ELI'S
HIPAA TRAINING ALERT
Your Guide To HIPAA Privacy And Security Success
Volume 3 • Number 4 April 2004

Privacy Compliance

THE ROCKY ROAD TO RECRUITMENT

▶ ***Need to get over those HIPAA hurdles? Here's help!***

While most of the medical community has efficiently and effectively carved out HIPAA privacy rule policies and procedures, the medical research community continues to hit roadblocks. HIPAA can easily blockade your research efforts, experts tell **Eli**.

GETTING STARTED

While once "you would talk to your patients about potential research opportunities and then give colleagues your patients' names, you can't do that easily anymore," says **Mark Barnes**, a partner in the New York, NY office of Ropes & Gray.

Instead, you must jump through more hoops merely to access the names of potential study participants. It was already difficult to recruit potential participants, so the added burden of the HIPAA regulation has only created more barriers in getting these studies off the ground, explains **Bill Sarraille**, an attorney at Sidley Austin Brown & Wood in Washington, DC.

"Though researchers can't quantify [HIPAA's effect], it's made a bad recruitment situation worse," he says. This type of problem has forced researchers to call into question both the necessity and the applicability of the regulation in the realm of research.

THE ROAD MAP

However, the concerns haven't arisen because researchers don't want to comply with HIPAA. Rather, "most researchers want to do the right thing for their research subjects and want to protect them and their information," clarifies **Kim Gunter**, a senior consultant at Philadelphia's Pricewaterhouse Coopers.

How to be in compliance isn't set in stone for the research community, experts agree. Yet, in order for the community to move forward and really quantify the effect HIPAA has had on research, there has to be a uniform standard across the board. For now, you "have to craft and document what you're doing in such a way that it can be interpreted that you were in the confines of the rule," Gunter says.

Unfortunately, this lack of regulatory guidance makes many potential participants anxious, and they become more sensitive to the attitudes of researchers. If you have a problem with HIPAA — your participants know it, Sarraille says.

Add to that the onerous paperwork participants must read and sign, and you can see why they aren't lining up to be involved in research. "It does scare people," Barnes says. "They're presented with all this legalese in a document and it makes them scared to enter a trial — they don't really know what they're signing and what the consequences are," he explains.

LET'S TALK ABOUT IT

As always, communication is the key. You need to convey what is, and always has been, the rule of research: Participants' privacy is important. "The study coordinator needs to convey the sincere and committed nature of the institution to handling PHI appropriately," Sarraille asserts. The message many participants are receiving is less that their information will be protected than it is "your information may not be protected," he adds.

You also "have to educate the subjects," Barnes reminds. Clear communication and education that enforces researchers' commitment to patient privacy will take the sting out of the paperwork, he says.

"If you give the communication that surrounds these documents short shrift, you run the risk of losing that [participant] and losing the meaning you're trying to convey," Sarraille warns.

> **If you give communication short shrift, you run the risk of losing that [participant] and the meaning you're trying to convey.**
>
> **— Bill Sarraille, *attorney***

"Recruitment" *cont. on p. 30*

THE BOTTOM LINE

The overwhelming response to HIPAA from the research community is confusion. That's where most experts are calling on the Department of Health and Human Services to step in. "Everyone has interpreted it differently and there needs to be a clear directive," Gunter expresses.

If the rules are revised to more naturally reflect the research community, or if guidance is issued that clearly defines how the research community should implement the HIPAA regulation, research can go from being a regulatory murky area to possibly thriving, she posits.

Lesson Learned: For now, you must take the time and expense to put potential participants at ease. Through effective communication and education about the privacy rule, you can "improve the sense of security subjects have in their personal health information," and turn medical research into a positive and rewarding experience that benefits all involved, Sarraille predicts. ❖

Privacy Quiz

ARE YOU READY TO RECRUIT?

▶ ***3 questions to get you started***

1. HIPAA has caused confusion because:
   a. researchers don't like rules.
   b. it is too complex for research.
   c. there is no clear guidance, so everyone is interpreting the rule differently.

2. Participants are hesitant to be involved because:
   a. research studies are spooky.
   b. they fear researchers are not committed to protecting their health information.
   c. research is not really important.

3. The best methods of alleviating participants' fears are:
   a. communication and education.
   b. forms and signatures.
   c. intimidation and scare tactics.

Answers

1. ***C:*** The Department of Health and Human Services has failed to introduce clear guidance on how the medical research community should handle HIPAA compliance. Therefore, implementation varies from site to site.
2. ***B:*** Participants know when you are more hassled by HIPAA than committed to it. Your attitude toward privacy rule compliance could be pushing participants out the door!
3. ***A:*** Talk to your patients about HIPAA and assure them that you are 100 percent committed to protecting their information. Clear communication and education could save your study!

Regulations

WHAT THE REGS SAY ABOUT ... REVIEWS PREPARATORY TO RESEARCH

Here's what the HIPAA privacy rule says about uses and disclosures for reviews preparatory to research:

45 CFR §164.512(1)(ii)

A covered entity may use or disclose protected health information for research, regardless of the source of funding of the research, provided that the covered entity obtains from the researcher representations that:

(A) Use or disclosure is sought solely to review protected health information as necessary to prepare a research protocol or for similar purposes preparatory to research;

(B) No protected health information is to be removed from the covered entity by the researcher in the course of the review; and

(C) The protected health information for which use or access is sought is necessary for research purposes. ❖