From: OC GCP Questions
To: [redacted]
Subject: HIPAA Inquiry
Date: Friday, February 06, 2015 11:47:38 AM

Good morning –

I can speak to federal FDA regulations only. 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 sponsors can ask and receive the requested information.

You might want to review this guidance documents listed below.

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 consult your reviewing IRB as you state the ICD states that photo maybe used for marketing purposes.

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

From: [redacted]
Sent: Wednesday, February 04, 2015 4:51 PM
To: OC GCP Questions
Subject: HIPAA Inquiry

Hello,
I work for a company that conducts clinical trials. One of our clients (sponsor) has requested that we send them copies of the signed ICF. Their lawyers are insisting that they have them on file to be able to use the subjects photos for marketing purposes. I explained that it a violation of HIPAA. Plus, it states in the ICF that their photos may be used for marketing purposes. Do you have any recommendations on how to get around this or create some other type documentation to fulfill their request?

Thank you,
[redacted]