From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Friday, February 28, 2003 6:07 AM
To: [purged]
Subject: RE: advice needed

"Dear Dr. [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.
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,
Pat Beers Block

-----Original Message-----
From: [purged]
Sent: Wednesday, February 19, 2003 2:55 PM
To: swoollen@oc.fda.gov
Subject: advice needed

Mr. Woollen, one again I write to you for assistance. We are a dedicated study site and not affiliated with a physician's office. We only conduct clinical trials for the pharmaceutical and device industries. My question is this: Are dedicated study centers considered to be "covered" or "not covered" facilities in so far as the HIPAA regulations are concerned? Thank you again for your advice and assistance.

[purged]