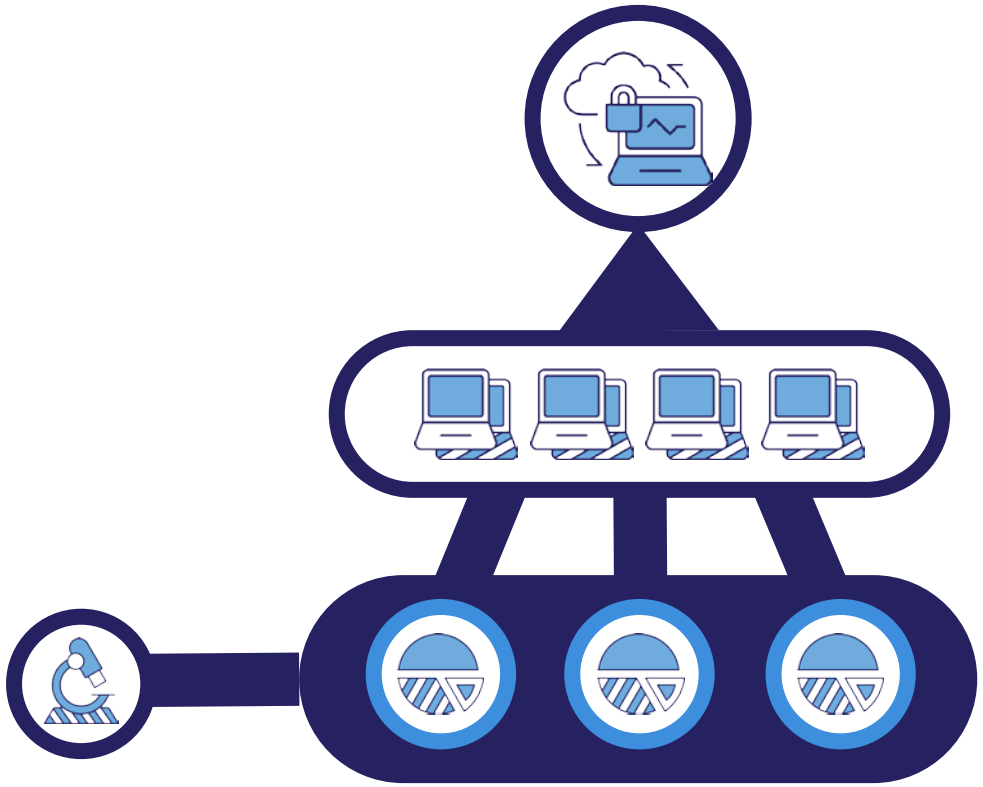
I WILL:

- know and follow **all applicable federal, state, and local laws** regarding human data access and privacy.
- contact the *All of Us* Research Program Resource Access Board (RAB) within 24 hours if I become aware of **any uses or disclosures of *All of Us* data that endanger the security or privacy of research participants**, including any unintended re-identification of participants through the process of my work.

I will NOT:

- use *All of Us* Research Program data for **research that is discriminatory or stigmatizing** of individuals, families, or communities.
- **attempt to re-identify** research participants or their relatives.
- **use or disclose the information** other than as permitted by this DUA.
- **make copies of or download individual-level data** resources outside of the *All of Us* research environment without approval from RAB.

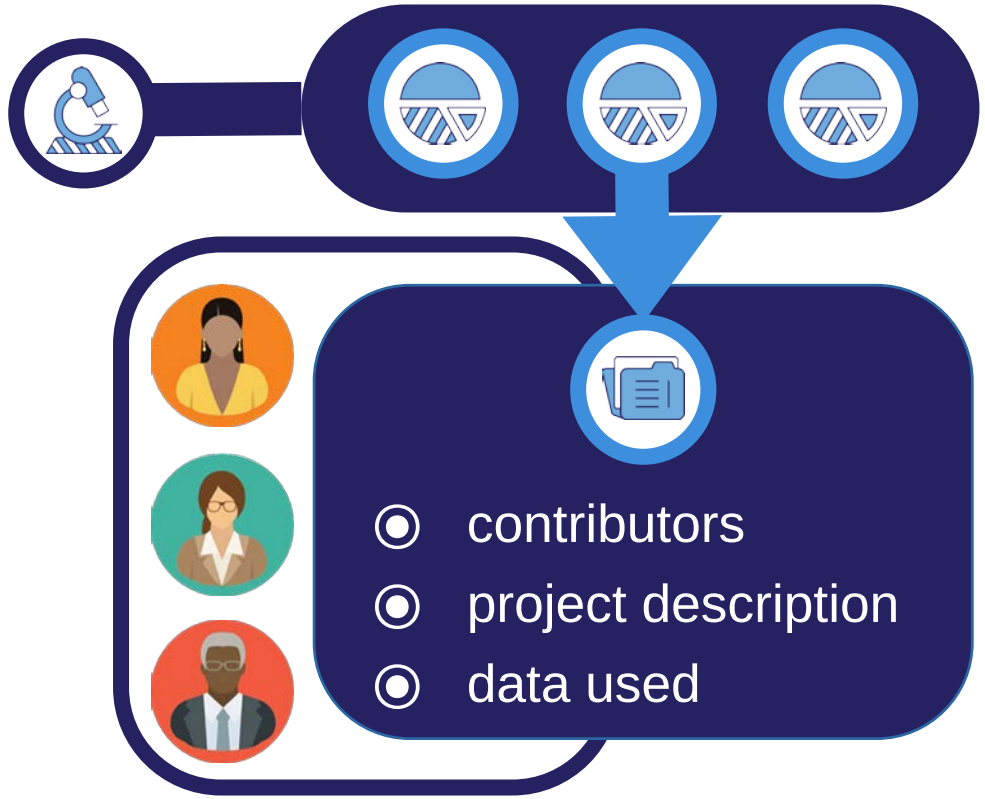
The *All of Us* Approach to Data Access



NIH will invest to level the playing field so diverse researchers can play

- *All of Us* data will be available to **all types of users**
- The *All of Us* Data Resource will employ a **cloud-based analysis platform**
- Access will be **tiered**
- Users will be granted **data passports**

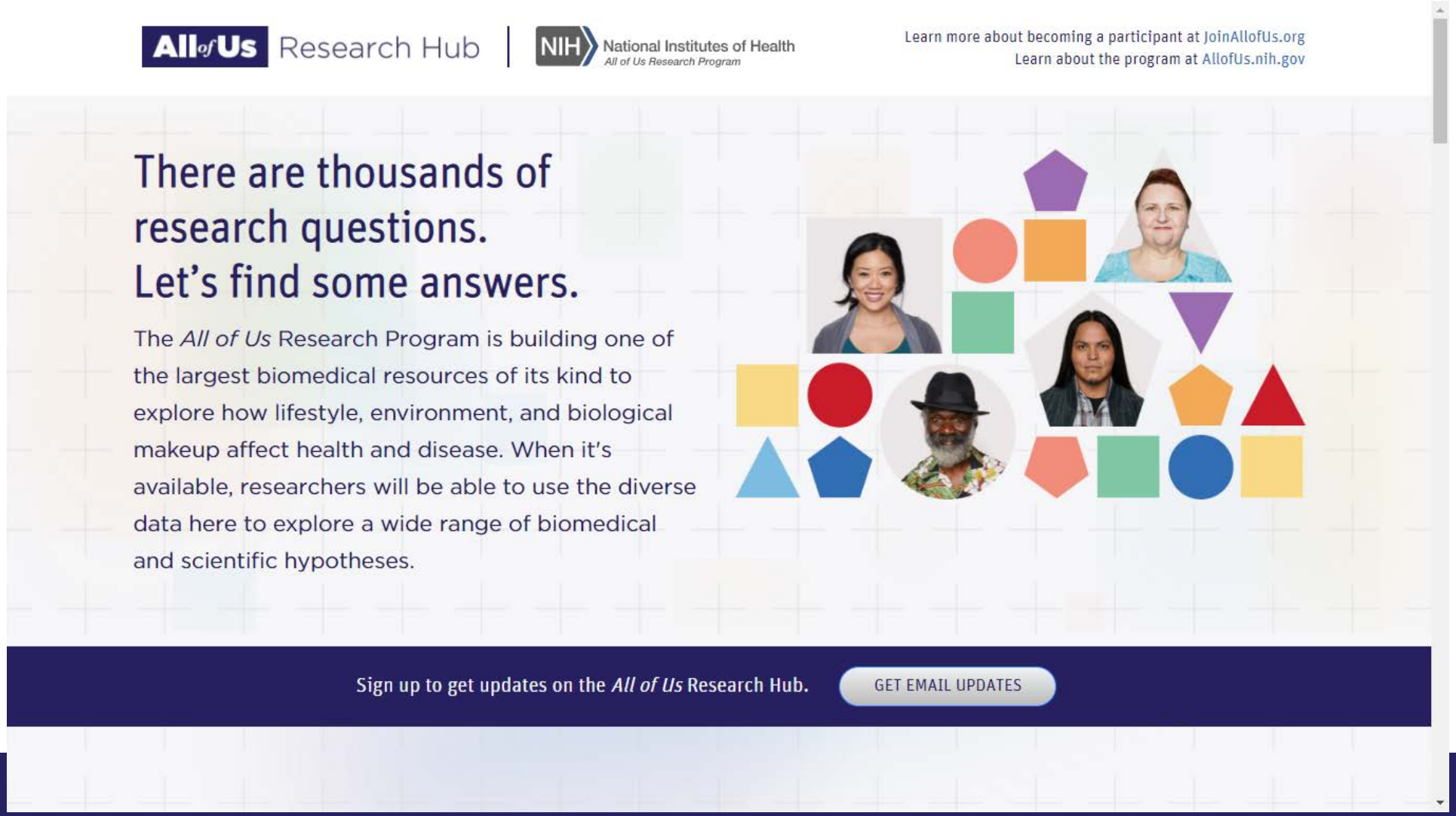
The *All of Us* Approach to Data Access



NIH will invest to level the playing field so diverse researchers can play

- *All of Us* data will be available to **all types of users**
- The *All of Us* Data Resource will employ a **cloud-based analysis platform**
- Access will be **tiered**
- Users will be granted **data passports**
- Project information will be made **public** and **auditable**

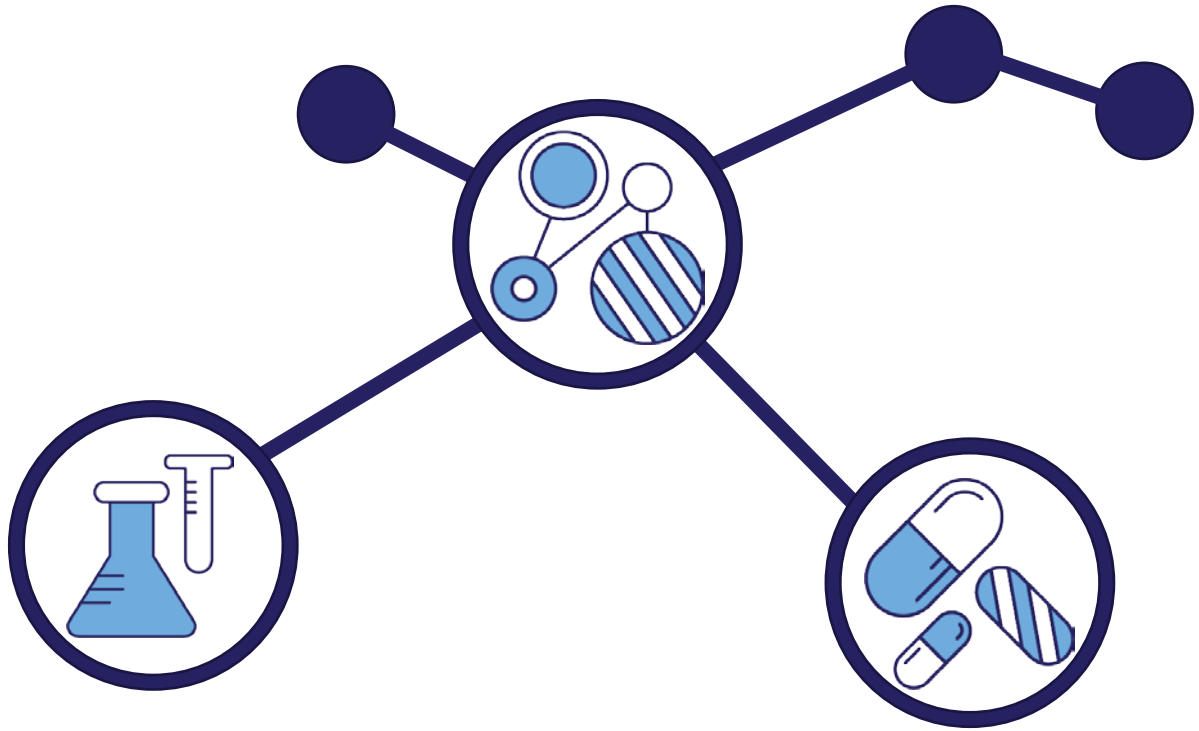
All of Us Research Hub



www.ResearchAllofUs.org

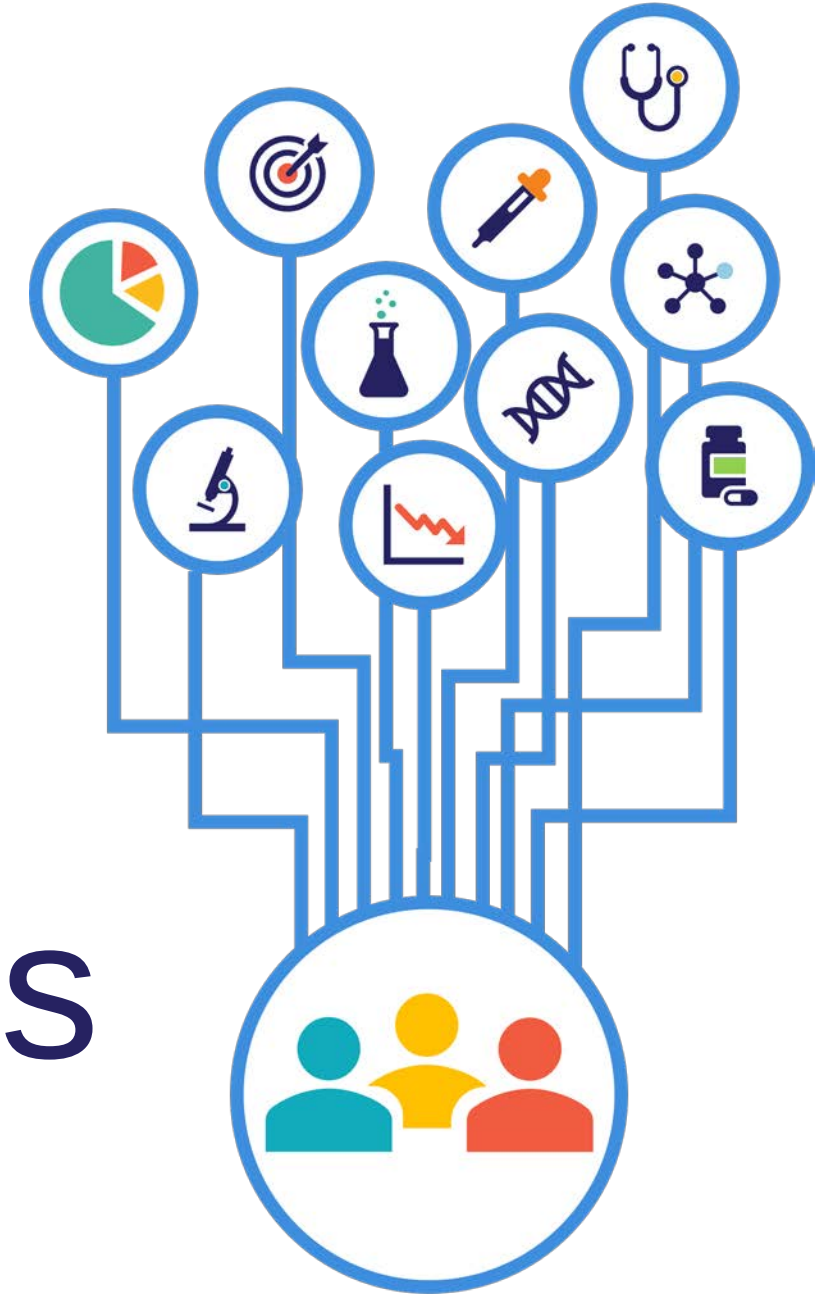
Sample Scientific Opportunities

- Develop quantitative **estimates of risk** for a range of diseases by integrating environmental exposures and biological 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
- Use **mobile health technologies** to correlate activity, physiological measures, and environmental exposures with health outcomes
- Develop **solutions to health disparities**
- Create a platform to enable **trials of targeted therapies**
- **Empower study participants** with information to improve their own health



sharing data with

participants



Research Participants Want Information Back

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.

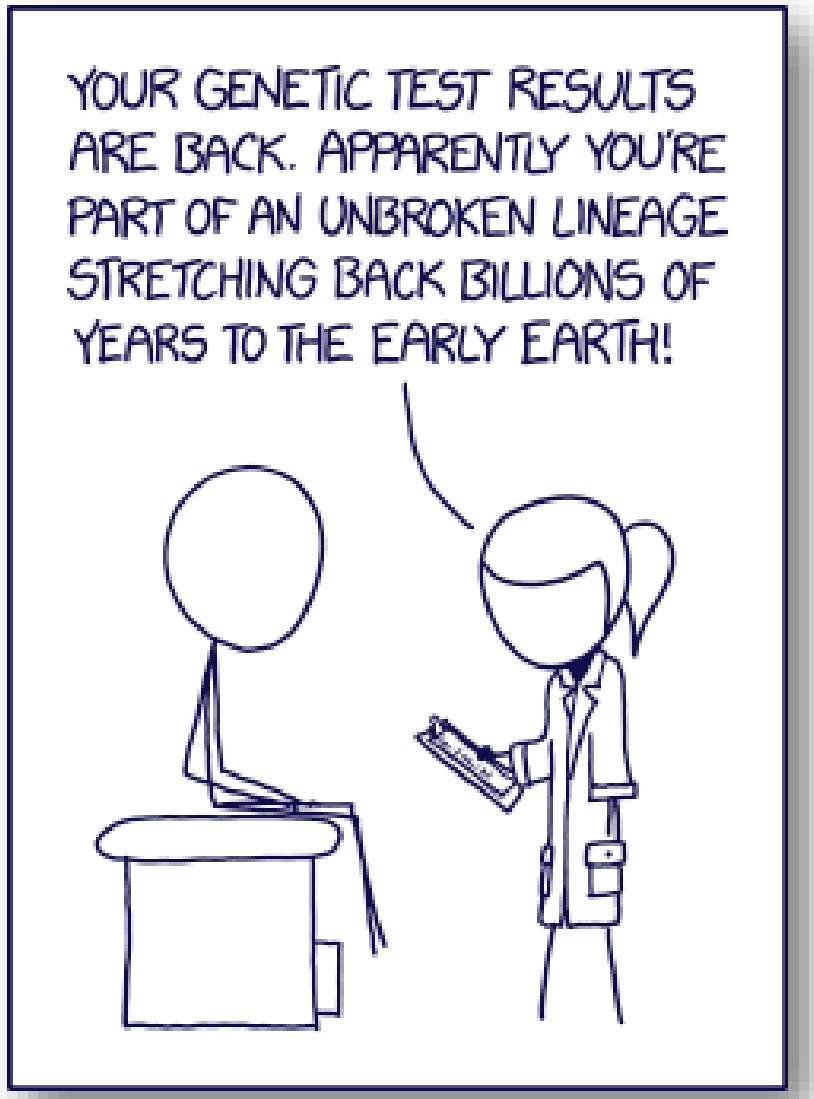
54% said they would definitely or probably participate if asked—not predictive of enrollment numbers, but encouraging.

- Little variability among demographic groups
- Most important incentive for participation: **learning about one's health information**

Kaufman DJ, Baker R, Milner LC, Devaney S, Hudson KL (2016):
A Survey of U.S. Adults' Opinions about Conduct of a Nationwide Precision Medicine Initiative Cohort Study of Genes and Environment.
PLOS ONE 11(8): e0160461. doi:10.1371/journal.pone.0160461

Balancing Paternalism with Autonomy

- What information should participants receive? What information do participants have a right to receive?
- What are the potential benefits and harms to the receipt of that information?
- Are there means of mitigating negative outcomes resulting from the return of information?
- Where is the apposite limen between research and clinical care?
- Is there an obligation to provide participants with a choice to receive some or all of the information?



National Institutes of Health

Return of Genetic Results in the *All of Us* Research Program

Workshop
March 6-7, 2017

All of Us RESEARCH PROGRAM

WORKSHOP GOALS:

- Assess the state-of-the-field for the return of genomic information.
- Establish guidelines for return of genetic results considering the distinctive features and core principles of the *All of Us* Research Program.

Key Insights

- Ask participants if they want data about themselves, and how they want it
- Develop multiple means of communication
- Challenges of the digital divide and low literacy/health literacy
- Start small, test, and then build
- Be realistic and clearly communicate with participants
- Build upon best practices

National Academies Report

- Support decision making regarding the return of results on a study-by-study basis
- Promote high-quality individual research results
- Foster participant understanding of individual research results
- Revise and harmonize current regulations

All of Us ELSI Priorities: The Four Buckets

Policy Implications

Value to Stakeholders

Research Practice

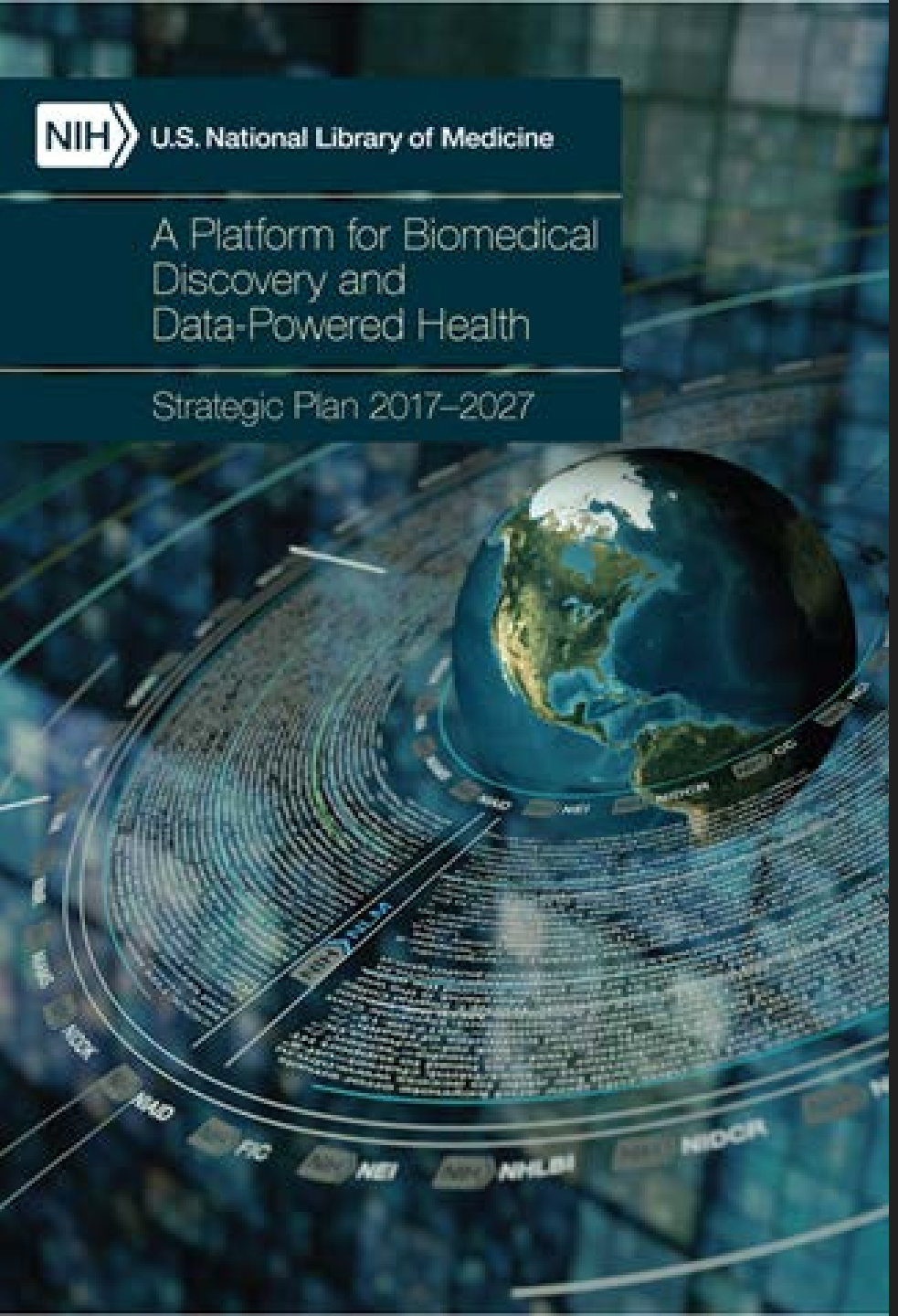
Convenings Support

The *All of Us* Approach to Return of Results

- Opportunities for participant education will be provided to promote informed decision making.
- Participants must opt in to receive information carrying more than minimal risk.
- Medically actionable pathological genetic variant positivity will be returned in a way to maximize participant safety and understanding.
- Support services will be available to anyone, regardless of results.

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


NIH
U.S. National Library of Medicine
A Platform for Biomedical Discovery and Data-Powered Health
Strategic Plan 2017–2027
NIAID
FIC
NEI
NHLBI
NIDCR

All of Us + NLM

Goals of the NLM Strategic Plan 2017-2027

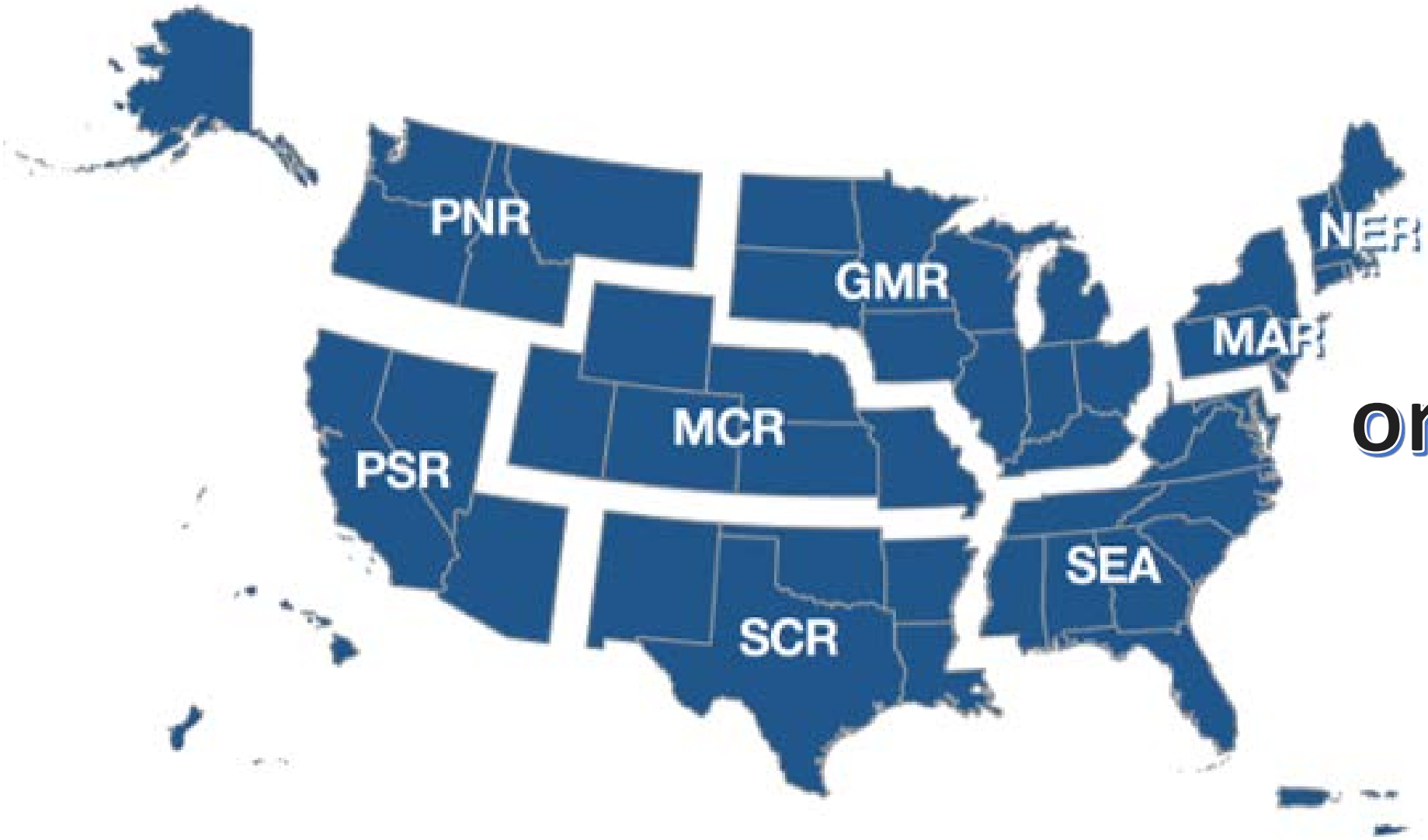
All of Us RESEARCH PROGRAM — NIH NLM

Community Education

Community Engagement

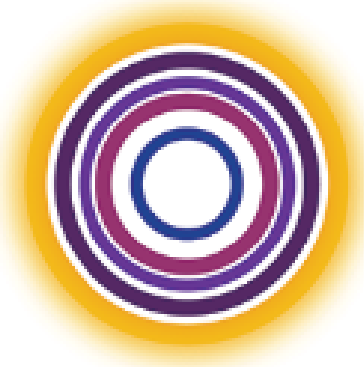
AoU Learning Platform

National Network of Libraries of Medicine (NNLM)



7100+ organizational members

*training
*funding
*community partnerships

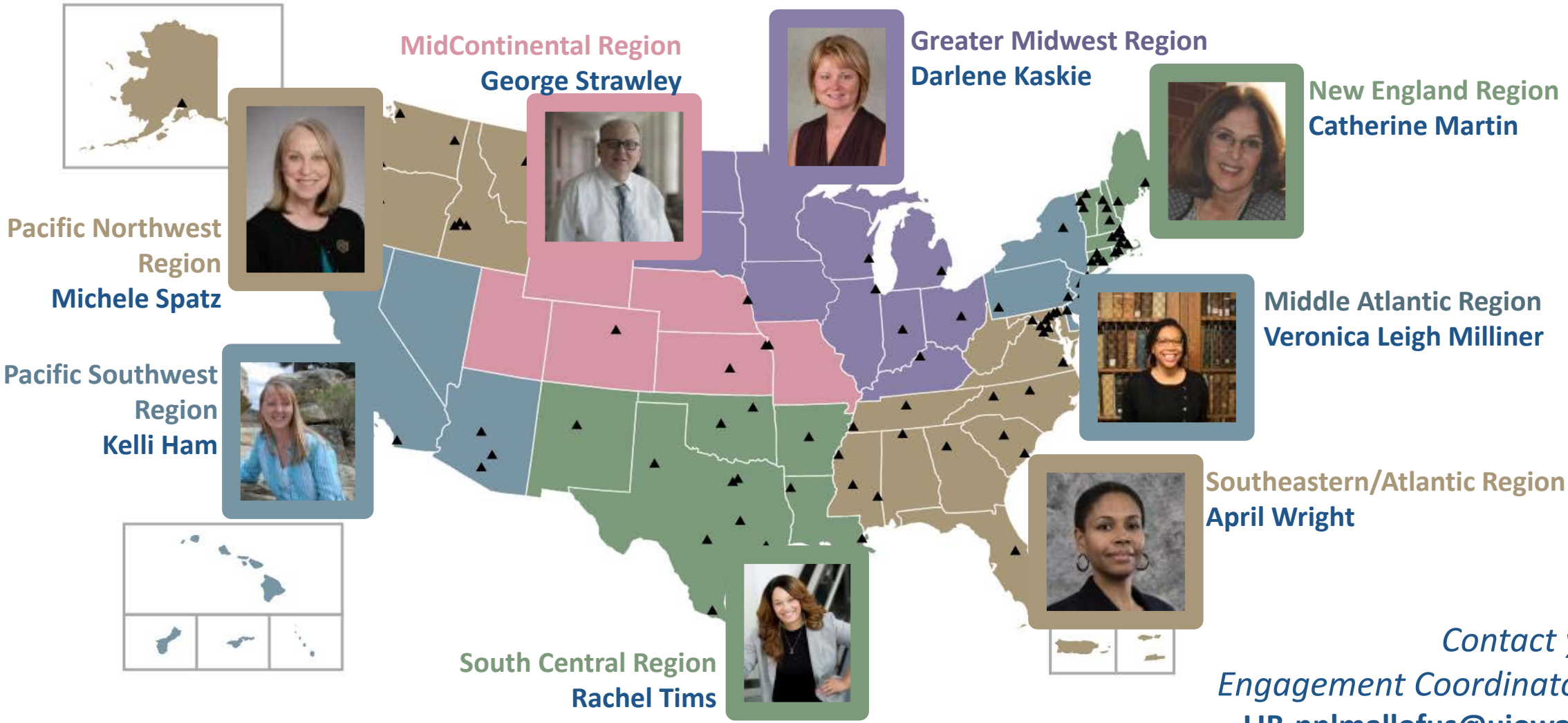


Public Library Association

CELEBRATING 75 YEARS

A DIVISION OF THE AMERICAN LIBRARY ASSOCIATION

NNLM *All of Us* Community Engagement Network



Pacific Northwest Region
Michele Spatz

Pacific Southwest Region
Kelli Ham

MidContinental Region
George Strawley

Greater Midwest Region
Darlene Kaskie

New England Region
Catherine Martin

Middle Atlantic Region
Veronica Leigh Milliner

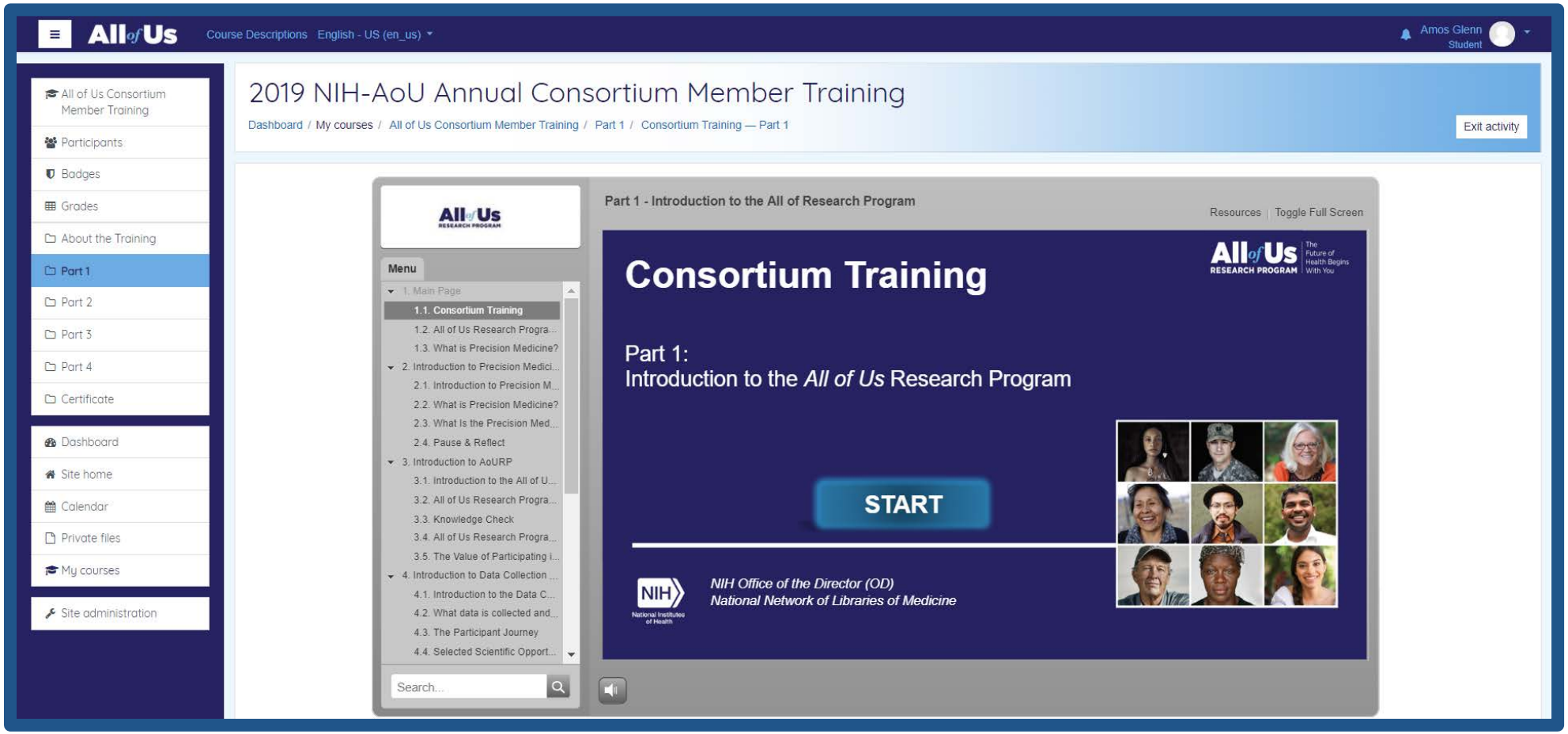
Southeastern/Atlantic Region
April Wright

South Central Region
Rachel Tims

Contact your Engagement Coordinator at
LIB-nnlmallofus@uiowa.edu

NNLM *All of Us* Training and Education Center

AoU Learning Platform



Community Engagement through NNLM + *All of Us*

Education Topics

All of Us Training

Digital Literacy

Evaluating Health Information

Genetics

Health Literacy

Health Numeracy

Researcher Ethics

Return of Genomic Results

Engagement Activities

Book Mobiles/Book Bikes

Citizen Science Projects

Community Conversations

Health/Science Fairs

Health and Wellness

Programming

Online Games

Summer Reading

NNLM + *All of Us:* Community Engagement Examples

TRAINING
opportunities and consultations

FUNDING
for projects to "blanket the nation"

CONNECTING
communities via libraries

NNLM + *All of Us:* Community Engagement Examples

TRAINING
opportunities and consultations

FUNDING
for projects to "blanket the nation"

CONNECTING
communities via libraries

NNLM + *All of Us:* Community Engagement Examples

TRAINING
opportunities and consultations

FUNDING
for projects to "blanket the nation"

CONNECTING
communities via libraries

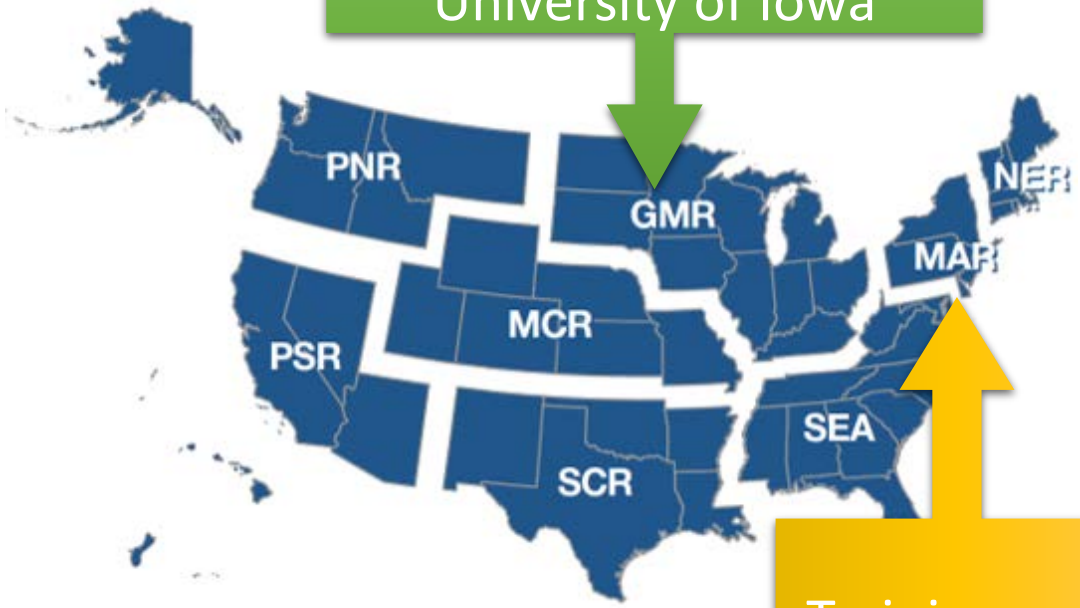
NNLM *All of Us* Partnership Leadership Team

Amanda J. Wilson
Head, National Network Coordinating Office
National Library of Medicine
amanda.wilson@nih.gov

Jennifer R. Jones
Executive Director, NLM Training and Education Center for the *All of Us* Research Program
NNLM Middle Atlantic Region
jrj25@pitt.edu

Brittney Thomas
Manager, NNLM *All of Us* Community Engagement Center
NNLM Greater Midwest Region
brittney-thomas@uiowa.edu

Community Engagement
at
University of Iowa



Training and Education
at
University of Pittsburgh

Learn More

JoinAllofUs.org
ResearchAllofUs.org

@AllofUsResearch
#JoinAllofUs