From: OC GCP Questions
To: [redacted]
Subject: HIPAA completion by research subject
Date: Thursday, July 16, 2020 11:44:13 AM
Attachments: [redacted]

Good morning –

Thank you for your inquiry. The FDA regulations do not specifically address how to make corrections or changes to an IRB-approved document such as the ICF. When the regulations are silent, IRBs, institutions, sponsors, CROs, and investigators are free to develop their own procedures and practices as long as applicable regulatory requirements are met. However, there are some other FDA regulations mentioned below that should be taken into consideration when determining the procedures and practices for making corrections or changes to IRB-approved documents, such as the ICF.

According to the FDA IRB regulations at 21 CFR 56.111(a)(4) and (5) - see www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.111, and copied below for reference:

Sec. 56.111 Criteria for IRB approval of research.

(a) In order to approve research covered by these regulations the IRB shall determine that all of the following requirements are satisfied:

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by part 50.

(5) Informed consent will be appropriately documented, in accordance with and to the extent required by 50.27.

The IRB typically issues the IRB-approved ICF to be used by the PI/site. IRB-approved documents are usually not altered without a request for a change submitted to the IRB first for consideration.

Also, according to the IRB regulations at 21 CFR 56.108(a)(3) and (4) - see www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.108, and copied below for reference:

Sec. 56.108 IRB functions and operations.

In order to fulfill the requirements of these regulations, each IRB shall:

(a) Follow written procedures:

(1) For conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution;

(2) for determining which projects require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since previous IRB review;

(3) for ensuring prompt reporting to the IRB of changes in research activity; and

(4) for ensuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects.

Again because this situation is not specifically addressed in FDA's regulations or guidance, sponsors and sites are free to develop their own procedures for handling such mistakes. For example, sites could ask the subject to write a note explaining the error in the subject's file. If the IRB objects to having such a note written on the original form, then sites could use a coversheet or separate piece of paper that could be attached to the informed consent document (ICD) with the explanation and the subject's signature. Because the explanation would be on an attachment, rather than the ICD, it should deflect any concerns that the ICDs are being "altered."

Making a change to an IRB-approved document without consulting the IRB, especially when this change results in differences across copies of the same document, is not recommended.

Please note - FDA does not enforce the HIPAA regulations. This is the purview of the Office of Civil Rights. You can find information about HIPAA-related issues on their website at www.hhs.gov/ocr/privacy/. You should find contact information available there as well, should you not find the answers to your specific questions on the website.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Clinical Policy and Programs
Office of Good Clinical Practice (OGCP)
U.S. Food and Drug Administration

From: [redacted]

Sent: Wednesday, July 15, 2020 3:05 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: HIPAA completion by research subject

Good Morning,

I work as a clinical research monitor in an academic institution where our office acts as Sponsor on submissions going to FDA.

One of our study teams recently contacted me about a situation regarding research-related HIPAA.

Subject correctly completed four of the five lines on the form: 'Health Information About ___', Signature, Date and Print.
However, subject failed to complete one of the five lines, "Relationship to Participant".

Relationship to participant: _____

I have asked site to file a Deviation for form not being completed properly at the time of consent.

I would like to get your opinion on how to proceed with the blank line issue.

I have been instructed in the past that for errors noted AFTER consent process, corrections should not be made ON the form. Instead, subject should write a note on a separate sheet of paper explaining the error, have subject sign and date and include in subject's file.

In this case, should the line be left blank and explained in NTF as stated above?
Or is a nurse allowed to complete this portion of the form (write in 'self') and explain in NTF?

Thank you for any guidance that you can provide.