From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Monday, June 30, 2003 7:44 AM
To: [purged]
Subject: RE: HIPAA Questions

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/). OCR has ultimate responsibility for interpreting the provisions of 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.

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: Friday, June 27, 2003 11:14 AM
To: gcpquestions@oc.fda.gov
Subject: HIPAA Questions

> I would appreciate some clarification on the following HIPAA questions:
>
> 1. What is the definition of a "Hybrid Organization"? Under what conditions
> can
> an investigator/private physician apply for waiver from HIPAA as a hybrid
> organization?
>
> 2. What is the responsibility on the part of the sponsor of clinical trials
> to insure that the
> study site is in compliance with HIPAA? Should the sponsor have policies
> and procedures
> in place to insure compliance?
>
> 3. Should there be documentation of training on HIPAA for CRAs, and study
> site personnel?
>
> 4. De-identification of sera samples from the sponsors perspective, if you
> could please
> elaborate on this.
>
> 5. Does the IRB need to authorize/approve of statement regarding HIPAA for
> study subject's
> review and is this to be included in the Informed Consent or where it is
> under separate cover
> from Informed Consent?
>
> Thanks,
> [purged]