From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Monday, August 18, 2003 7:28 AM
To: [purged]
Subject: RE: HIPAA vs a medical release

Dear Mr. [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/). Should you continue to have questions about the implementation of HIPAA after you have reviewed information posted to the OCR web site, you may e-mail OCR directly, or call that office at (800) 368-1019.

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 will also be electronically available from the OCR web site.

I've taken the liberty of forwarding your e-mail message to the OCR email account, ocrmail@hhs.gov .

I hope this information is helpful.

Sincerely,

Carolyn Hommel

Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
5600 Fishers Lane, Room 9C24
Rockville, MD 20857
Phone: 301/827-3340
Fax: 301/827-1169
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 or

otherwise obligate or commit the agency to the views expressed.

-----Original Message-----
From: [purged]
Sent: Friday, August 15, 2003 9:02 AM
To: OCRPrivacy@hhs.gov; gcpquestions@oc.fda.gov
Subject: hipaa versus a medicla release

happy friday !

my question is this: we are currently setting up a pregnancy registry study and the intention is to have study patients sign a medical release for their medical records because there is no physician acting in a principal investigator role for the study. the study will be run from a thrid party and does not consist of any treatment. the study protocol requires just the gathering of health information regarding pregnancy, and successful birth of woman who have been taking one of our drugs either while pregnant or just prior to conception....

our quandry is that we can't seem to find any guidance on whether we need to obtain a hipaa authorization even though we obtain a medical release ?

thanks in advance,

[purged]