MessageFrom: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Thursday, March 13, 2003 2:00 PM
To: [purged]
Subject: RE: FDA Form 1572 & HIPAA

Dear Ms. [purged],

One can never ask too many questions! Thank you for your inquiry regarding HIPAA and its implementation. There are a number of guidance documents about HIPAA that are available from the Department of Health and Human Service's (DHHS) Office of Civil Rights (OCR) web site (http://www.dhhs.gov/ocr/hipaa/). We suggest you visit this web site and review these guidances. Should you continue to have questions about the implementation of HIPAA after you have reviewed information posted to the OCR web site, there are instructions on that web site for submitting your questions to OCR. At this time, OCR is the office that is taking the lead in addressing all HIPAA related questions.
You may want to note that most covered entities have until April 14, 2003, to comply with the patient privacy rule; under the law, certain small health plans have until April 14, 2004 to comply.
Additional guidances, including one that is expected to address frequently asked questions related to the implementation of HIPAA for FDA regulated products, are being developed. Once these documents are finalized, they too will be electronically available from the OCR web site.
I hope this information helps.
Sincerely,
Patricia M. Beers Block
Special Assistant to the Director
Good Clinical Practice Program (HF-34)
Office of Science and Health Coordination
Office of the Commissioner/FDA
301-827-3340
This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind nor otherwise obligate or commit the agency to the views expressed.

-----Original Message-----
From: [purged]
Sent: Wednesday, March 05, 2003 4:04 PM
To: gcpquestions@oc.fda.gov

Subject: FDA Form 1572 & HIPAA

First of all, I apologize if I've sent this question to the wrong area. We've had so many questions regarding HIPAA and how it relates to Sponsors conducting clinical research. The conferences we've attended have not been able to address our questions. We're hopeful that you can provide us some insight as we struggle to deal with HIPAA and our requirements as Sponsors.

We certainly appreciate the protection HIPAA provides to individuals from healthcare facilities they visit. Some of our questions that haven't been fully addressed are as follows:

1. When it comes to enrolling in a clinical trial are we as sponsors required to ensure that investigators are HIPAA compliant?

2. Currently we ensure that informed consent is obtained from all subjects in a study....will we also have to ensure an authorization has been provided and signed by the subject regarding their protected health information (PHI).

2. If yes, will the FDA Form 1572 ever be revised to state that investigators should comply with HIPAA?

3. We generally collect date of birth, and race/ethnicity information. This information is viewed as PHI. Although the information is shared from site to sponsor via case report forms, the data tabulations will be provided to the FDA in our submission for approval (NDA). Does this make us a business associate of the site.....? What about the FDA?

4. Should we be putting information in our protocols regarding HIPAA?

5. Am I asking too many questions????

I really hope you can point me in the right direction and I do appreciate your time in reading my e-mail.

thank you!

[purged]