From: OC GCP Questions
To: [redacted]
Subject: compliance / PHI question for clinical trial
Date: Wednesday, December 24, 2014 11:38:26 AM

Good morning --

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.

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.

Happy Holidays to you too!

Kind regards,

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

From: [redacted]
Sent: Wednesday, December 24, 2014 11:21 AM
To: OC GCP Questions
Subject: compliance / PHI question for clinical trial

Good Morning,

I was asked by a sponsor to provide, prior to IRB approval, initials and ages of subjects, who experienced an adverse event related to an approved study drug. This information was intended for the feasibility of a new clinical trial. I was advised that this was permissable as per http://privacyruleandresearch.nih.gov/pr_08.asp#8e.

Now the sponsor is requiring an adverse event forms, prior to IRB approval, for these subjects which will include PHI [name, DOB, sex, height, weight, date of event] as per http://www.fda.gov/Safety/MedWatch/HowToReport/ucm085589.htm.

The sponsor states that according to this FDA document we are allowed to release the PHI without IRB approval since the HIPAA privacy rule is not intended to disrupt safety reporting.

Is it permissible to release this information?

Thank you in advance for your time and guidance and Happy Holidays.

[redacted]