



The
Precision
Medicine
Initiative

The *All of Us* Research Program

American Medical Association's Federation of Medicine

February 2, 2018



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Grand opportunities to scale research discoveries for precision medicine

- Taming Wild New Data Types: which are meaningful to research? Standards & comparability? Roadmap of future?
- Diverse, Longitudinal Engagement at Scale: how to achieve, especially in times of increasing social division?
- Opportunities for evidence-based policy to support the science and translation of precision medicine: what are the gaps? Roadblocks?
- Expanding the Researcher Pool: from citizen science to community colleges? New incentives to data/knowledge share?
- Researching New Business Models: what do insurers, pharma, providers look & act like in precision health era?

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 the robust ecosystem

of researchers and funders hungry to use and support it



21st Century Cures Act

- H.R.34, 21st Century Cures Act, enacted December 13, 2016 (Pub.L. 114-255)
- Broad bi-partisan support
- Provisions relevant to All of Us:
 - Provides the Precision Medicine Initiative with \$1.455 billion over 10 years
 - Provides flexible funding mechanism, Other Transaction Authority
 - Language on diversity, data sharing, privacy
 - Provides important privacy protections critical for engendering trust
- Senate hearing tomorrow on implementation

H. R. 34

One Hundred Fourteenth Congress
of the
United States of America

AT THE SECOND SESSION

*Began 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”.

Important Privacy Protections/Policies

Certificates of Confidentiality

- All of Us Research Program data is currently covered by Certificates of Confidentiality
- The new provision in Cures:
 - Requires issuance of a certificate to all investigators “engaged in biomedical, behavioral, clinical, or other research in which identifiable, sensitive information is collected”
 - Prohibits disclosure (except in limited circumstances), and is inadmissible in court
 - Allows for disclosure with the participant's consent

Freedom of Information Act

- Section 2013 of the Cures Act implements similar privacy protections on data held by the federal government.

PMI Privacy and Trust Principles

- Articulate a core set of values and responsible strategies for engendering public trust to serve as a foundation for PMI.

Major Building Blocks of the Research Program

DATA AND RESEARCH CENTER (DRC)

Big data capture, cleaning, curation, & sharing in secure environment

Vanderbilt, Verily, Broad Institute

BIOBANK

Repository for processing, storing, & sharing biosamples

Mayo Clinic

PARTICIPANT CENTER

Direct volunteer participant enrollment, digital engagement innovation, & consumer health technologies

*Scripps Research Institute
(with multiple partners)*

PARTICIPANT TECHNOLOGY SYSTEMS CENTER

Web & phone-based platforms for participants

Vibrent Health

HEALTH CARE PROVIDER ORGS (HPOs)

Clinical & scientific expertise network, enrollment & retention of participants

20+ regional med centers, FQHCs, VA, future awards to grow network

COMMUNICATIONS & ENGAGEMENT

Comms, marketing, & design expertise; Engagement coordination & community partners network

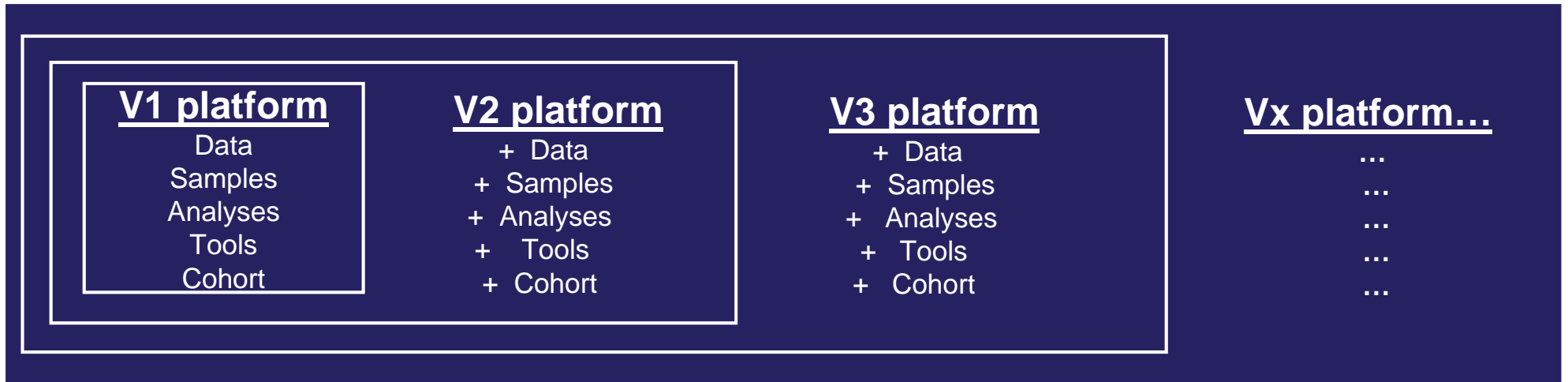
Wondros, HCM, future awards to grow network of community partners

All of Us Research Program Data

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

- Participant questionnaires
- Electronic health records
- A baseline physical evaluation
- Biospecimens (blood and urine samples)
- Mobile/wearable technologies
- Geospatial/environmental data

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



All of Us Research Program Participant Activities



1. Learn



2. Discuss



3. Enroll &
Consent



4. Questionnaires



5. Physical
Measures



6. Bio-Samples



7. Lifestyle &
Health Data
Contributions



8. Research
Projects &
Publications



9. Return of
Information



10. Duration

Two Methods of Engagement



DIRECT VOLUNTEERS



**HEALTH CARE PROVIDER
ORGANIZATIONS**

Build direct volunteer capacity

- **Vision:** Make it possible for anyone, anywhere in the country to participate in biomedical research.
- **Where we are:**
 - Built a network of partners
 - Reach of 37,000 facilities or providers covering 97% of US ...but we cannot fully staff all at once.
- **Question:**
 - How can this approach become a national resource independent of *All of Us*?
 - What decisions or choices do we need to make now to facilitate this over time?



WONDROS



WebMD



vibrent



VANDERBILT
UNIVERSITY

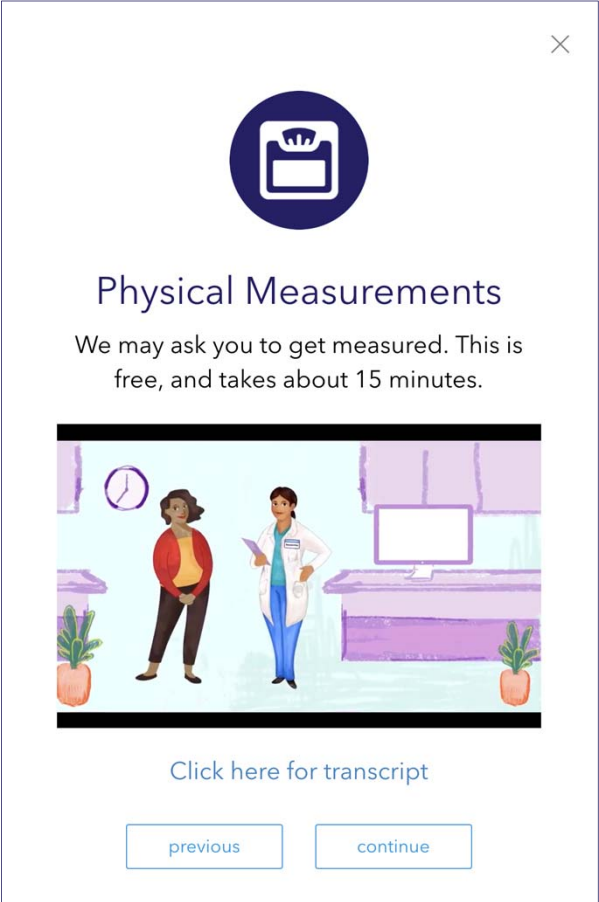


patientslikeme®



Consent / e-Consent

- Recruit 18+ years old initially; kids plan in Q1
- eConsent or paper long-form
- 6th grade reading level; English & Spanish initially
- eConsent process includes modules on:
 - Participant Provided Info (PPI) + Linkage + Re-contact
 - Physical Measurements (PM) + Biospecimen
 - Sensors or wearable devices
 - EHR
 - Genetic information
- Videos expand on key concepts
- Separate opt-in & signature for some modules, including EHR and genetics (state laws)



The screenshot shows a digital consent interface. At the top right is a close button (X). Below it is a dark blue circular icon containing a white medical clipboard with a crown on top. The main heading is "Physical Measurements". Below the heading is the text: "We may ask you to get measured. This is free, and takes about 15 minutes." Underneath this text is a video player showing an illustration of a doctor in a white coat and blue scrubs talking to a patient in a red jacket in a clinical setting. Below the video player is a link: "Click here for transcript". At the bottom are two buttons: "previous" and "continue".

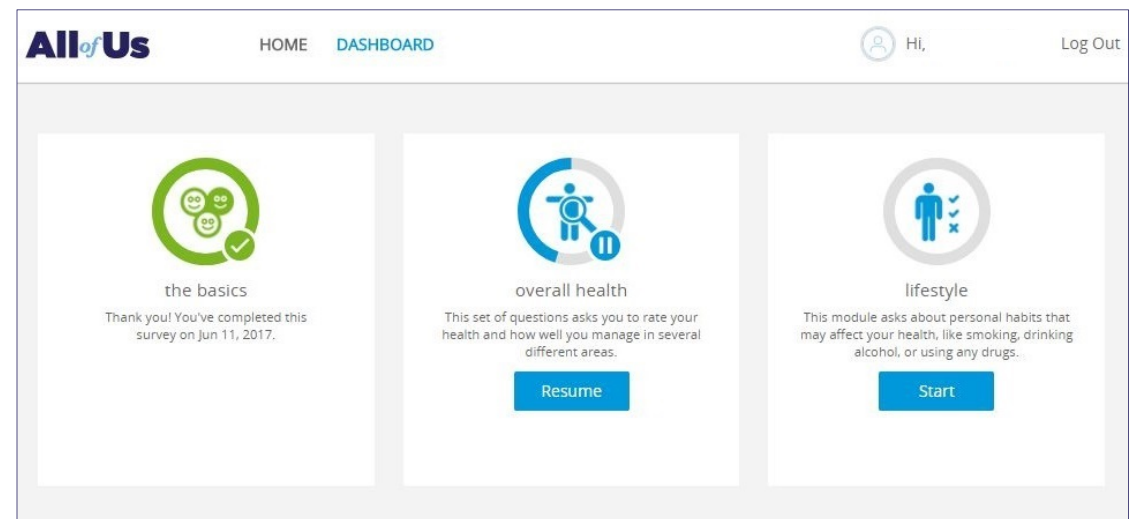
PPI/Survey Modules for Launch

PPI Enrollment Surveys

1. The Basics
2. Overall Health
3. Lifestyle

In Development (++)

4. Personal Health History
5. Medications
6. Family History
7. Health Care Access and Utilization
8. Sleep
9. Environment/exposures



Physical Measurements

Physical Measurements

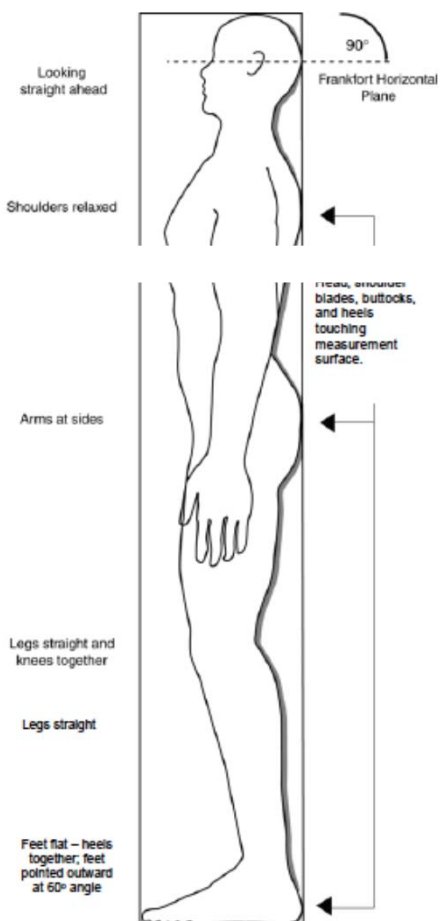
- Blood pressure
- BMI
- Heart rate
- Height
- Hip circumference
- Waist circumference
- Weight

Biospecimen Collection

- Blood (or saliva)
- Urine

Participants will have access to their physical measurements through:

- The Participant Portal
- In Writing



All of Us

Thank you for taking part in the *All of Us* Research Program. By sharing your information, you're helping shape the future of health care. This form has your physical measurements from your visit today.

Date of Visit: _____

Height: _____ Weight: _____ Body Mass Index (BMI): _____

Hip Circumference: _____

Waist Circumference: _____

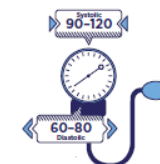
Blood Pressure (Systolic/Diastolic): _____ / _____

Heart Rate (Beats per Minute): _____

Adult Body Mass Index (BMI) Groupings:



Normal Blood Pressure Range:



Normal Heart Rate Range:



You will see blood pressure and heart rate information on the right. This is to give you a broad sense of what is thought to be "normal" for an average person. Your "normal" may be different from this for many reasons. These reasons may include your age, level of fitness, and general health. Concerns or questions about your measurements? Please speak to your health care provider or contact the *All of Us* Support Center at 1-844-842-2855 or help@joinallofus.org.

The National Institutes of Health offers many resources to help people learn more about heart health. It also has tools to help people maintain a healthy weight.

Visit: <https://www.nhlbi.nih.gov/health>.



Your preliminary findings suggest a potential concern with your blood pressure _____ / _____, or heart rate _____. We recommend an evaluation by a health care provider as soon as possible.

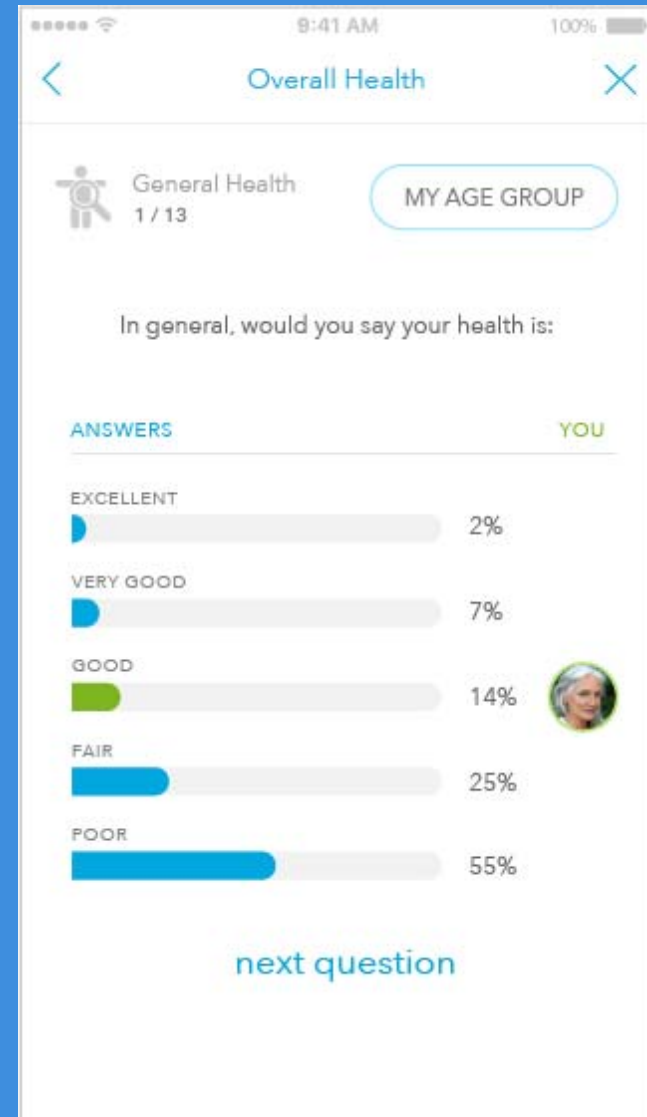
Division: Medicine, National Institutes of Health, All of Us, The All of Us logo, and "The Future of Health Begins with You" are service marks of the U.S. Department of Health and Human Services.

Joinallofus.org

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



Technology to Support Integration of Health Data

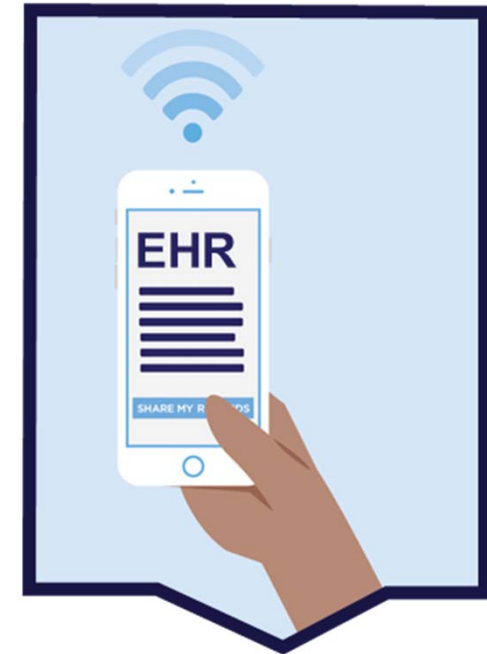
Building capacity for the entire research community:

- EHR data from disparate sources: Sync 4 Science, data aggregators
- Claims data: CMS-NIH collaboration (PCORTF): Medicare Beneficiary Claims Data to Research Studies
- Medications: directly from pharmacies
- Genetic testing reports: Sync 4 Genes, **Sync for Genes** has been created to leverage HL7 FHIR infrastructure for communicating information from clinical genomic labs in a format for universal use across medicine.

Electronic Health Records

- Participants will be asked to authorize linkage of their EHR information.

Initial Data Types	Expanded Data Types (May Include)
<ul style="list-style-type: none">• Demographics• Visits• Diagnoses• Procedures• Medications• Laboratory Visits• Vital Signs	<ul style="list-style-type: none">• Clinical Notes• Radiology, cardiology, and other reports• Mental Health Reports• Substance Abuse, Alcohol use, and Tobacco use• More laboratory results, potentially including genomics



Sync 4 Science Vendor Partners



RUSH MyChart

Allow Access to Your Account

SAS Pilot Prep Demo App wants your permission to access the following information:

- Allergies
- Demographics
- Health Goals
- Implants
- Medications
- Problems
- Immunizations
- Care Team
- Documents
- Health History
- Lab Results
- Plan of Care
- Procedures
- Vitals

Would you like to grant these permissions?

This app was not created by your healthcare organization. Approving this request allows third parties (this app, its developers, and its associates) access to your personal health information which may include HIV/AIDS, mental health, developmental disorder or other sensitive information. Note that these third parties might not be obligated to protect your health information under the same privacy regulations as your healthcare providers and some apps might use data for advertising or other secondary purposes. Review this app's Terms and Conditions to be sure that you are comfortable with the app's use of your data before granting access.

Keep me logged in to MyChart

ALLOW ACCESS **DENY ACCESS**



Personal Health Information Sharing

You have signed into the **Community Health Center, Inc.** patient portal to approve sharing your personally identifiable health information (including Protected Health Information as understood under the HIPAA law) maintained at **Community Health Center, Inc.** with a third party, the **Pilot Prep Demo Research App** via their research application.

You will first be asked to confirm:

Tyler Test the person whose personally identifiable health information would be shared

Community Health Center, Inc. the organization that maintains the information

Pilot Prep Demo Research App the third party that would receive the information

for how long any new information would be shared

the type of information that would be shared

You will then have the opportunity to review what you confirmed before you would approve sharing your personally identifiable health information.

[Read More](#)

Don't share my health information Initiate Health Information Sharing



Authorization Needed

I, ZTEST, MONIQUE, (Not you? [Sign out](#)) request that University of Missouri Health Care (UNIV_MO - P810) share the following health information with Pilot Prep Demo Research App.

University of Missouri Health Care (UNIV_MO - P810) will share this information for 10 minutes:

- personal information
- immunization records
- conditions
- allergies and intolerances
- procedures
- ...

[View full list of information.](#)

The information you share may be subject to re-disclosure. Consult Pilot Prep Demo Research App's terms of service and privacy policy.

I, as the authorized representative, am allowing access to the records of:

- ZTEST, MONIQUE (Self, 125)

[Expecting different people?](#)

Please email me a copy of this authorization.

Clicking **Deny** will not impact treatment, payments for treatment, enrollment, or eligibility for benefits at University of Missouri Health Care (UNIV_MO - P810).

Authorize **Deny**



FollowMyHealth™
QA ENVIRONMENT

You have given permission to **TestApp** to access your FollowMyHealth Account.

TestApp will be allowed to view and download the following data in your FollowMyHealth account:

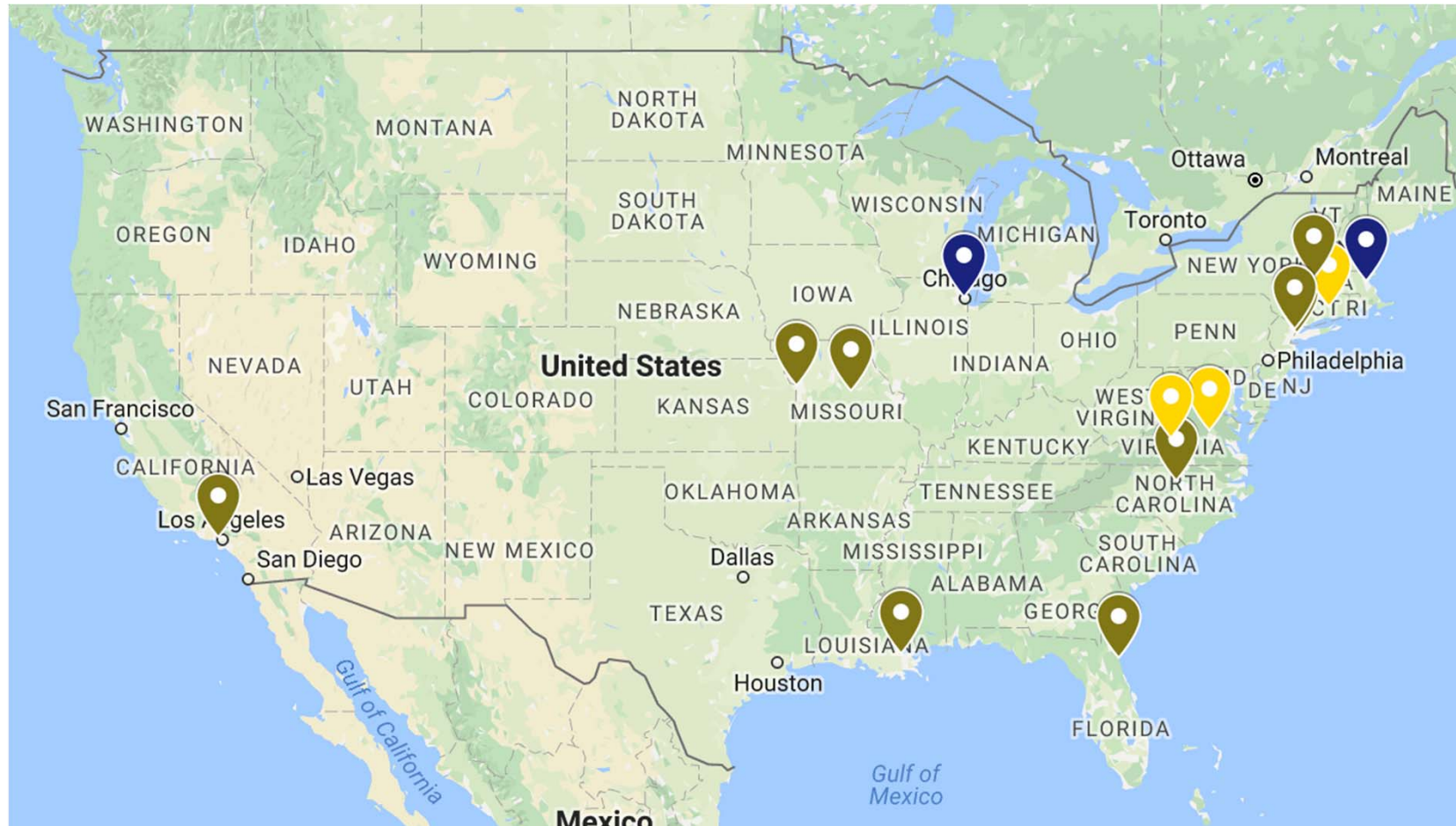
Allergies Medications Demographics Social History Immunizations Results Conditions

TestApp will be allowed to view and download your medical information from the following healthcare organizations:

- Data I entered myself

Close

Sync-4-Science Pilot Sites



Beta Phase, Leading to National Launch Spring 2018

- Currently we have >13,000 participants enrolled at >100 sites
- Through the fall and winter, will enroll ~15,000-25,000 participants
- Test the initial protocol, call center, online tools & interfaces, language of consent & questionnaires, workflow for staff at each location, biobank shipments, etc.
- National launch in Spring 2018

Welcome!

You are one of the very first people to experience the
All of Us Research Program.

Ultimately, *All of Us* will include at least one million people who will share information about themselves for this groundbreaking research program. Developing a research program of this size is not easy. We want to be sure we get it right.

We're still in the early stages of creating the features, tools, and resources we want to have available for all participants. Before we open the program widely, we are enrolling a limited number of people as beta testers. In the meantime, please take a look around the site.

Is there anything you'd like to see that isn't there?
Anything that you found confusing or hard to use? Or that you particularly liked?


Have Feedback?

Feedback button

Look for this feedback button at the bottom right of each screen to tell us what you think.

The website you are about to visit will be updated throughout the beta phase. Please come back to visit again if you get the chance.

Thank you for your help, and welcome to the *All of Us* Research Program!



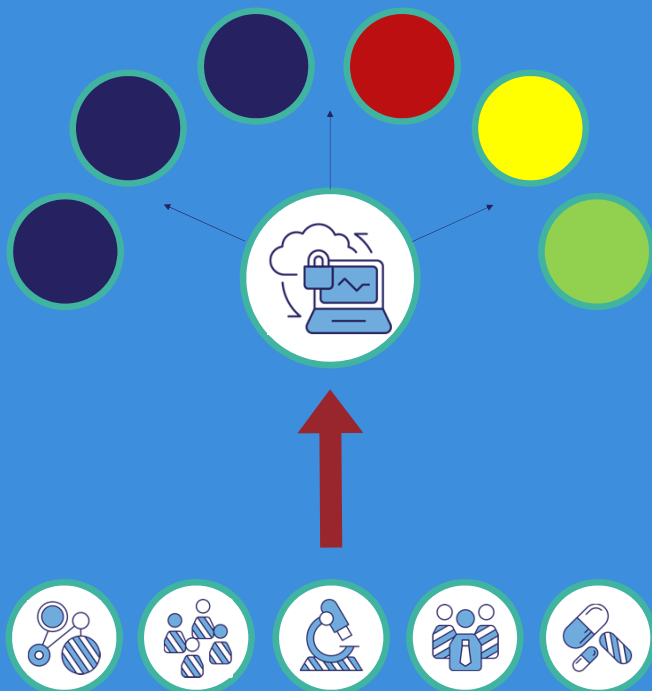
Eric Dishman
Director, *All of Us* Research Program
National Institutes of Health | U.S. Department of Health and Human Services

**Click “We’re in beta” at top of
<https://www.joinallofus.org/>**

Data Access

Work Stations

Public Posting:
researchers
project description
data used
publications



Researcher Based Access

- No data removal
- Tiered access approval
- Data passport model
- Broad access, researchers from all sectors, citizen scientists, etc

Data Passport:

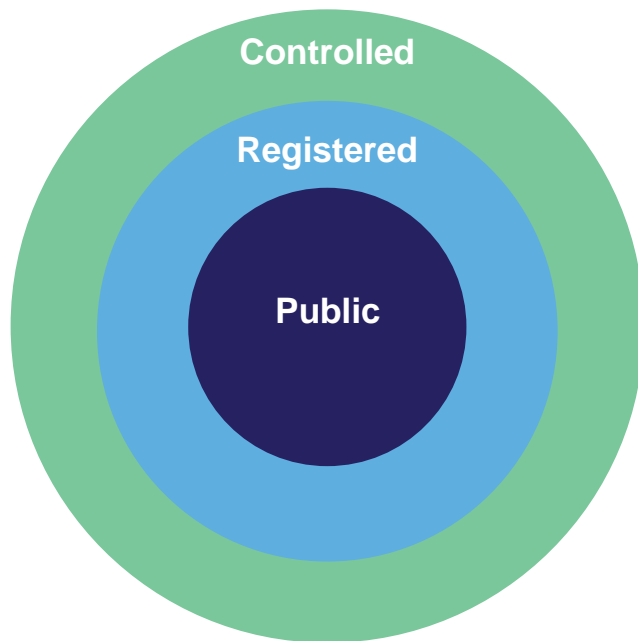
All of Us data is consented for general research use; no specific data use restrictions.

Access to All of Us data resources will be researcher-based, not project-based, manner.

Researchers will be granted “data passports” to access Registered- and/or Controlled-access datasets.

All research uses will be posted publicly (provision in Cures)

Data Tiers



Public - Data that poses minimal risks to the privacy of research participants. Fully open without login.

anyone, anywhere, anytime

Registered- Data that has some risk of identifying research participants and therefore poses some privacy risk to participants.

requires data use agreement, identity verification, ethics training, approval

Controlled - Data that poses more risk to the privacy of research participants.

requirements for registered access + institutional signing official

Engagement Strategy

UNDERREPRESENTED IN BIOMEDICAL RESEARCH
Building Trust
Creating Value within Communities



The Challenges Before Us

- We must **build trust** with participants and providers by being open and honest partners.
- We must **address concerns** and **seek expert advice** on issues such as:
 - Privacy and security
 - How data will be used
 - How vulnerable populations will be protected (e.g. children)



Historical Transgressions in Research

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



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
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 while the study of the disease's effects continues.

HOME / NEWS / LOCAL / MASS.

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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***All of Us* Research Program: Triple Engagement Strategy**



Health Care Provider Organizations

- Regional medical centers
- Federally Qualified Health Center pilot sites
- Veterans Affairs medical centers



Participant Center

Scripps Research Institute leads “direct volunteer” outreach with many partners, e.g.:

- Walgreens
- Blue Cross Blue Shield Association
- National Blood Collaborative
- WebMD



NIH Engagement Partners

- Community and faith-based organizations
- Patient advocacy groups
- Provider associations
- NIH Institutes and Centers

Snapshot of Engagement Activities & Investments



National Network of Inaugural Partners



National Partners

Regional Medical Centers

FQHCs

Community Partners

CII & PII Partners



Meeting People in Their Communities



Providers Are Valued Partners

How You Can Help

- Serve as a resource to patients when they ask you about *All of Us*; help them understand the value of research and what it means for them, their families, and future generations
- Support the *All of Us* Research Program by proactively speaking with patients and with other providers about the program, its value, and goals
- Help patients who enroll to understand the data and information that the program shares with them over time
- Learn more about the program; Become a program Ambassador; Enroll



Scientific Priorities

The *All of Us* Research Priorities Workshop

- **Date and Location:** March 21-23, 2018, in Bethesda, MD
- **Purpose:** Identify key research priorities that will capitalize on the *All of Us* Research Program's one million or more participants to help ensure optimal value for advancing precision medicine.
- **Planning Committee:** Senior leaders across NIH's Institutes and Centers.
- **Workshop Participants:** A broad array of stakeholders (e.g., researchers, participants, professional societies, advocacy groups); by invitation.
- **Outreach Plans:** Obtain substantial input on research questions and requirements prior to the workshop.
- **Updates:** You can subscribe at <https://www.joinallofus.org/news-and-events>



Three Big Questions for the workshop

1. Near Term

What are low-hanging fruit questions/measures for which the scale of *All of Us* could help accelerate knowledge & breakthroughs in precision medicine?

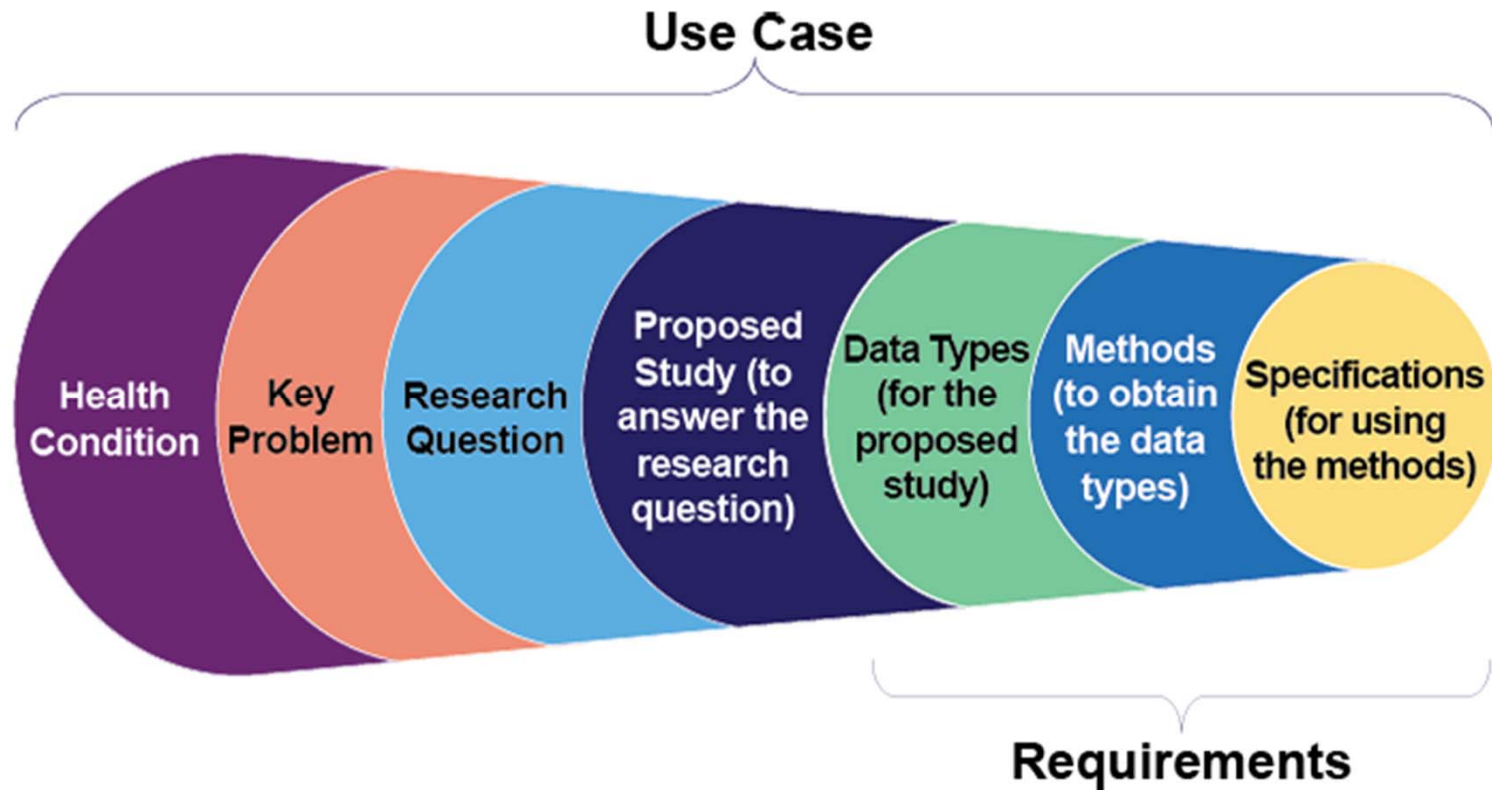
2. Mid-Term

What kinds of questions might this Program answer where additional work selecting among measures/instruments is needed?

3. Long Term

What kinds of questions are ripe for a program of this size but for which we need fundamental science & tech to develop the instruments and methods?

Funnel from broad research areas to specific protocols & instruments



Need research communities to walk through a winnowing down process from research areas to specific elements we can consider for the next protocol.

Crowdsourcing Use Cases -- IdeaScale Webpage

ideascale

register log in

All of Us WELCOME IDEAS FAQ

All of Us RESEARCH PROGRAM | The Future of Health Begins With You

Share Your Ideas

All of Us Wants Your Ideas!

Are you interested in helping researchers understand more about why people get sick or stay healthy? If so, we need your ideas to help make the [All of Us Research Program](#) the best resource it can be to support future research.

<https://allofusresearchpriorities.ideascale.com/>

RPW Webpage -- one-stop-shop for information about the RPW



U.S. Department of Health & Human Services

National Institutes of Health



National Institutes of Health
All of Us Research Program

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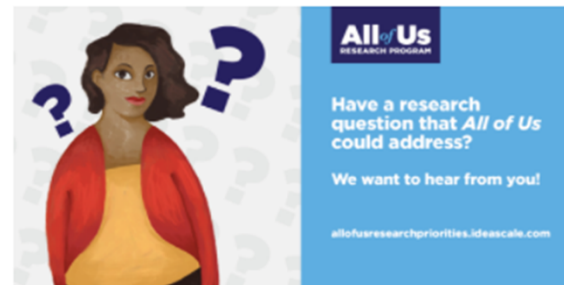
[All of Us](#) > [News, Events, & Media](#) > [All of Us Research Program Seeks Input on Research Priorities](#)

All of Us Research Program Seeks Input on Research Priorities

December 19, 2017

We need your help!

The [All of Us Research Program](#) aims to build one of the largest, most diverse datasets of its kind for health research, with one million or more volunteers nationwide, who will sign up to share their information over time. Researchers will be able to access participants' de-identified information for a variety of studies to learn more about the biological, behavioral, and environmental factors that influence health and



Questions?

Sign up for updates: joinallofus.org
@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.

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  		
Community Partners    	Communication & Engagement  	Platform Development     					