From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Monday, April 07, 2003 11:27 AM
To: [purged]
Subject: FW: HIPAA authorizations and IRB responsibilities

Dear Ms. [purged],

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. The Office of Civil Rights is the lead office within the Department for addressing any and all HIPAA questions at this time.

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.

Most 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: Friday, April 04, 2003 9:30 AM
To: 'gcpquestions@oc.fda.gov'
Subject: HIPAA authorizations and IRB responsibilities

Dear Good Clinical Practice Program :

I have a question regarding FDA good clinical practice regulations and policy specifically related to the HIPAA privacy rule. We are currently providing training to our staff on the HIPAA privacy rule as it relates to the clinical trials we are responsible for monitoring. We have been instructing staff to ensure that investigator sites have an IRB approved informed consent form (with HIPAA required elements included) or a stand alone HIPAA authorization form, where required. We have been notified that one central IRB we are working with does not find it necessary to review and approve the HIPAA authorization form provided by the sponsor. They stated that it is considered a separate authorization from the consent forms and therefore not covered under their jurisdiction. They referenced the HHS web site for HIPAA privacy rule "frequently asked questions".

We are aware of this reference (see below) and felt that it only addressed HHS regulations. Our studies are run under 21 CFR (not 45 CFR) so we did not feel that this addressed the question for our purposes.

Q: When must an IRB review and approve patient authorizations for use or disclosure of protected health information related to human subjects research activities in order to satisfy requirements of Department of Health and Human Services (HHS) regulations at 45 CFR part 46?

A: Under HHS regulations at 45 CFR 46.117(a), IRB review and approval of patient authorizations for use or disclosure of protected health information required by the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule at 45 CFR 164.508 is only required if the authorization language is going to be part of the IRB-approved informed consent document for human subjects research.
HHS regulations at 45 CFR part 46 do not require that stand-alone authorizations for use or disclosure of protected health information, not incorporated into the IRB-approved informed consent document, be reviewed and approved by the IRB.

Because of the ICH requirement for IRBs to review "written information to be provided to subjects" (Guideline for GCP section 3.1.2) along with the fact that the IRB is responsible for safeguarding the rights of trial subjects, we thought that the IRB was required to review and approve the HIPAA authorization form. Would you be able to clarify this situation for us?

With Kind Regards,
> [purged]
> * Fax: 215-699-6288
> * crawfordg@iconus.com
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"WorldSecure <iconus.com>" made the following
annotations on 04/04/2003 09:29:43 AM

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