From the Winter 2002 Newsletter

LEGAL BRIEFS

The HIPAA Privacy Rule and Its Impact on Research

by Kelly Fitzpatrick, JD
news@vhaethics contributor

Individuals who are acquainted with federally funded research on human subjects also are well acquainted with the Common Rule and its requirements. They may not be as familiar, however, with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), particularly the Privacy Rule contained in HIPAA and the recently approved modifications relating to research, which went into effect October 15. This article will compare relevant sections of the original Privacy Rule and the modifications as they relate to biomedical research. As will become apparent, the modifications reduce redundancy in requirements imposed by both the original Privacy Rule and the Common Rule. More important, the changes eliminate the need for a parallel but separate track of requirements-one for the Privacy Rule and the other for the Common Rule-that might have impeded research.

Congress created HIPAA with the intention of improving the health care system by making health benefits portable and continuous, increasing penalties for health care fraud, and simplifying health insurance administration. The goal of the Privacy Rule, as a corollary to HIPAA, is to protect patients' rights regarding their individually identifiable health information, given the significant harm that could result from unregulated access to and use of an individual's personal health information. In the research context, the Privacy Rule fills a significant gap. Whereas the Common Rule protects participants in federally funded research, it does not apply to privately-funded research. The Privacy Rule, however, applies to all research.

The Privacy Rule also attempts to alleviate the longstanding tension between protecting the privacy of research participants and allowing researchers to conduct research. For example, the National Institutes of Health (NIH) report that nearly 32 percent of eligible women offered a test for breast cancer risk decline to take it, citing concerns about health insurance discrimination and loss of privacy as the reason. By supplementing privacy protections, the Privacy Rule intends to encourage patients to participate in research by minimizing privacy risks without impeding the vitally important conduct of research.

Despite this good intention, many individuals criticized the original Privacy Rule as imposing undue burdens on researchers and participants. The most onerous requirements were those relating to patient authorization and waivers. The Department of Health and Human Services (DHHS), which authored the Privacy Rule, recently addressed these concerns by instituting several modifications.

The Privacy Rule allows researchers to use and disclose protected health information for research purposes with an authorization from the research participant that meets the requirements outlined in §164.508 of the Privacy Rule. The first version of the Privacy Rule required a research-related authorization to contain several special elements of information in addition to nine core elements required for the use or disclosure of health information in a non-research context. The new Privacy Rule eliminates the special authorization elements, creating a single set of required core elements for all purposes. Additionally, the original Privacy Rule prohibited researchers from combining the authorization for use and disclosure of protected health information with other legal permission related to the research study, with a few narrow exceptions. The new one simplifies the authorization procedure by allowing researchers to combine privacy-related authorizations and informed consent documents.

As an alternative to obtaining authorization from research participants, the Privacy Rule allows a researcher to use or disclose protected health information for research purposes by obtaining a waiver from an Institutional Review Board (IRB). The original Privacy Rule required inclusion of a statement that the IRB had determined that the waiver satisfied eight criteria. This stood in stark contrast to the four criteria required under the Common Rule, and fueled concerns that IRBs would have to create a separate procedure to evaluate two discrete sets of criteria. In response to these concerns, the new Privacy Rule reduces the list of criteria to three, two of which are comparable to two Common Rule criteria: (1) The use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals; and (2) the research could not practicably be conducted without the waiver or alteration. The third criterion is that the research could not practicably be conducted without access to and use of the protected health information.

Questions and Answers

Q: What criteria must IRBs use to determine whether use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals?
A: Under the proposed modifications to the Privacy Rule, a determination of minimal risk to privacy will depend on the presence of three elements: (1) an adequate plan to protect the identifiers from improper use and disclosure; (2) an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is required by law; and (3) adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted.

Q: One of the core elements required to appear in an authorization document pertains to the expiration date or expiration event associated with the research study. What if a researcher does not know when the research will end?
A: The proposed modifications to the Privacy Rule provide that the statement "end of the research study" or similar language could meet the requirement for an expiration date or event where the authorization is for a use or disclosure of protected health information for research.

Q: With regard to the same core element, what if a researcher is simply developing a research database or repository?
A: The proposed modifications to the Privacy Rule provide that the statement "none" or similar language is sufficient to meet the requirement of providing an expiration date or event in the case of research databases or repositories.

Q: How does the Privacy Rule address transitioning research that is ongoing after the compliance date?
A: The original Privacy Rule mandated different transition requirements for research that includes treatment (i.e., clinical trials) and for research that does not include treatment (i.e., records research). Moreover, it did not explicitly address transition requirements for research studies ongoing after the compliance date where the legal permission of the individual had not been sought. In order to alleviate confusion and to ensure that research is not disrupted, the proposed modifications to the Privacy Rule make none of these distinctions. Instead, the modification grandfathers in research where a participant has signed an informed consent document, or an IRB has waived informed consent, in accordance with the Common Rule. Additionally, the proposed modification permits use or disclosure of protected health information that is created or received before or after the compliance date if the researcher has obtained, prior to the compliance date, an authorization or other express legal permission from an individual to use or disclose protected health information for the research study.

Conclusion
In sum, DHHS has enacted modifications relating to many concerns that researchers had voiced about the original Privacy Rule. As a result, the changes will avoid realizing critics' worst fears. Most notably, whereas the original rule would have required IRBs to implement a burdensome parallel process, the modification brings privacy requirements into closer alignment with the Common Rule, thereby enabling IRBs to integrate the privacy requirements into their routine deliberative process.