

Report on Patient Privacy Volume 18, Number 3. March 31, 2018 'All of Us' Study Set to Launch Soon; Massive Project Will Test Privacy, Security Safeguards

By HCCA Staff

Within the next four years, the National Institutes of Health (NIH) hopes to enroll up to 1 million people in its landmark research program called All of Us. But whether the program meets that goal may depend in large measure on participants' confidence in the security of their protected health information (PHI). To ensure success, All of Us has imposed perhaps unparalleled levels of safeguards and requirements, including 30-day notification in the event of a breach.

All of Us is the new name for an initiative that began under former President Obama called the Precision Medicine Initiative. The HHS Office for Civil Rights (OCR) helped develop the privacy framework that underpins the program and issued related guidance on patients' access to their medical records. OCR also enforces compliance with the HIPAA privacy, security and breach notification rules. Last month OCR announced its second settlement of the year, \$100,000 with a now-defunct document storage and shredding organization (see story, p. 4).

In the fall, NIH began a controlled enrollment in the program. As of February 23, All of Us had more than 16,000 "full" participants who had not only consented to be part of the study but had completed all portions of the protocol, Katie Rush, All of Us spokeswoman, tells *RPP*.

All of Us is set to launch its national enrollment campaign this spring. "We're in the process of finalizing our date for the announcement," Rush says. NIH Director Francis Collins recently told *The Washington Post* the goal is to reach 1 million participants by 2022.

Currently the program has more than 90 "awardees/subawardees in our consortium that support various aspects of the program, from outreach and enrollment to data collection and storage," she says.

Eric Dishman, All of Us director, explained at a recent meeting of the program's advisory panel that the rollout will be "grass-roots" and accompanied by "broad-based invitations," health fairs and similar events. "At that point, we'll unleash...the formal relationships that we have with both the community partners that we've announced."

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