HIPAA and Research

PHRC Members Special Edition

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There are actually two species of hippopotami in Africa; the Nile hippo and the pygmy hippo. They differ in size just about 10 fold. Although the HPIAA Privacy Rules will impact the activities of the research community, the impact should be much less (perhaps not ten-fold) to the members of the PHRC panels.

Over the past several weeks, we have been sending information out to the members of the research community regarding the impending start date of the privacy components of the Health Insurance Portability and Accountability Act (HIPAA). The impact of the privacy rules on research, once thought to be onerous is not unreasonable or unworkable. We have been using a variety of formats to get the message to the research community including the use of a newsletter. This is a special edition devoted to members of the Partners Human Research Committee.

What is the Privacy Rule?

The Privacy Rule is only a portion of the HIPAA regulations. It establishes the conditions under which protected health information (PHI) may be used or disclosed by *covered entities* for any purpose including research. It defines the means by which individuals/human research subjects are informed of how their health information will be used or disclosed and it gives individuals a number of rights with regard to their health information.

- Where research is concerned, the Privacy Rule protects the privacy of individually identifiable health information, while at the same time, ensuring that researchers continue to have access to medical information necessary to conduct vital research.
- The Privacy Rule is similar to existing rules and regulations (under the Common Rule, 45 CFR 46 and FDA, 21 CFR 50, 56) but has some unique features. The Privacy Rule does not alter or replace these existing regulations.
- Researchers will still be able to access health information, for research purposes. If the information is not identifiable, the Privacy Rule adds no new requirements. If the information is identifiable, then new Privacy Rule requirements must be fulfilled.

To introduce you to the Privacy Rule – here are just a few of the Frequently Asked Questions:

Exactly what is "protected health information"?

Any identifiable person-specific information collected orally, electronically or in writing related to a person's past, present or future:

- Physical or mental health or condition
- Delivery of or payment for healthcare services

What do you mean by identifiable?

Identifiable includes the obvious personal information such as name, social security number, telephone number, address and medical record number as well as any data element that could reasonably be expected to identify an individual such as zip code or date of birth. The Privacy Rule lists 18 data elements as identifiers. Information that contains any of these data elements is considered identifiable and is protected under the Privacy Rule.

What must a researcher do to use protected health information?

If a researcher wishes to use protected health information, he/she must obtain either a waiver of authorization (from the PHRC) or an authorization from the subject.

Is there a difference between consent and authorization?

Yes. Under the Privacy Rule, a patient's authorization allows for the use and disclosure of PHI for research purposes. In contrast, an individual's informed consent is consent to participate in the research study as a whole, not simply a consent for the research use or disclosure of PHI. For this reason, there are important differences between the Privacy Rule's requirements for individual authorization, and the Common Rule and FDA's requirements for informed consent. The Privacy Rule does not replace or change the existing aforementioned rules – hence investigators must be in compliance with all applicable regulations.

While this sounds a bit daunting, the new submission forms actually lead researchers through the morass by asking all of the right questions and directing them to the correct process.

Will the Privacy Rule change the way investigators recruit subjects?

Investigators will need to pay a bit more attention to their recruitment methods. In particular, investigators should be careful not to note a potential subject's identity during a prescreening process. The collection of PHI during prescreening from an identifiable individual who does not enroll in a study is still subject to the Privacy Rule. Since this person has not provided authorization for the use of the information, it is best to either not collect the persons full name or other identifiers during a pre-screening, or to remove any pre-screening identifiers from the data set.

Will the PHRC accept sponsor language on the consent related to HIPAA?

Several corporate sponsors of human research have attempted to require their own specific language to the consent/authorization forms. Pharmaceutical and medical device companies are not covered entities according to the definitions within the HIPAA Privacy Rule. We will only accept our own language on our consent/authorization forms.

What is involved when a researcher requests a waiver of authorization?

The PHRC must review any requests for a waiver of authorization. The PHRC protocol submission for a waiver now includes both the Privacy Rule criteria for waiver of authorization as well as the Common Rule criteria for waiver of informed consent. The Privacy Rule criteria are similar to the Common Rule criteria, but are specific to privacy issues. The PHRC will review this as a single review.

The PHRC will also need to pay a bit more attention to the recruitment methods, especially the pre-screening process.

You can familiarize yourself with the intricacies of the Privacy Rule and see the previous editions of the HIPAA Newsletter by visiting the PHRC website at: http://healthcare.partners.org/phsirb/