

Report on Research Compliance Volume 15, Number 2. February 28, 2018 OCR Issues Guidance on HIPAA, Research

By Theresa Defino

The HHS Office for Civil Rights (OCR), which enforces HIPAA regulations, has issued new guidance that applies to research involving protected health information (PHI). Specifically, the guidance addresses remote access for activities deemed “preparatory to research” and individuals’ authorization for use of PHI for research.

Guidance on aspects of HIPAA and research presumed to impede research was required by the 21st Century Cures Act, landmark legislation passed at the end of 2016. The act included a host of requirements for federal agencies besides OCR. For example, NIH was required to revamp its process for certificates of confidentiality and develop recommendations to “enhance rigor and reproducibility of scientific research funded by” NIH (RRC 2/17, p. 1).

Working with the Food and Drug Administration and the U.S. Department of Agriculture, NIH is also taking steps required by the act to review regulations governing animal research (see story, p. 3).

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