From: OC GCP Questions
To: [redacted]
Subject: Question related to CRF data collection
Date: Thursday, August 23, 2018 9:03:00 AM
Attachments: [redacted]

Good morning –

I am not sure why more information would need to be collected than what is required by the protocol. This might cause a subject confidentiality issue as I am unsure as to what additional health information is being collected. This might also create a HIPPA issue.
FDA does not have responsibility for the implementation of HIPAA. HIPPA is the responsibility of the Office of Civil Rights. 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 www.hhs.gov/ocr/privacy/, and OCR also has HIPAA Frequently Asked Questions that can be accessed at www.hhs.gov/ocr/privacy/hippa/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 and/or institution.

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: Wednesday, August 22, 2018 8:39 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: RE: Question related to CRF data collection

Good morning. Thank you for the reply! We understand that source documents can record more information than what's identified on the CRF. However, do you think it's an issue that CRF collects more data than what protocol defines?

Best regards,
[redacted]

From: OC GCP Questions [mailto:gcpquestions@fda.hhs.gov]
Sent: Wednesday, August 22, 2018 8:59 PM
To: [redacted]
Subject: [EXTERNAL] Question related to CRF data collection

Good morning –

FDA's regulations require that the investigator "...establish and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation. Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and

medical records including progress notes of the physician, the individual's hospital chart(s), and the nurses' notes...." [See 21 CFR 312.62(b).]

That said, it is not against FDA regulations to record more information than what is identified on the CRF. If this becomes a routine practice, perhaps the CRFs need to be modified. The CRF should mirror what is required by the protocol.

Kind regards,

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

U.S. FOOD & DRUG ADMINISTRATION

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From: [redacted]
Sent: Tuesday, August 21, 2018 4:45 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Question related to CRF data collection

Dear FDA Officer,

I have a question regarding data collection in CRF. If protocol does not clearly define/require to collect the information of family disease history, is it allowed to collect such data in CRF?
According to reference from ICH-GCP as quoted below, does it mean that only data/information clearly specified/required by the protocol can be collected in CRF? Thank you!

1.11 Case Report Form (CRF)
A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject.
5.18.4 - (m) - (i)
The data required by the protocol are reported accurately on the CRFs and are consistent with the source documents.

Best regards
[redacted]

[redacted]