

## Report on Research Compliance Volume 15, Number 2. February 28, 2018

### National Launch of Landmark 'All of Us' Study Set for Spring; Portal for Researchers to Follow

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By Theresa Defino

Officials with the government's Precision Medicine Initiative, launched in 2015 under then-President Obama, have been quietly building the infrastructure necessary to enroll a million individuals in a long-term study now called the "All of Us" research program. But expect the program to get a lot noisier in the coming months. Now counting more than 11,000 "full" participants, the program is set to launch its national enrollment campaign this spring.

At this point, however, what exactly will be studied is itself under study. Researchers and others are being invited to submit their ideas, and the program will hold a "research priorities workshop" in March "to identify key research priorities and requirements (such as data types and methods) for future versions of the All of Us protocol."

Perhaps in the spring of 2019, All of Us will open a portal just for researchers, Eric Dishman, All of Us director, explained at a recent meeting of the program's advisory panel.

The program is addressing how to "make this data accessible," Dishman said. "We want to expand who's able to do biomedical research. While we're not there yet, all of the work on the researcher portal is happening."

What Dishman referred to as the "unheralded part of these research programs," such as building the platform and conducting "data curation and cleaning," is occurring now, he said.

"You'll hear a lot more in the future about the researcher portal," he added at the Jan. 19 meeting held at NIH. Approximately one hour of the meeting was open and webcast. The advisory group also met in closed session, which a program spokeswoman said was necessary to discuss "confidential information about funding and awards."

All of Us promises to be a unique program for a number of reasons besides the 1 million enrollees, who are referred to not as research subjects but participants.

In addition, the program has its own lingo: people who enroll on their own are called direct volunteers, or DVs; medical systems that are involved both in management and recruitment are known as health provider organizations, or HPOs. Answers to surveys used in the study completed by participants are called participant provided information (PPI).

The program is especially interested in enrolling people who are underrepresented in biomedical research, called URBs for short. All of Us is currently defining this concept with a white paper expected to be published before the national launch, Dishman said.

### Many Universities Participating

Enrollment is occurring in 25 states through 18 "community partners," a number that continues to grow and will

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keep expanding past the national launch date, Dishman said. All of Us is adding sites in locations that aren't represented.

A number of universities and institutions are already involved. Mayo Clinic is serving as the depository for blood and urine samples provided by participants.

Vanderbilt University was selected as the primary data and research center; it is working with Broad Institute and Verily Life Sciences, a subsidiary of Alphabet, the parent company of Google.

In addition, data and research center subawards were made to Columbia University Medical Center, Northwestern University Feinberg School of Medicine, and the University of Texas Health Science Center at Houston School of Biomedical Informatics.

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