

All of Us program bringing diverse populations to health research

Research program marks first anniversary
Americans stepping up to share their health data with All of Us

ANA PAVON COULD NOT FIGURE OUT why her 5-year-old son was acting strangely. In 2011, he developed jerking motions, facial tics and sometimes shouted uncontrollably. After seeing many doctors over weeks, he was diagnosed with Tourette syndrome.

Her son's trial-and-error medical experience motivated Pavon to join the All of Us Research Program, one of the largest and most diverse research cohorts in the nation. The Leesville, California, resident, who is Hispanic, hopes the nationwide program might one day improve health care for Hispanics and other U.S. populations underrepresented in medical research, including people with Tourette syndrome. She now serves as a participant ambassador for the program, sharing her experience.

"I know to do this, we must be included in research," Pavon said at a May event marking the first anniversary of the All of Us Research Program. "Our population is different. Our health needs are different. We need to participate."

Launched in May 2018 by the National Institutes

of Health, the All of Us Research Program hopes to have 1 million people in the U.S. take part in an unprecedented biomedical research program. As of May, over 192,000 people across America had started the process of joining, and over 142,000 had completed all of the initial steps.

All of Us participants provide medical information to ultimately improve health outcomes and ways of preventing and treating chronic illnesses and diseases for millions of people. The research program embraces precision medicine, which aims to treat individuals based on their unique diversity and medical history. It uses

advances in genomics, state-of-the-art methods to manage and analyze large datasets, and health information technology to improve biomedical discoveries for all people.

"The goal is to help speed up medical research and usher us into this new era of precision medicine, where prevention and treatment are no longer one-size-fits-all, but tailored to the individual," NIH President Francis Collins, MD, PhD, said at the May event. "Too often, such diverse communities

have been left out of the research, and therefore left behind when cures are discovered. So All of Us aims to make a profound commitment to



Photo courtesy NIH/All of Us

About 80% of people who have completed initial signup are from underrepresented groups.

understand and chip away at those vexing health disparities."

So far, 80% of participants who have completed signup are from groups underrepresented in medical research, All of Us Director Eric Dishman told *The Nation's Health*. Racial and ethnic minorities, seniors and people with disabilities are part of the diverse demographic.

"They just haven't been included in the science, and they are often not included in the cures," Dishman said.

High participation from underrepresented groups, more than half of whom are racial and ethnic minorities, has happened in large part because of the program's community partners across America. Hundreds of partners and thousands of people have increased awareness and educated the public about All of Us.



Photo courtesy FiftyForward

In April, members of FiftyForward Donelson Station in Nashville, Tennessee, learned about the All of Us program from FiftyForward peer ambassador Delois Caldwell, right.

Groups use connections to build trust Partners leading All of Us enrollment in communities

INFORMATION ON THE HISTORIC ALL OF US Research Program is reaching people across the country, thanks to local engagement partners and their longtime ties to the communities they serve.

"The work of All of Us — to partner with diverse groups of people to improve the health of future generations — that really spoke to us," said Kelsey Mahaffey, All of Us project director at FiftyForward, which serves older adults and seniors in the Nashville, Tennessee, area.

FiftyForward is one of nearly three dozen official All of Us community engagement partners working to educate and enroll people in the study, which aims to gather data from at least 1 million people for a decade to help speed up health research and medical breakthroughs.

Since its official launch in May 2018, 142,000 people have completed the initial protocol of All of Us, a program of the National Institutes of Health, with 80% of those enrollees representing communities historically underrepresented in research, including over 50% from racial and ethnic minority groups. Gathering a cohort that represents the

diversity of the U.S. population is a driving force behind All of Us recruitment work, which ranges from workshops to webinars to peer ambassadors.

In Dearborn, Michigan, the Arab Community Center for Economic and Social Services, an All of Us community engagement partner, recently partnered with Detroit-based Henry Ford Health System to host pop-up clinics where visitors could learn about and enroll in the program.

APHA member Farah Erzuouki, MPH, the center's public health manager, said All of Us is an important opportunity to engage communities that have historically been left out of and underrepresented in health research. In fact, she said the chance to "be counted" is often a compelling recruitment message during outreach events.

"When we heard about All of Us, we knew the



Image courtesy NIH/All of Us

Launched in 2018, the All of Us Research Program is working to recruit at least 1 million people, with a goal of creating one of the largest and most diverse research databases in the nation. As of May, 142,000 people had completed initial signup steps.

All of Us program bringing diverse populations to health research



The future of health begins with you

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Diverse research cohort to spur new insights

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Community engagement partners, such as the American Academy of HIV Medicine, the National Hispanic Council on Aging, the National Black Nurses Association and APHA, help motivate diverse groups to join and remain in the program. Other organizations, such as the Asian Pacific Community in Action and the Personalized Medical Coalition, share program information to help raise awareness.

Partners include regional medical centers, federally qualified health care centers and the Veterans Administration.

All of Us plans to follow participants for more than a decade. With the data, researchers will be able to explore early signs and symptoms of diseases such as Type 2 diabetes and Alzheimer's, comparing individual environmental and biological factors.

Genetic sequencing and family health history can help researchers identify All of Us participants who may be predisposed to Alzheimer's and other forms of dementia.

"By following their lifestyle choices through surveys, wearable devices recording exercise and sleep, diet diaries and potentially microbiome samples, we will be able to see if any of these variables can influence an individual's risk for developing a condition," Collins said.

Cancers, infections and diseases involving mental health, vision and hearing will also be explored, he said.

The data collected can help scientists tackle health disparities, spurring research in prevention that is customized and "tailored to people in different communities, maybe based on where they live or their race or ethnicity," Dishman said.

A diverse cohort will enable researchers to explore why blacks have a higher mortality rate than whites from heart disease, Type 2 diabetes and hypertension, Dara



Photo courtesy NIH/All of Us

The All of US Research Program plans to follow participants for more than a decade to build a robust health database.

Richardson-Heron, MD, All of Us chief engagement officer, told *The Nation's Health*. It could also offer insights into why Hepatitis B is more common among Asian and Pacific Islanders.

"In addition to addressing any of the socio-economic factors at play, greater diversity in research participation could potentially illuminate information and findings that foster enhanced understanding and, most importantly, prevention of health disparities," Richardson-Heron said.

In South Side Chicago, about 250 black men have signed up for All of Us, Robert Winn, MD, associate vice chancellor and director for community-based practice at the University of Illinois Cancer Center, said at the anniversary event.

"The program matters because it is getting people engaged who have not been engaged," he said. "More than science, it's about the health of the nation."

Nora Volkow, MD, director of NIH's National Institute on Drug Abuse, said that All of Us is expected to reveal data that could help tackle America's opioid crisis.

In the U.S., 12 million people misuse opioids and 2.4 million have an opioid use disorder, Volkow said. The trajectory of addiction usually

begins with chronic pain, followed by reliance on opioid pain medications, with some users transitioning to heroin. Rural residents, people in poverty, people with public health insurance or who are unemployed or women are among those with a prevalence for chronic pain, she said.

All of Us may help identify environmental and genetic factors, which are currently poorly understood, that lead to better prevention and treatment strategies for specific populations,

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— Robert Winn

Volkow said.

The research program is also a springboard for global research. The data will eventually be available for cross analysis with other studies and cohorts. Also, other science research projects will be able to use the All of Us platform, benefiting from the program's work.

Meanwhile, a host of safeguards have been created to make sure the All of Us data is stored reliably and participants' identities are protected. Data are encrypted and direct identifiers of participants are removed. Also, participants can opt out of the program at any time.

On May 6, All of Us announced the launch of its interactive public data browser, offering a first look at the data from participants.

The ResearchAllofUs.org website provides summary statistics from the program's growing database. Anyone can log in to see the data, from researchers to participants to the general public.

In winter, All of Us plans to launch a platform currently referred to as a research workbench, which one day is expected to be one of the world's largest and most diverse datasets for precision medicine. Analytical tools are being developed to help researchers make sense of the data.

"It will be a rich dataset of clinical, social, behavioral and environmental data at an unprecedented scale," Dishman said.

Eventually, All of Us will include data from children, which excites Tina Cheng, MD, MPH, pediatrics director at Johns Hopkins University School of Medicine.

"With advances and biomedical sciences, biotechnologies and bioinformatics, there is tremendous potential in harnessing big data from well-designed cohort studies starting early in life to understand underlying causes of pediatric disorders and early-life antecedents of adult chronic disease," Cheng told *The Nation's Health*.

As the program develops, NIH will hold additional workshops to discuss scientific opportunities in more detail and chart future research. In five years, the cohort is anticipated to near 1 million participants, Dishman said, with data from half fully curated.

Dishman expects All of Us to be a model on how to include underrepresented populations in large studies.

"So many groups are coming to us already, saying, 'We want to leverage your protocol and want to combine datasets,'" he said. "So certainly five years out, I think you will find our data combined with other international cohorts. That's the future we are all headed toward."

For more information on All of Us, visit www.allofus.nih.gov. To sign up as a participant, visit www.joinallofus.org. ■

— Mark Barna

Ambitious US study changing landscape of health science

Better health for all through inclusive science research: Q&A with All of Us' Richardson-Heron

Dara Richardson-Heron, MD, is the chief engagement officer for the All of Us Research Program, a long-term federal study dedicated to building one of the largest biomedical datasets in the world. Heron leads efforts to engage 1 million people, including groups typically underrepresented in health science studies. The National Institutes of Health program launched in May 2018, and one year later, 80% of the 142,000 people who have signed up are from underrepresented groups, including over half who are racial and ethnic minorities.

What is the goal of the All of Us Research Program?

To accelerate health research and medical breakthroughs enabling individualized prevention, treatment and care for all of us. That's actually (NIH's) mission as well. And in order to do this, we are creating a research resource of 1 million or more people who will share their health data. This will include answering survey questions, sharing electronic health records and giving biosamples, which currently consist of blood and urine, and also physical measurements. We hope our program will span at least 10 years.

What's really exciting is that the data won't focus on one specific demographic or condition, but it will cover a broad range of conditions and data types. We really want to create a database to serve as a resource to researchers who are studying all kinds of health care questions.

One of our top priorities is to achieve a demographically, geographically and medically diverse participant community by intentionally including those individuals who have historically been underrepresented in biomedical research. That's really a major aim of our program.

What are some of the successes of the project over the first year?

One of our greatest successes is the fact that we currently have more than 140,000 diverse participants who have completed all phases of our research program protocol. And you know, this is really exciting because of those 140,000 participants, 80% represent communities that have been historically underrepresented in research. And of those, more than 50% are from racial and ethnic minority

groups. Participants hail from all 50 states. Already, our program is one of the largest, and certainly one of the most diverse, research cohorts in the nation.

And this success is due in large part to the outstanding work of our more than 100 partner organizations. Those organizations include our community and provider partners who are responsible for increasing awareness about and interest in our program.

We also have what we call our health care provider organizations. And that consists of regional medical centers, federally qualified health care centers and the Veterans Administration, where individuals can complete all phases of the program.

We also have our direct volunteer program — a novel approach where individuals can sign up online and be connected to a location nearby to provide their blood and urine specimens, and also give their physical measurements.

Just this past year, our program partners have held more than 1,500 events in more than 35 states to raise awareness about our program. I personally had the pleasure to speak to more than 60 communities across the country, sharing the great news about our program's progress and really doing my level best to encourage more people to participate so that everyone can benefit from the great work.

Another exciting advancement is we now have more than 300 sites that are collecting physical measurements and samples. And these are run by

our health care provider organizations and our other partners. We are so excited about all the activity and progress that has been made over the past few years.

How is All of Us different from other long-term health research programs?

We have the opportunity to analyze data that is provided by a diverse group of participants so that researchers really may be able to learn new information about the impacts of not only race and ethnicity, but also the impact of lifestyle.

Researchers may be able to use this information to identify patterns and trends that will enable them to learn more about chronic illnesses, and as a result, develop more tailored prevention and treatment strategies, helping all of us to stay healthy longer.

Other large research groups collect limited types of data. They are often focused on a specific disease. But our program will combine surveys, data from electronic health records, blood and urine samples, physical and environmental measurements, information from wearable technologies, like Fitbit, and eventually other data types.

Another way that our program is different is that this data will not only be shared with researchers, but it will also be shared with participants. And of course, participants will have the ability to learn more about themselves, and they will also have choices about how much or how little information they want to receive.



Richardson-Heron

How might this cohort impact prevention and treatment of chronic illness?

A program as diverse as the All of Us Research Program will provide us with the data that truly reflects the rich diversity of the United States. With that information, we can start looking much more closely at illnesses that are currently not well understood, or not effectively being treated in some communities.

Our diverse cohort will enable researchers to identify previously unknown information and trends that might answer questions, such as why do African Americans have a higher mortality rate from chronic diseases such as heart disease, diabetes and hypertension? Why is hepatitis B more common in Asian and Pacific Islander populations? Why do Hispanics have higher rates of obesity than non-Hispanic whites?

And certainly, we are not just focused on disease. We are also focused on prevention. There are some positive things that we see in communities, such as why do Hispanics live longer than other Americans? We want to learn about that resilience gene.

How do you build the trust of underrepresented individuals so they are comfortable taking part in a federal health study? After all, the U.S. has a history of unethical research on minorities.

We are intentionally not shying away from these issues. Instead, we are partnering directly with key stakeholders

who are our trusted community and provider organizations and participant partners.

And we are acknowledging and addressing these realities head-on and sharing the progress that has been made to prevent these historic transgressions and breaches of trust that have happened in the past, such as human subjects protection, education and training, institutional review boards, and other laws and policies that protect human research participants.

But simultaneously, we must share the great news that research has the potential to be a powerful change agent — one with the potential to begin chipping away at the really unacceptable health disparities that we see in many communities.

And certainly at the All of Us Research Program, we are doing our level best, with both our words and our deeds, to make it abundantly clear that we are committed to helping those who have concerns understand that the only way we can learn more about, and hopefully one day eliminate, health disparities, is to have much more robust and diverse participation in research and clinical trials. You really can't have precision medicine for all if all of us aren't reflected in the research. ■

— Interview conducted, edited and condensed by Mark Barna

For more information on the All of Us Research Program, listen to our podcast, which will be online at www.thenationhealth.org on June 28. To enroll in All of Us, visit www.joinallofus.org.



Images this page courtesy NIH/All of Us

The All of Us Journey is an exhibit that travels to communities across the country to educate people about the research program. All of Us also has partner organizations that, as of May, have held over 1,500 events in more than 35 states.

Health providers play important role in All of Us enrollment

WHEN IT COMES to large-scale, longitudinal health studies such as the All of Us Research Program, blood bank donors are the ideal participants, according to David Wellis.

“Our donors are already engaged and they want to help the community,” said Wellis, PhD, CEO of the San Diego Blood Bank. “But the biggest thing we can contribute is diversity. Blood donor populations — not only in San Diego, but across the country — pretty much mirror the diversity of their communities.”

Over the past year, in fact, Wellis reports that the San Diego Blood Bank has enrolled several thousand people in All of Us, a program launched last year to gather health data from at least 1 million people as part of the national Precision Medicine Initiative. The blood bank, a member of the California Precision Medicine Consortium, is among dozens of health care provider organizations nationwide working to enroll All of Us study participants.

In San Diego, the bank has dedicated space for people to enroll and have their biological specimens taken. Their mobile banks are equipped for enrollment, as well, which lets staff engage with residents across the city and even in its more rural outskirts. The partnership is such a good fit, Wellis is now helping blood banks in

Houston and Seattle go online as All of Us enrollers. He said the next big challenge will be sustaining enrollee engagement over the long term.

“A study like this is really about engaging populations as partners in research,” Wellis told *The Nation’s Health*. “It’s really an amazing project — we’re going to learn so much along the way.”

Across the country in Florida and Georgia, a consortium of four health care provider organizations — known as the SouthEast Enrollment Center — had enrolled as of May more than 8,800 All of Us participants, all of whom completed a health visit, survey and provided specimens.

Olveen Carrasquillo, MD, MPH, a professor of medicine and public health sciences at the University of Miami Miller School of Medicine, which leads the southeast consortium, noted that of those enrolled, almost 80% are black and Hispanic and nearly 30% have low incomes. The group’s five-year goal is to enroll 90,000 people.

Initial outreach efforts began inside the University of Miami Health System, Carrasquillo said, where researchers worked closely with clinicians to identify and engage with potential enrollees, noting that the consent process for the study is extremely detailed. More recently, All of Us researchers began accom-

panying clinicians who volunteer in the community. In the future, the researchers hope to partner with local organizations.

“This data is such a gift — it’ll have so many downstream benefits,” Carrasquillo told *The Nation’s Health*.

For more on All of Us health care provider organizations, visit www.allofus.nih.gov. ■

— Kim Krisberg



Image courtesy NIH/All of Us

All of Us posters, like this one written in Spanish, are a way partners are generating interest in the health research program.

Partners work on the ground in communities

PARTNERS,
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stakes were too high not to be involved,” Erzouki told *The Nation’s Health*. “This is the first research program of this scale to include our voices and communities. It could be the first time that we understand, on such a broad level, what our community is facing.”

The center’s engagement activities primarily focus on outreach and education, such as hosting informational events and spreading the word on social media.

More recently, however, the center has been focusing on “bridging the gap between education and enrollment” with events such as the pop-up clinics, Erzouki said. She noted that while the center’s decades-long presence in the community makes it an ideal engagement partner, some people have privacy concerns about having their personal data collected, and so effective messaging should reflect that.

Getting counted is a message that often resonates with rural residents said Laura Hudson, MPA, director of program services and contracting at the National Rural Health Association, an All of Us community engagement partner.

“We want to make sure the populations living in rural places are represented in the All of Us dataset so that their needs can be addressed in the future rounds of research,” she told *The Nation’s Health*.

The association’s efforts are focused on raising awareness among rural health partners nationwide, not on direct enrollment. To date, the association has distributed educational All of Us materials via webinars and electronic newsletters, potentially reaching over 21,000 rural health practitioners and supporters. The webinars include those specifically tailored to the country’s 42 state rural health associations.

Ryan Kelly, executive director of the Mississippi Rural Health Association and Alabama Rural Health Association, both of which received All of Us mini-grants via the National



Photo by Michele Late

All of Us volunteers share information at APHA’s 2018 Annual Meeting and Expo in San Diego. APHA is one of the partner organizations supporting the national research program.

Rural Health Association to drive engagement locally, said that while technology literacy is a challenge for rural enrollment, “it’s a variable that can be overcome with help.” Over the last year, the two state groups have been able to reach thousands of rural residents and health providers with information about the study, Kelly said.

“It was a no-brainer for us,” Kelly said about the associations’ participation. “Anything we can do to help foster more data collection and help find smart policies and ideas to curb negative health outcomes — we certainly wanted to be a part of it.”

In May, the New York State Public Health Association hosted an All of Us information booth at its annual meeting, which welcomed about 250 attendees, including health officials from every county in the state. APHA member Erin Sinisgalli, MPH, MCHES, executive director of NYSPHA, said the outreach event — supported with an All of Us mini-grant via APHA, an official community engagement partner — encouraged visitors to spread the word back in their home communities.

“This is a really exciting project that not only gives people the chance to enroll

themselves, but the chance to be part of something that all of us will be able to use in our public health work,” she said.

FiftyForward was among the first All of Us community engagement partners. Mahaffey said direct, personal interactions typically work best to engage older people.

“It’s a complex program to explain, so we find that the engagement process

takes multiple touch points,” Mahaffey told *The Nation’s Health*.

FiftyForward staff, for example, visit each of the organization’s seven centers every month with laptops and tablets to

provide members one-on-one help with the enrollment process.

Mahaffey said another key outreach strategy has been using peer ambassadors — people ages 50 and older already enrolled in All of Us — to engage with older adults in the community.

“They’ve been absolutely instrumental in this work,” she said. “The idea of leaving behind a legacy — that’s really resonating.”

For more on the work of All of Us community engagement partners, visit <https://allofus.nih.gov>. ■

— Kim Krisberg

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