In response to a congressional mandate in the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Department of Health and Human Services issued regulations entitled *Standards for Privacy of Individually Identifiable Health Information*. The HIPAA Privacy rule is intended to set minimum national standards for maintaining the privacy and enhancing the security of an individual’s Protected Health Information. This includes all Individually Identifiable Health Information that is in any type of format, either electronic or paper, that is maintained, stored, or transmitted by a Covered Entity. For most covered entities, compliance with these regulations, known as the Privacy rule, was required by April 14, 2003.

The Privacy Rule does not replace or act in lieu of Federal human subject protection regulations. The Privacy Rule establishes a category of health information, defined as protected health information (PHI), that a covered entity may only provide researchers access to use or disclose to others in certain circumstances and under certain conditions. In general, the Privacy Rule requires an individual to provide his/her signed permission, known as an Authorization, before a covered entity can use or disclose the individual’s PHI for research purposes. Under certain circumstances, however, the Privacy Rule permits a covered entity to use or disclose PHI for research without an individual’s Authorization. One way a covered entity can use or disclose PHI for research without an Authorization is by obtaining proper documentation of a waiver of the Authorization requirement by an Institutional Review Board (IRB) or another review body called a Privacy Board.

A Privacy Board is a review body established to act upon requests for a waiver or an alteration of the Authorization requirement under the Privacy Rule for uses and disclosures of PHI for a particular research study. A Privacy board may waive or alter all or part of the Authorization requirements for a specified research project or protocol. A covered entity may use and disclose PHI, without an Authorization or with an altered Authorization, if it receives the proper documentation of approval of such alteration or waiver from a Privacy Board.

The IRBs at UMKC interact with several covered entities that have their own Privacy Boards which review the researchers’ requests for Authorizations and waiver of Authorizations. Typically, the Privacy Board of the covered entity reviews the study privacy information and then makes that Authorization or waiver of Authorization documentation available to the corresponding IRB for recordkeeping purposes.

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