From: OC GCP Questions
To: [redacted]
Subject: PHI Entered into EDC
Date: Thursday, June 11, 2015 1:04:23 PM

Good afternoon –

For study subjects and from an FDA standpoint, there is nothing that prevents a sponsor from collecting personal information about subjects in their studies including DOBs. (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.

There should be adequate provisions in place to protect the privacy of subjects and to maintain the confidentiality of data. Note that neither the regulations or even guidance do not specifically address the methods used to maintain the confidentiality of records identifying the subject nor do they prohibit sponsors/CROs from receiving subject information, even with identifiers. Typically, study sponsors, CROs, and sites usually follow their own Standard Operating Procedures (SOPs) that direct document handling and maintaining confidentiality.

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.

Additionally below is the Office of Regulatory Affairs (ORA) said regarding subject records during a FDA inspection.

Although sometimes challenging, ideally FDA would like to see and get copies of, original unchanged records. If not possible, the de-identification of records should be done as to not obliterate the required info necessary to identify the subject and the evidence of his/her participation in the study. Usually a combination of subject initials and subject number on study records will suffice this requirement.

The Privacy Rule also indicates the following: "…the Privacy Rule provides that, unless the use or disclosure is otherwise permitted or required by the rule, the use or disclosure of the protected health

information of an individual, such as a research subject, is permitted only if the individual signs an authorization for the use or disclosure (45 CFR 164.508)."

One of the required elements of an Informed Consent Form is a statement describing the extent to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the FDA may inspect the records. By signing the ICF the study subject is, in part, authorizing the disclosure of study info to FDA.

You might be interested in FDA's guidance document on Protecting the Rights, Safety, and Welfare of Study Subjects. Link below.
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf

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. **Having relatives contact information included in the EDC without their permission maybe a HIPPA violation. I would send your email to one of the sites above to receive clarification from HIPPA.**

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
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Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Thursday, June 11, 2015 11:41 AM
To: OC GCP Questions
Cc: [redacted]
Subject: PHI Entered into EDC

Dear Friends,

We have a sponsor who is requiring us to enter subject contact information (name, address, telephone number, place of work, plus names, addresses and telephone numbers for two relatives) into a Subject Contact Form on the Admin option of their EDC.

The ICF does have this language included, but there is no place for the relatives (2) to agree to have their personal information put on the EDC.

The sponsor says that only certain specially trained individuals will have access to this information.

This seems like a HIPAA violation to me. Please advise.

Kindly,
[redacted]