From: OC GCP Questions
To: [redacted]
Subject: Data protection in clinical trials enquiry
Date: Friday, August 29, 2014 1:01:31 PM

Good afternoon ---

For FDA-regulated studies in a clinical trial some pharmaceutical companies may be considered the sponsor.

There is nothing that prevents a sponsor from collecting personal information about subjects in their studies. (Most, if not all, of which would be considered PHI under HIPAA). However, sponsors do not really need this information as their monitors and auditors can ensure that the data they receive coded for analysis does indeed come from specific study subjects who exist. Therefore, in most cases sponsors have refrained from collecting this type of information. However, our guidance document (see the link below) mentions implementing a more centralized monitoring system that may have caused sponsors to collect more such documents. With risk-based monitoring, sponsors do want more data earlier and so often they just ask for copies of everything collected at a study visit.

Oversight of Clinical Investigations – A Risk Based Approach to Monitoring
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269919.pdf

The ICH GCP E6 Good Clinical Practice: Consolidated Guidance, (which is recognized as official FDA guidance) mentions in section 6.10 that the sponsor should ensure the protocol or other written agreement specifies who has access to source data/documents (you can access this guidance at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf). I've copied below section 6.10 and other relevant sections of the ICH GCP E6 guidance for your consideration

6.10 Direct Access to Source Data/Documents

The sponsor should ensure that it is specified in the protocol or other written agreement that the investigator(s)/institution(s) will permit trial-related monitoring, audits, IRB/IEC review, and regulatory inspection(s) by providing direct access to source data/documents.

Direct access is defined as:

1.21 Direct Access: Permission to examine, analyze, verify, and reproduce any records and reports that are important to evaluation of a clinical trial. Any party (e.g., domestic and foreign regulatory authorities, sponsors, monitors, and auditors) with direct access should take all reasonable precautions within the constraints of the applicable regulatory requirement(s) to maintain the confidentiality of subjects' identities and sponsor's proprietary information.

It is expected that all parties involved with a study maintain the confidentiality of subject records and the extent that it is feasible is to be discussed as part of the informed consent process and be included in the informed consent document. The IRB is most often included in the informed consent document as one of the parties who may have access to the subject's records.

You may wish to consult the Health Insurance Portability and Accountability Act (HIPPA) For questions regarding issues pertaining to HIPAA, you may contact OCR directly at OCRPrivacy@hhs.gov. Here also is a link to OCR's general website for HIPAA http://www.hhs.gov/ocr/privacy/, and OCR also has HIPAA Frequently Asked Questions that can be accessed at http://www.hhs.gov/ocr/privacy/hipaa/faq/index.html. You may also wish to discuss your question with other in-house legal staff, including any Privacy Officer, within your sponsor organization.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have

additional questions.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

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.

From: [redacted]
Sent: Thursday, August 28, 2014 10:48 AM
To: OC GCP Questions
Cc: [redacted]
Subject: Data protection in clinical trials enquiry

Dear Sir/Madam,

I work for [redacted], a service provider to the pharmaceutical industry specialising in patient recruitment for clinical trials.

I tried phoning today and was directed to this email. I'm emailing to request your assistance with some desk research I'm conducting. Our understanding is that pharmaceutical companies by law are not allowed to hold sensitive personal data on patients taking part in their clinical trials, including any data that might identify those individuals. I'm looking for the specific US law that states this. Would you be able to help me source this information please?

I'm working to a deadline of Tuesday 2 September and would very much appreciate your help.

Kind regards,

[redacted]