How is "Research" defined under the HIPAA Privacy Rule?

The HIPAA Privacy Rule defines research as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."[1] For a discussion of how the Privacy Rule applies to research, see our Fast Facts here.

Defining what is and is not research is significant because the rules for collection, use, and exchange of protected health information (PHI) under the HIPAA Privacy Rule vary based on the purpose for which the information is being collected or used, such as for treatment, payment, research, marketing, etc. Some information may be released and used for research that would not be permitted for other activities. For example, PHI could be disclosed in a limited data set with a data use agreement for research purposes (or for public health or health care operations) that would not otherwise be allowed to be disclosed without authorization. A limited data set is PHI from which most identifying information has been removed (including all facial identifiers like name, address, and social security number) but including certain geographic and age information that would have had to be removed from the PHI for it to be fully deidentified. Another important distinction is collection and use of PHI for research versus collection and use of PHI for health care operations, such as quality improvement activities. As long as "the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities,"[1] quality improvement activities are considered health care operations and PHI may be used without authorization. PHI also may be released for research purposes with a patient's valid authorization or IRB waiver.

The definition of research is also significant for crafting and obtaining authorizations for the collection and use of PHI. While a patient's PHI may be used for treatment, payment, and health care operations without separate authorization, a specific notice and authorization is required to use PHI for research. The Privacy Rule identifies core elements and statements that must be included in the authorization, such as the purpose of the requested use or disclosure, the time frame the authorization will be valid, notice of the right to revoke authorization, etc.

Finally, note that only researchers who are covered entities (health care providers, health plans, or clearinghouses) or business associates of such entities under HIPAA are subject to the Privacy Rule. Researchers who are not covered entities or business associates must follow other federal and state laws that govern research activities, such as informed consent requirements and guidelines for the use of human subjects, but they would not be subject to the HIPAA Privacy Rule. Researchers using data pursuant to a data use agreement must comply with the terms of that agreement regardless of their status under HIPAA.

For more information on research rules, see http://www.healthinfolaw.org/topics/68. For more information about HIPAA, see www.healthinfolaw.org/federal-law/HIPAA. Follow us on Twitter at ***@HealthInfoLaw.***

[1] 45 CFR 164.501