

The *All of Us* Research Program

All of Us
RESEARCH PROGRAM



National Institutes
of Health

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#JoinAllOfUs

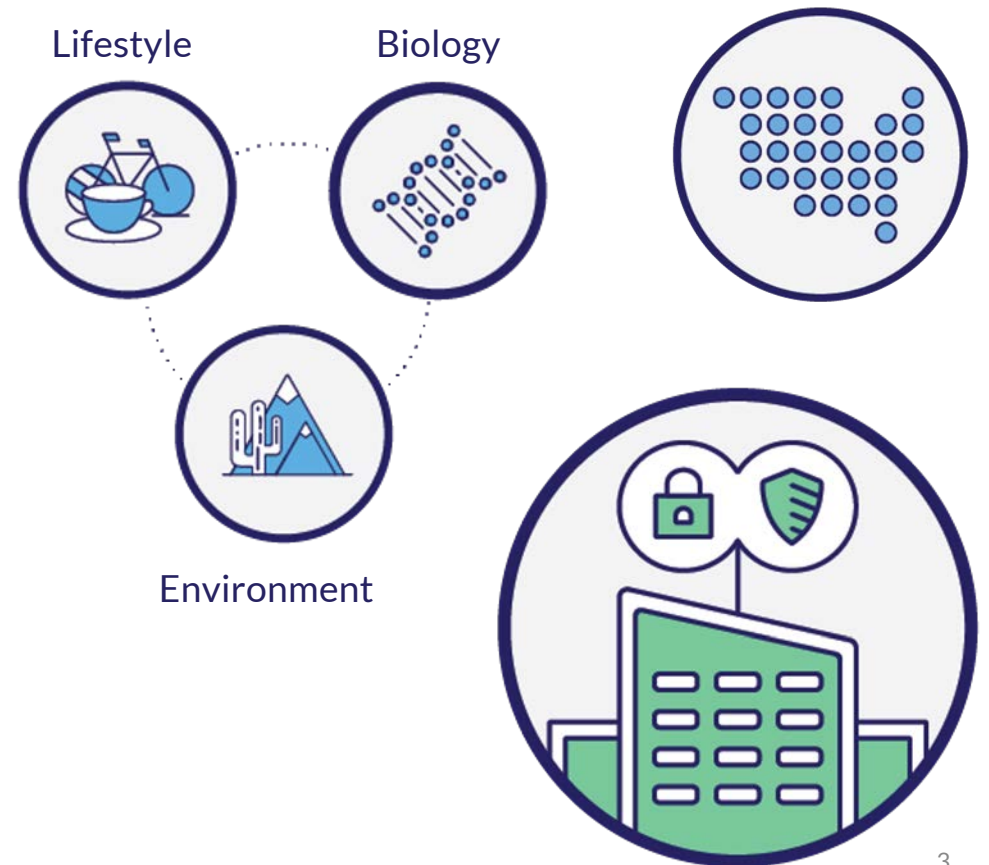
Goals

- Understand the mission, objectives, and scientific framework of the *All of Us* Research Program, and how it connects to PA practice and potential solutions to health concerns in the U.S.
- Learn where to find resources to share with patients and peers about recruitment for the *All of Us* Research Program
- Learn about available tools and data in the *All of Us* Research Hub and basic requirements for access and use

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.



All of Us Research Program Mission and Objectives

Nurture relationships

with **one million or more** participant partners, from all walks of life, for decades

Catalyze a robust ecosystem

of researchers and funders hungry to use and support it



Deliver the largest, richest biomedical dataset

that is easy, safe, and free to access

The All of Us Research Program: An Innovative Research Effort

- Diversity at the scale of 1 million people or more
- Focus on participants as partners
- Longitudinal design, ability to recontact
- Multiple data types: EHR, surveys, baseline physical measurements, biospecimens, genomics
- National, open resource for all: broadly accessible to all researchers with open-source software & tools
- Security and privacy safeguards for all participant data



Why the All of Us Research Program?



People/ Patients

- Patients may not be served well by treatments designed for the “average” patient.
- Many people & populations have been left out of biomedical research, and thus, often left out of health care solutions.
- Health problems can take years to unravel and require much trial and error treatment.
- Patients may not have access to or make use of their own health data.



Professional Providers

- Precision medicine is still in the early days, so providers do not have enough information available to provide precision care for many conditions.
- Developing individualized approaches to care often requires overtime.
- It can be difficult to coordinate care between many different providers, especially with medical records and key data scattered in different silos.



Biomedical Researchers

- Researchers spend a lot of time and resources creating new IT systems, databases, and analytic tools.
- They also face enormous costs & time just to recruit participants.
- Data collection is often not standardized, and data can be siloed and difficult to integrate.
- A single lab's resources may not be sufficient to answer the research questions that matter.

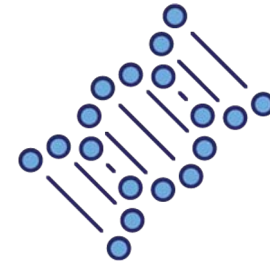
Why now?



We have technologies that can collect and crunch huge amounts of data.



More people are engaged in their health, and can track and share their data – like steps and sleep.



We have a greater understanding of human genes.

The time is right.

Two Methods of Enrollment



HEALTH CARE PROVIDER
ORGANIZATIONS



DIRECT VOLUNTEERS

Current Protocol



Enroll, Consent and Authorize EHR

Recruiting 18+ years old initially; plan to include children in future

Online, interactive consent

Includes authorization to share EHR data



Answering Surveys

- Initial surveys:
- The Basics
 - Overall Health
 - Lifestyle
 - Health Care Access & Utilization
 - Family Medical History
 - Personal Health History

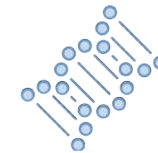
Additional surveys will be released on an ongoing basis.



Physical Measurements*

Blood pressure
Heart rate
Height
Weight
BMI
Hip circumference
Waist circumference

*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

Coming soon:
Integrated apps to track mood & cardio-respiratory fitness



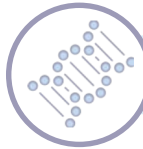
Consent and EHR Authorization



Participant Surveys



Physical Measurements



Biosamples



Mobile/Wearable Tech

- Participants must be 18 years or older
- Online video consent
- Consent process includes authorization to share EHR data with researchers



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



Consent and
EHR Authorization



Participant Surveys



Physical Measurements



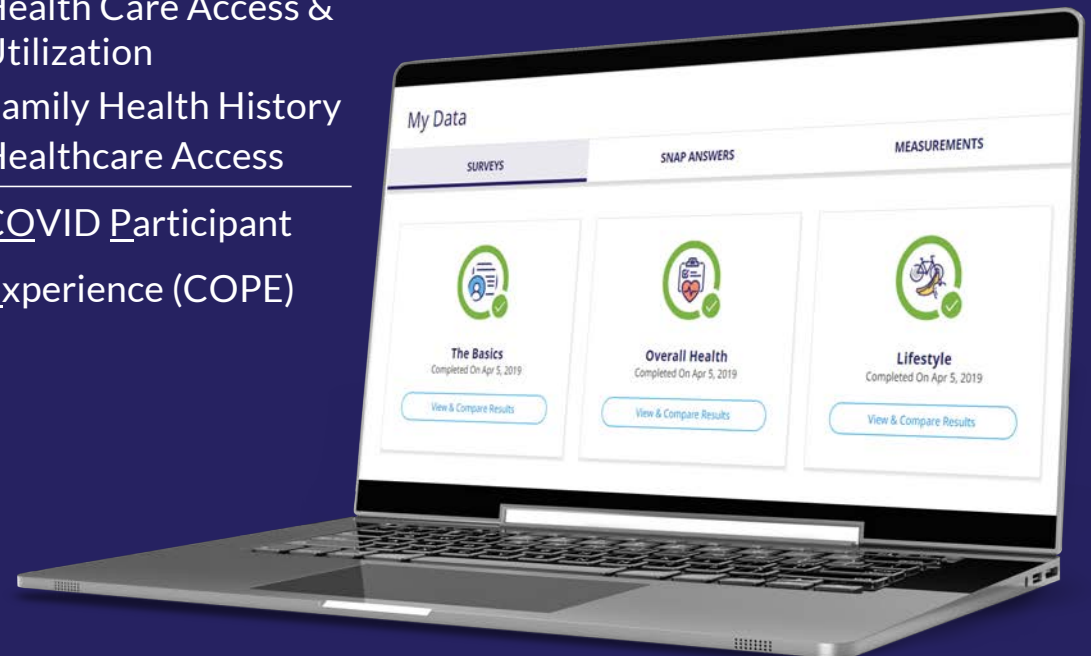
Biosamples



Mobile/Wearable Tech

Current Surveys:

- The Basics
- Overall Health
- Lifestyle
- Health Care Access & Utilization
- Family Health History
- Healthcare Access
- C O V I D P a r t i c i p a n t E x p e r i e n c e (COPE)





Consent and EHR Authorization



Participant Surveys



Physical Measurements



Biosamples



Mobile/Wearable Tech

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

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:

(These apply to both men and women.)

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 1-844-842-2655 or help@jionallofus.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.

Joinallofus.org



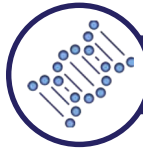
Consent and
EHR Authorization



Participant Surveys



Physical Measurements

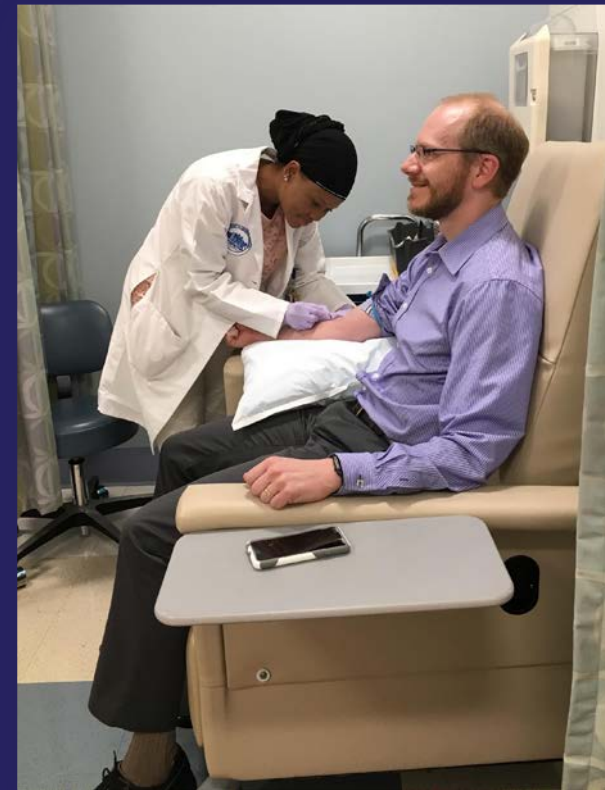


Biosamples



Mobile/Wearable Tech

- Blood
- Saliva (if blood draw is unsuccessful)
- Urine





Consent and
EHR Authorization



Participant Surveys



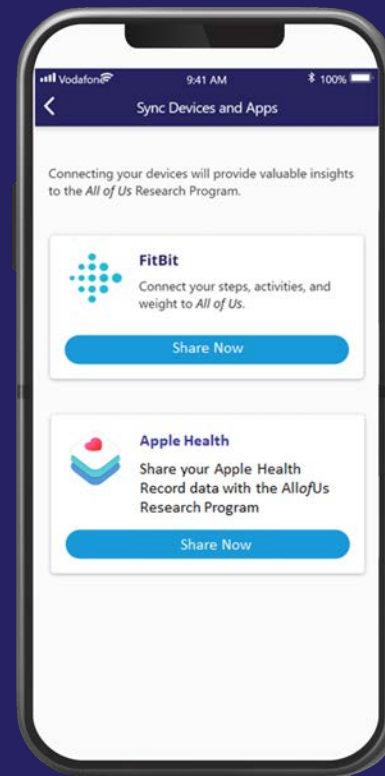
Physical Measurements



Biosamples



Mobile/Wearable Tech



- Data from wearable fitness devices, including Fitbit and Apple HealthKit
- Additional integrations in the future

Genomics Plans

- Infrastructure
 - Three Genome Centers: to generate genotyping & whole genome sequencing for 1M participants
 - Genetic Counseling Resource: to support the responsible return of information to interested participants
- Return of Information

Over time, the program anticipates providing several kinds of information of interest to participants:

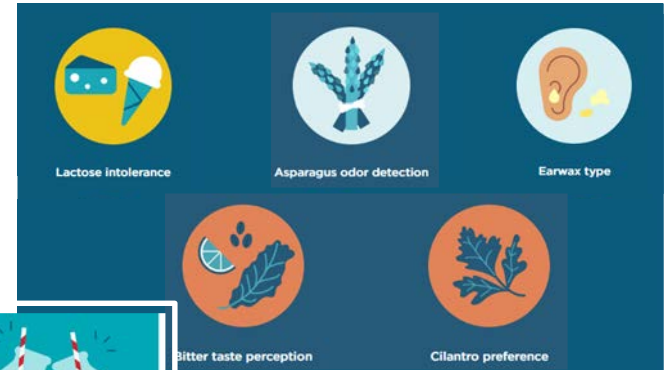
 - Traits and ancestry
 - Drug-gene interactions
 - Genetic findings connected with risk of certain diseases

All of Us
RESEARCH PROGRAM



Genetics Engagement Module (GEM) with Color

Ancestry Analysis



Lactose Intolerance

Lactose intolerance means you have trouble digesting lactose contained in dairy products like milk or ice cream.



Simple Traits

Linda, you are likely to be lactose intolerant.

What we looked at and why

A position in your DNA was analyzed that influences how much lactase your body makes. Lactase is an enzyme that breaks down lactose, a sugar found in milk and other dairy products.

- People who do not experience lactose intolerance produce enough lactase enzyme and are usually able to digest lactose.

DNA marker	Gene	Your result
rs4988235	MCM6	GG

*Each of your parents provides you with a nucleotide at this position, but we don't know which parent gave you

Scientific Framework

Scientific Framework

Enable research that will:

- Increase wellness and resilience, and promote healthy living
- Reduce health disparities and improve health equity in populations that are historically underrepresented in biomedical research (UBR)
- Develop improved risk assessment and prevention strategies to preempt disease
- Provide earlier and more accurate diagnosis to decrease illness burden
- Improve health outcomes and reduce disease impact through improved treatment and development of precision interventions

Current Status

Current Progress

- Opened doors nationally on May 6, 2018
- >271K participants have completed the full protocol, from all 50 states
 - >80% are underrepresented in biomedical research;
 - >50% are racial/ethnic minorities
- Built significant infrastructure to support the program:
 - 100+ academic, VA, FQHC, technology, & community partners
 - 320+ clinics enrolling participants and still expanding
 - Bilingual website, participant portal, app, and call center
 - Biobank with 24-hour shipping process and capacity for 35M+ vials
 - Interactive mobile exhibits that travel the country

All of Us
RESEARCH PROGRAM



Status of the Program

373,000+

Participants

237,000+

Electronic Health
Records

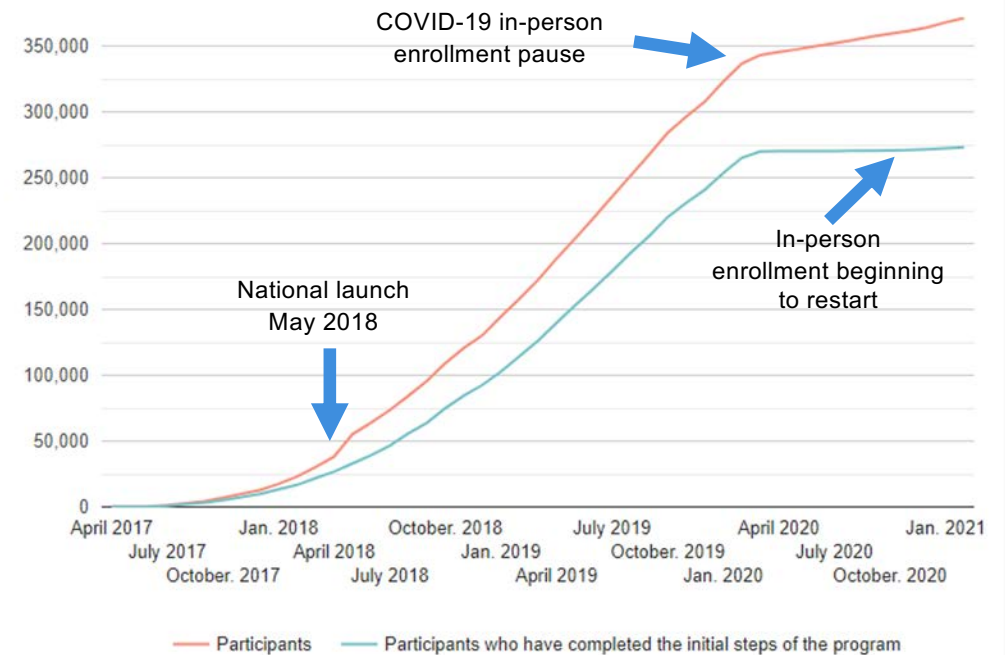
273,000+

Participants who have
completed initial steps
of the program

281,000+

Biosamples

Enrollment Numbers



Our Promise

What is the promise for participants?

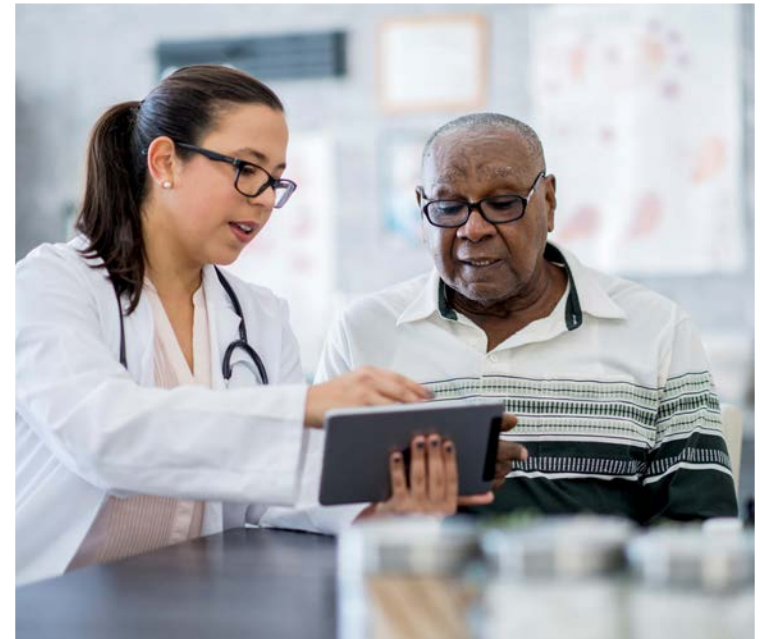
- An opportunity to help fight disease and improve the health of future generations.
- A chance to learn about your own health, including personalized risk factors or exposures.
- The ability and choice to access your own data, including increasingly rich health records.
- An opportunity to ensure that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



Help accelerate medical breakthroughs by sharing information about All of Us with your patients!

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.
 - 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.

Beta testing of our initial dataset and researcher tools began in May 2020.

Research Hub

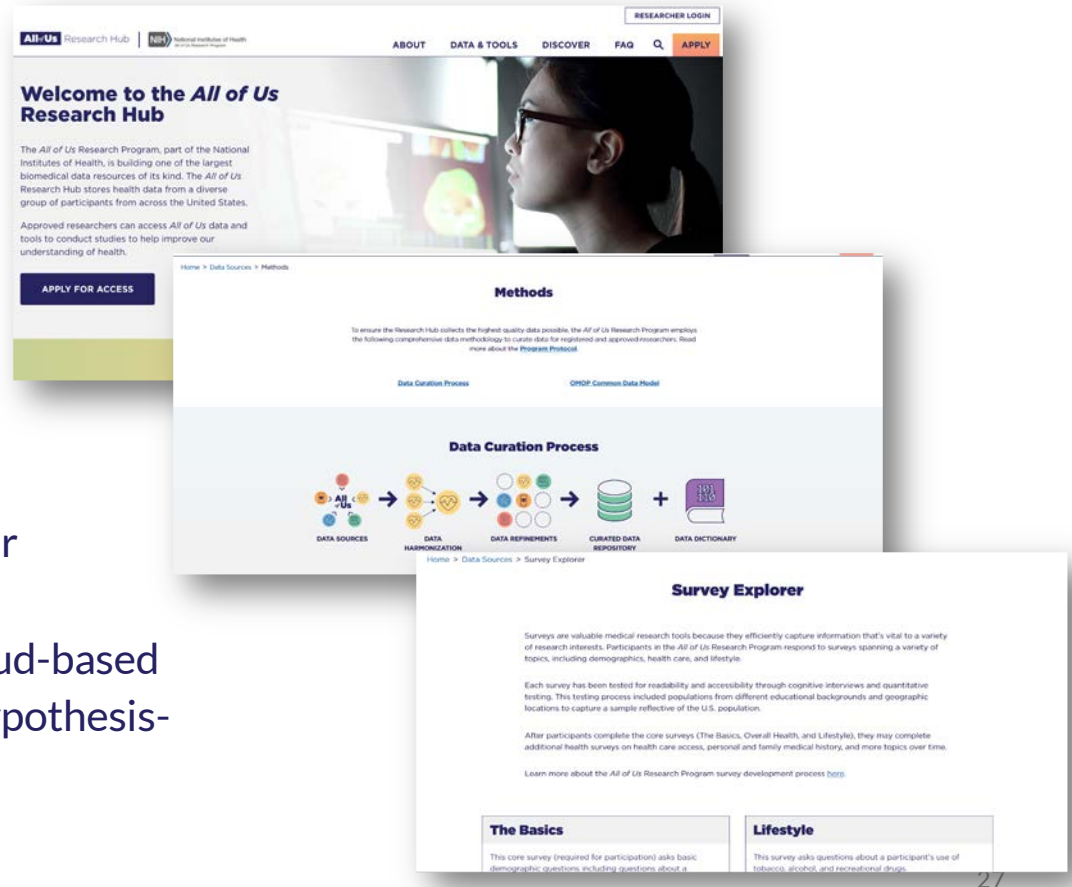
Research Hub Website

ResearchAllofUs.org

Goal: To provide more information around program data and tools

Components:

- Data Snapshots: broad cohort metrics
- Data Browser: interactive tool
- Survey Explorer: source information for participant-provided information
- Researcher Workbench: restricted cloud-based platform designed to execute rapid, hypothesis-driven research



Status of the Program

373,000+

Participants

237,000+

Electronic Health
Records

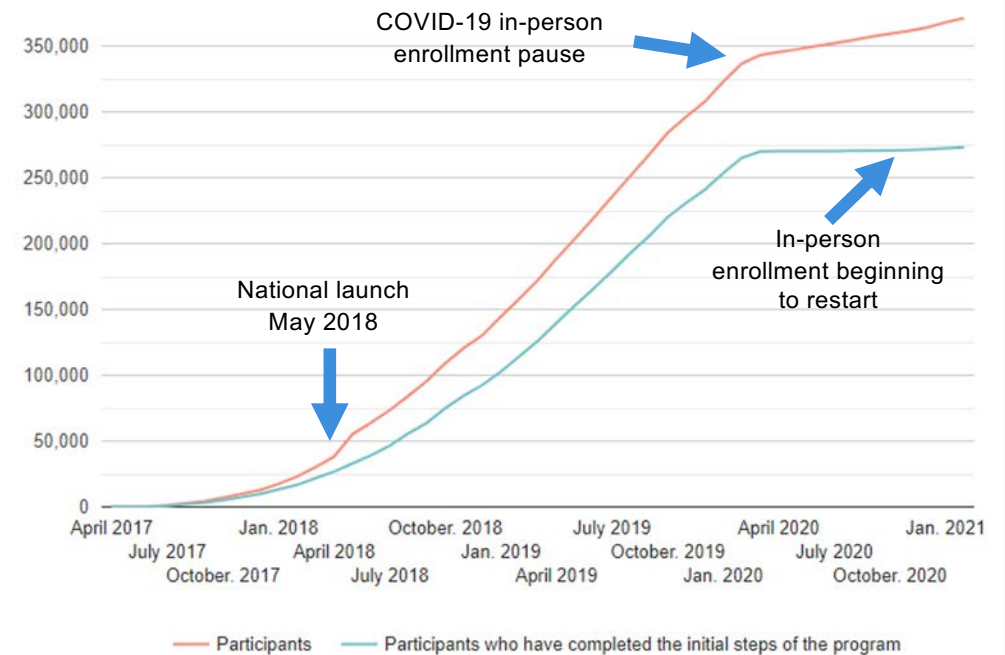
273,000+

Participants who have
completed initial steps
of the program

281,000+

Biosamples

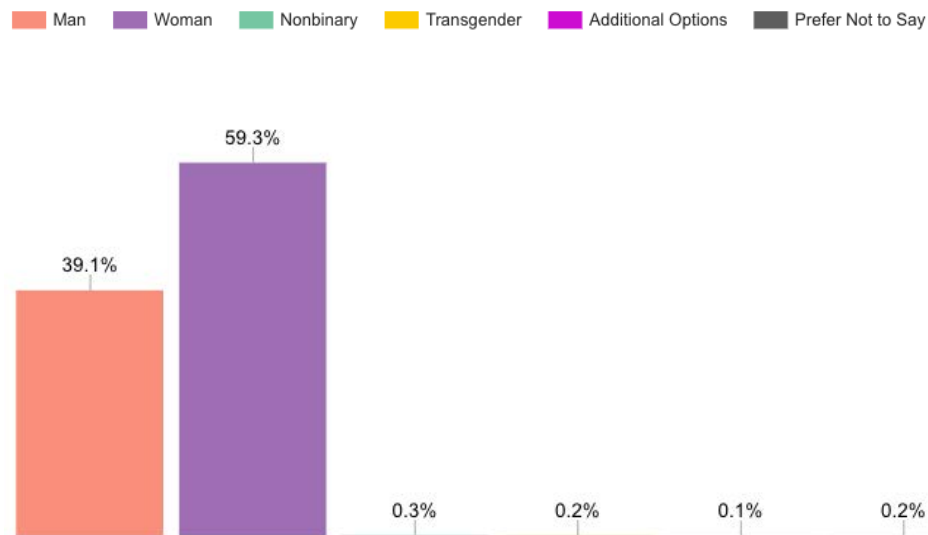
Enrollment Numbers



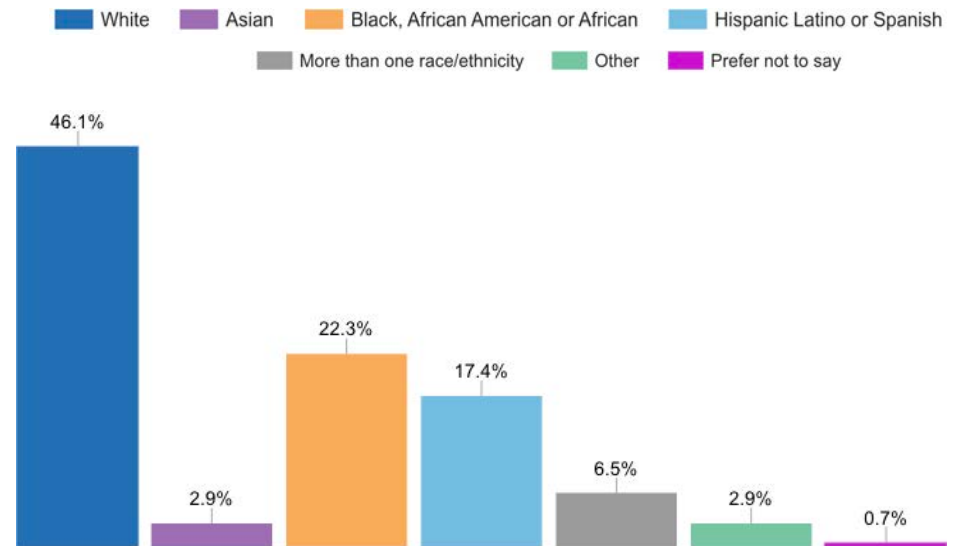
Selected Data Snapshots

(Updated 3/1/21)

Gender Identity



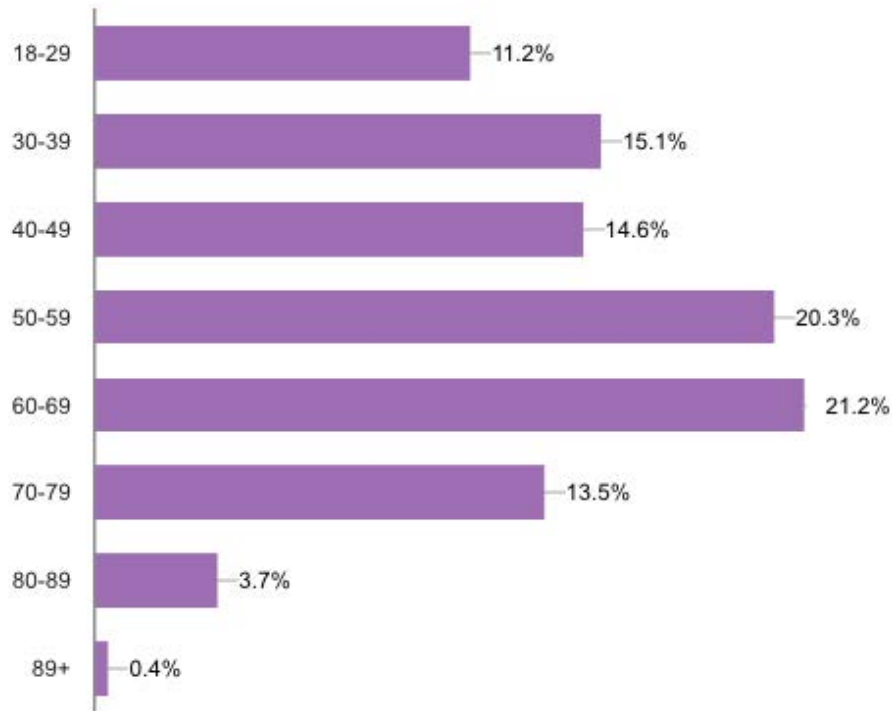
Race & Ethnicity



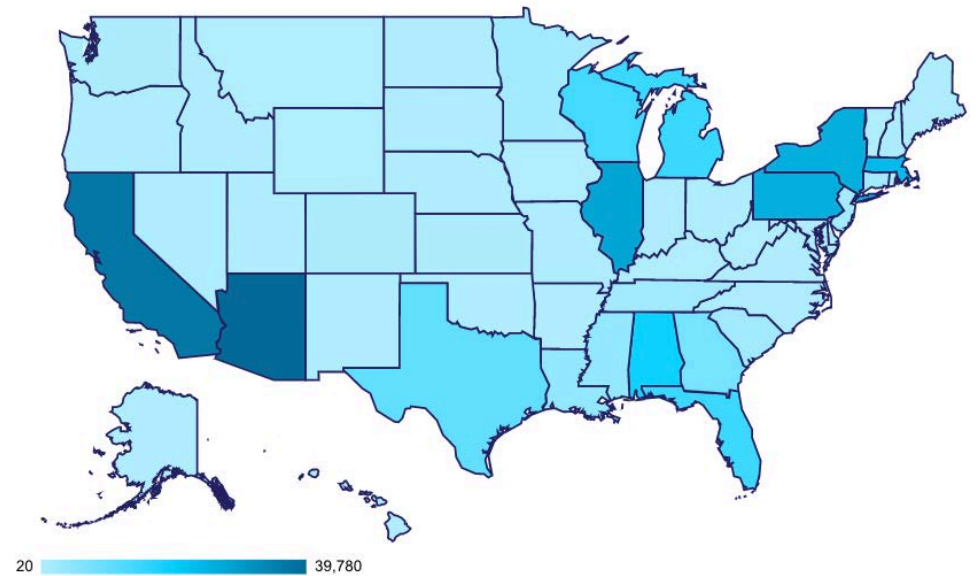
Selected Data Snapshots

(Updated 3/1/21)

Age



Geography



All 50 states
Bilingual enrollment
Interactive mobile
exhibits

A Quick Look at the Data Browser

Search for specific keywords or browse using the different options underneath.

The screenshot displays the All of Us Data Browser interface. At the top, there is a search bar labeled "Search Across Data Types" with a "Keyword Search" input field. Below the search bar, a note states "Data includes 316,760 participants and is current as of 10/1/2020." To the right of the search bar are three icons: a lightbulb for "FAQs", a document with a play button for "Introductory Videos", and a database cylinder for "User Guide".

The main content is organized into two sections: "EHR Domains" and "Survey Questions".

EHR Domains:

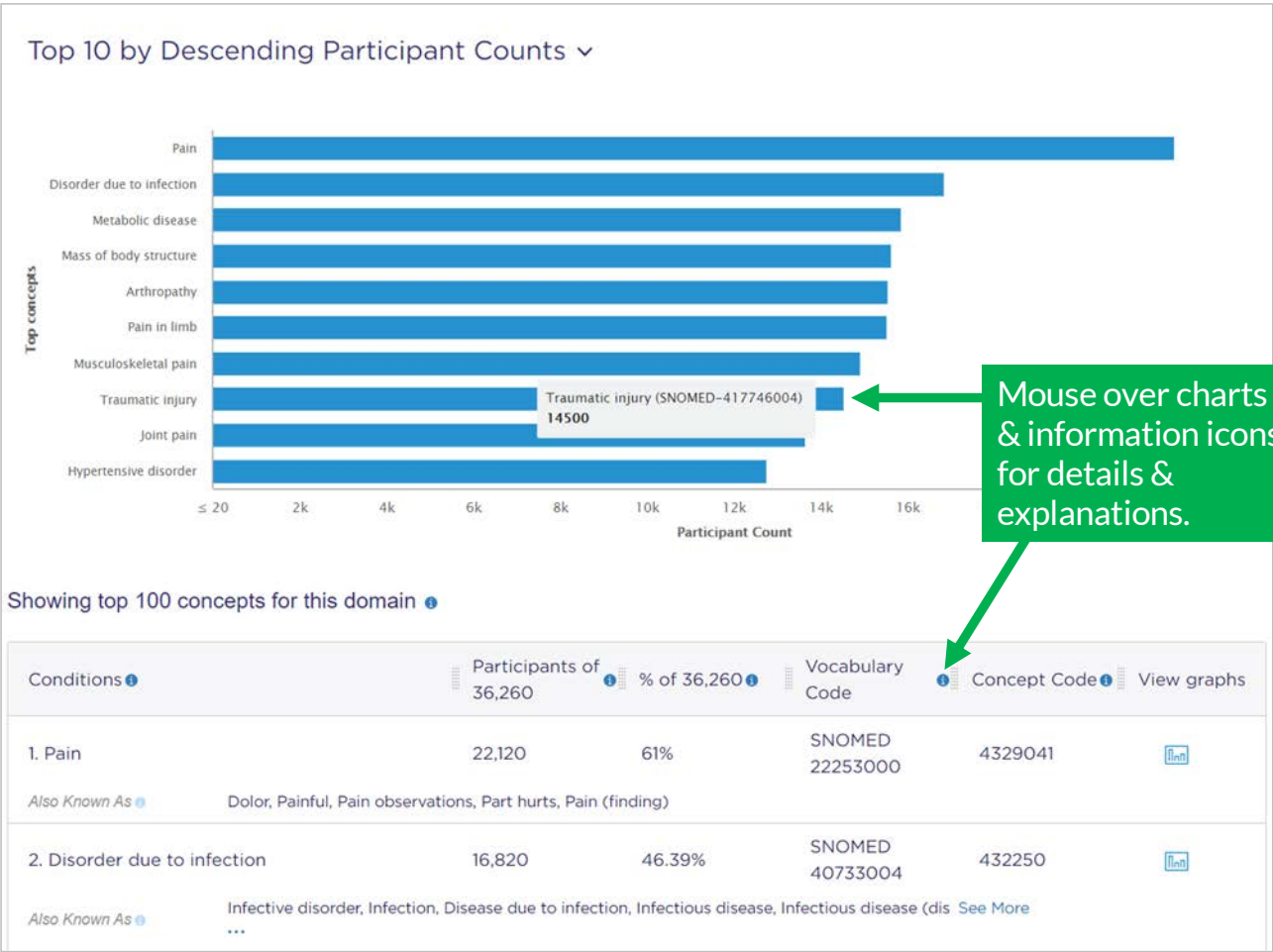
- Conditions:** 24,773 medical concepts, 192,000 participants in this domain. View Top Conditions.
- Drug Exposures:** 27,311 medical concepts, 174,660 participants in this domain. View Top Drug Exposures.
- Labs & Measurements:** 13,631 medical concepts, 182,000 participants in this domain. View Top Labs & Measurements.
- Procedures:** 27,702 medical concepts, 182,000 participants in this domain. View Top Procedures.

Survey Questions:

- The Basics:** 28 questions available, 316,760 participants in this domain. This survey includes participant demographic information. View Complete Survey.
- Overall Health:** 21 questions available, 316,760 participants in this domain. Survey includes information about how participants report levels of individual health. View Complete Survey.
- Lifestyle:** 26 questions available, 316,760 participants in this domain. Survey includes information on participant smoking, alcohol, and recreational drug use. View Complete Survey.
- Personal Medical History:** 465 questions available, 89,640 participants in this domain. This survey includes information about past medical history, including medical conditions and approximate age of diagnosis. View Complete Survey.
- Health Care Access & Utilization:** 57 questions available, 98,940 participants in this domain. Survey includes information about a participant's access to and use of health care. View Complete Survey.
- Family Health History:** 186 questions available, 92,080 participants in this domain. Survey includes information about the medical history of a participant's immediate biological family members. View Complete Survey.
- COVID-19 Participant Experience (COPE):** 151 questions available, 62,920 participants in this domain. Survey includes information about the impact of COVID-19 on participant mental and physical health. View Complete Survey.

Data Browser: Top conditions

Available data gives insight into the participant cohort & research opportunities.



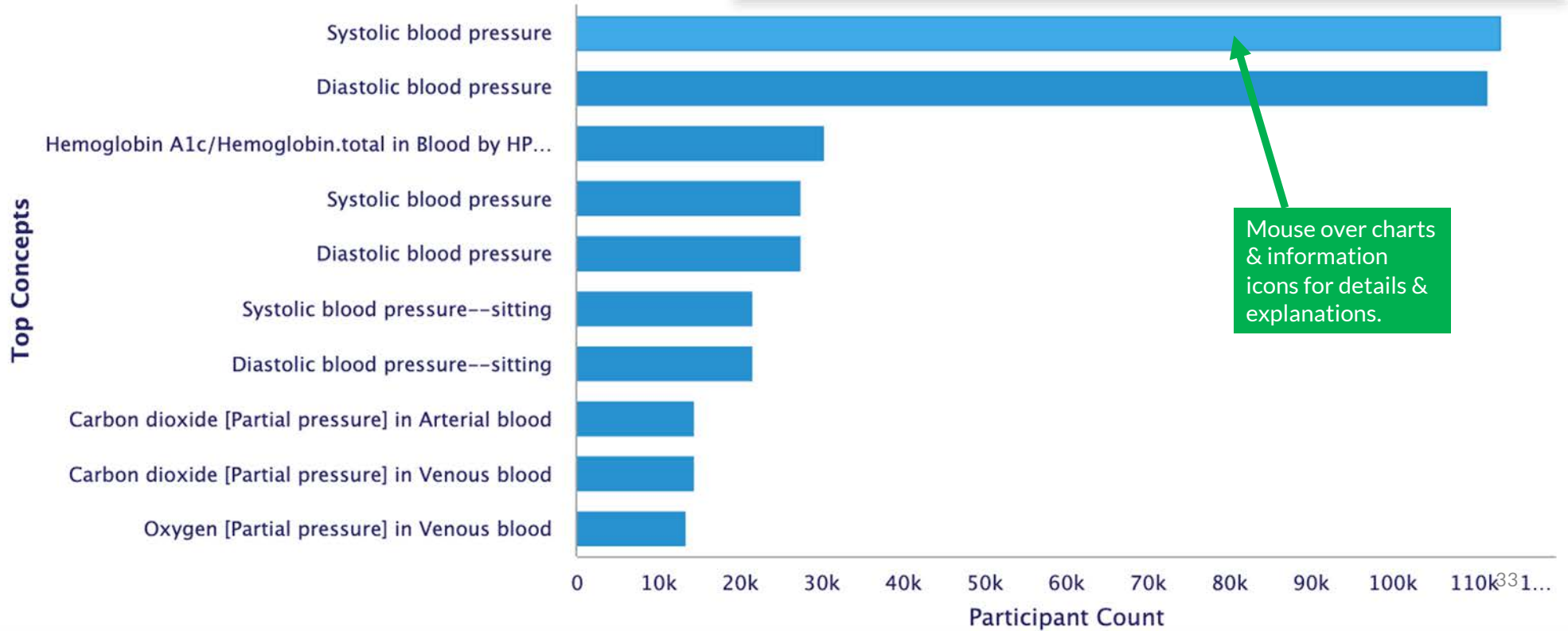
Mouse over charts & information icons for details & explanations.

Example: Blood pressure; Labs & Measurements

Researchers can view all labs & measurements

Top 10 by Descending Participant Counts ▾

Systolic blood pressure (LOINC-8480-6)
Participant Count: **113340**



Mouse over charts & information icons for details & explanations.

Example: COVID-19 Participant Experience (COPE) Survey

Total unique participants

62,920

Participants completed this survey

151

Questions Available

Available data gives insight into the participant cohort & research opportunities.

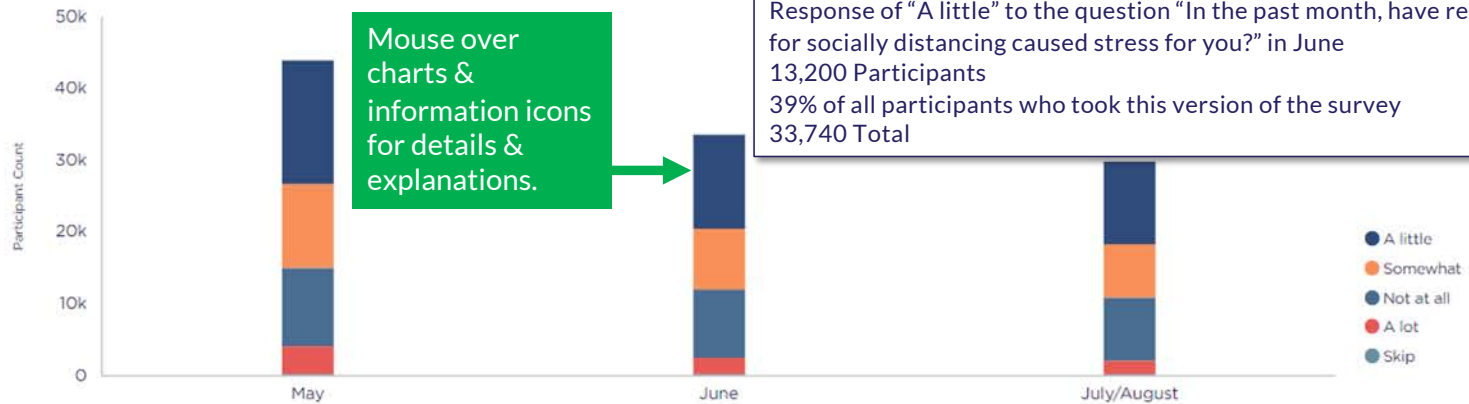
Survey versions

Month	Participants	Number of Questions	Download PDF
May	44080	148	Survey as PDF
June	33700	149	Survey as PDF
July/August	29920	148	Survey as PDF

Download different versions of the survey as PDFs

In the past month, have recommendations for socially distancing caused stress for you?

See Answers



COPE: Explore the survey

The screenshot shows the All of Us Research Hub website. At the top, there are logos for All of Us Research Hub and the National Institutes of Health (NIH). Navigation links include ABOUT, DATA & TOOLS, DISCOVER, FAQ, and an APPLY button. A breadcrumb trail reads: Home > Data & Tools > Survey Explorer > COPE Survey.

Participant Surveys: COPE

The coronavirus disease 2019 (COVID-19) is having widespread and wide-ranging effects on *All of Us* participants and their communities. *All of Us* created the COVID-19 Participant Experience (COPE) survey to learn more about the way the pandemic is affecting people's lives, particularly their mental health. The survey included questions about social distancing, general well-being, mood, stress, and more.

The first COPE survey was offered May 7, 2020. More surveys went out in May, June and July, and stayed up until late September. A shorter version of the survey will be available in November, December, and January.

In the past month, have recommendations for socially distancing caused stress for you? ^

Original source question text
Have recommendations for socially distancing caused stress for you?

From which existing source was this question derived?
CDC COVID-19 Community Survey Question Bank

Year of Original Source
2020

Brief Description
The CDC COVID-19 Community Survey Question Bank, an online resource maintained by the U.S. Centers for Control and Prevention, contains community survey questions made available for use in COVID-19 research efforts.

URL
<https://cde.nlm.nih.gov/formView?tinyId=Kcceysolt>

Left sidebar menu:

- The Basics Survey
- Family Health History Survey
- Healthcare Access & Utilization Survey
- Lifestyle Survey
- Overall Health Survey
- Personal Medical History Survey
- COPE Survey**

Enrollment

Two Methods of Enrollment

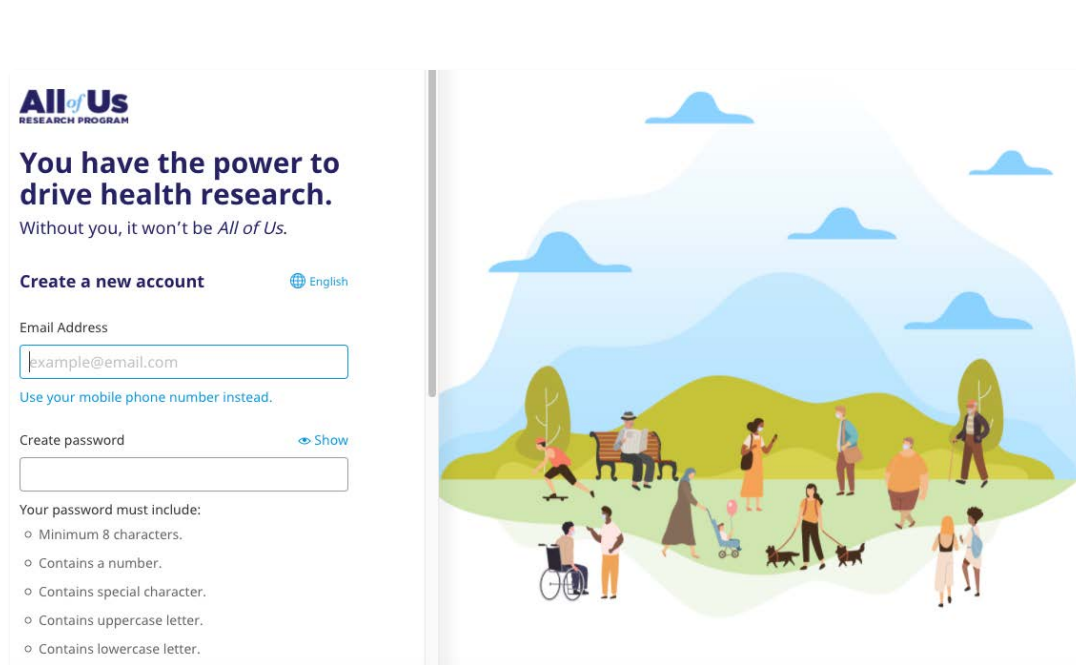


HEALTH CARE PROVIDER
ORGANIZATIONS



DIRECT VOLUNTEERS
Joinallofus.org

Enrolling in and Engaging with All of Us



All of Us
RESEARCH PROGRAM

You have the power to drive health research.
Without you, it won't be *All of Us*.

Create a new account English

Email Address

Use your mobile phone number instead.

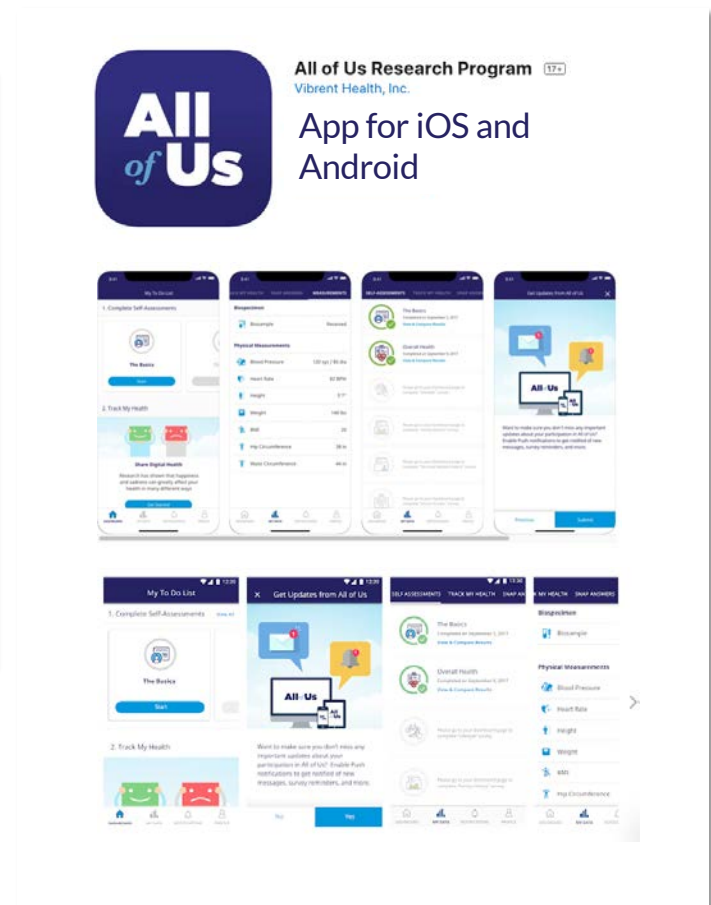
Create password Show

Your password must include:

- Minimum 8 characters.
- Contains a number.
- Contains special character.
- Contains uppercase letter.
- Contains lowercase letter.

The illustration shows a diverse group of people in a park-like setting with mountains in the background. People are engaged in various activities: a person in a wheelchair, a person pushing a stroller, a person walking a dog, a person sitting on a bench, and a person walking with a cane.

joinallofus.org



All of Us
RESEARCH PROGRAM

All of Us Research Program 17+
Vibrent Health, Inc.

App for iOS and Android

The image displays several screenshots of the All of Us app. The top row shows the app's main dashboard with sections for '1. Complete Self-Assessments', '2. Track My Health', and 'Share Higher Health'. The middle row shows a 'Get Updates from All of Us' notification screen. The bottom row shows a 'My To Do List' screen with tasks like 'The Basics' and 'Physical Measurements', and a 'My Health' screen with various health metrics like Blood Pressure, Heart Rate, Height, Weight, and Eye Circumference.

Enrolling in and Engaging with All of Us

Enrollment and Engagement Partners

To reach its goal, the *All of Us* Research Program is partnering with leading institutions, organizations, community partners, and participant representatives across the country.



Health Care Provider Organizations (HPOs)

Learn more about the program and enroll at one of our partnering HPOs, which include regional medical centers, community health centers, and medical centers run by the U.S. Department of Veterans Affairs (VA).



Participant Center

The Participant Center helps people enroll who do not have access to a participating HPO. It also provides information about the program.



Community Engagement Partners

These organizations tell their communities what the *All of Us* Research Program is and how to join. Some of these organizations help health care providers learn about the program.



Champions

All of Us champions support the mission and goals of the *All of Us* Research Program by sharing information on the program with their communities to help raise awareness.

joinallofus.org/enrollment-and-engagement-partners

Health Care Provider Organizations (HPOs)

All participating Health Care Provider Organizations (HPOs), people can learn more about the *All of Us* Research Program and also join. Many HPOs in the program have organized themselves into regional networks known as consortiums. Our HPO network is made up of regional medical centers, community health centers, and medical centers run by the U.S. Department of Veterans Affairs (VA).

Health Care Provider Organizations (HPOs)	Member of	State
Baylor Scott and White Health	Trans America Consortium	TX
Boston Medical Center	All of Us New England	MA
Brigham and Women's Hospital	All of Us New England	MA
Brigham and Women's Faulkner Hospital	All of Us New England	MA
Cedars-Sinai	Cedars-Sinai Medical Center	CA

Community Engagement Partners

These organizations tell their communities what the *All of Us* Research Program is and how to join. Some of these organizations help health care providers learn about the program.

Partner	City	State
Asian Health Coalition	Chicago	IL
Delta Research and Educational Foundation	Washington	DC
Fifty Forward	Nashville	TN
National Alliance for Hispanic Health	Washington	DC
Stanford University School of Medicine	Palo Alto	CA

The Participant Center

People interested in joining the *All of Us* Research Program but do not have access to participating health care provider organizations will be able to enroll online through the National Direct Volunteer Program. The center's role is to help participants enroll across the country, by providing additional community-based enrollment sites, as well as educational information through established collaboration with trusted partners. The center will also seek direct input from participants to design and implement strategies that will keep diverse groups of participants engaged long-term.

Blue Cross Blue Shield Association	Blue Cross Blue Shield Association
Community Blood Center of the Carolinas	Community Blood Center of the Carolinas
DNC Technology	DNC Technology
ENGI Health	ENGI Health
Mortgage Marketing Group	Mortgage Marketing Group

Champions

All of Us champions support the mission and goals of the *All of Us* Research Program by sharing information on the program with their communities to help raise awareness.

Partner	City	State
Alpha Kappa Alpha Sorority, Inc.	Chicago	IL
Alpha Phi Alpha Fraternity, Inc.	Baltimore	MD
Alzheimer's Association	Chicago	IL
American Association of Dental Research	Alexandria	VA
American Association of Kidney Patients	Tampa	FL
American Diabetes Association	Arlington	VA

For more information about our partners please visit: allofus.nih.gov/funding-and-program-partners

All of Us Consortium Members (beyond community partners, as of December 2020)

The Participant Center

<p>HPO Network (Health Care Provider Organizations)</p> <p>California Precision Medicine Consortium (CAPMC)</p> <p>All of Us Wisconsin</p>	<p>RMCs</p> <p>Illinois Precision Medicine Consortium</p>	<p>All of Us New England</p> <p>All of Us Pennsylvania</p>	<p>Trans America Consortium</p> <p>University of Arizona and Banner Health</p>	<p>New York City Consortium</p>	<p>All of Us Southern Network</p> <p>FQHCs (Federally Qualified Health Centers)</p>	<p>All of Us SouthEast Enrollment Center</p>
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<p>Participant Technology Systems Center (PTSC)</p>	<p>Biobank</p>	<p>Data & Research Center (DRC)</p>	<p>Genomics Partners</p>
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All of Us Consortium Members (beyond community partners, as of December 2020)

The Participant Center



HPO Network (Health Care Provider Organizations)



Participant Technology Systems Center (PTSC)



Biobank



Data & Research Center (DRC)



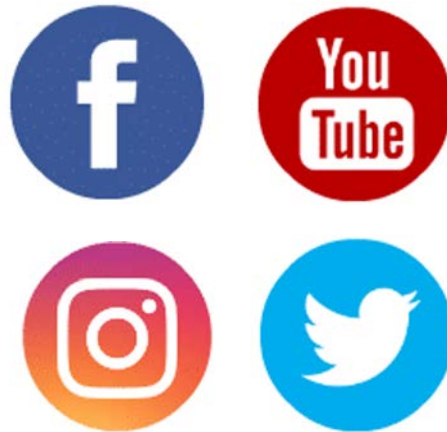
Genomics Partners



For more information...



ResearchAllofUs.org
(includes the Data Browser)
JoinAllofUs.org



@AllofUsResearch
#JoinAllofUs



National Institutes
of Health

AllofUs.nih.gov

It takes All of Us...

