From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Wednesday, March 05, 2003 4:03 PM
To: [Redacted]
Subject: RE: ICF source documentation

Dear Ms. [Redacted]:

This is in response to your question whether a site must document the informed consent process in their source documents.

The regulations state, "The case history for each individual shall document that informed consent was obtained prior to participation in the study." [See 21 CFR 312.62(b).] Case histories, of course, include many documents: "...case report forms and supporting data, including, for example, signed and dated consent forms, any medical records, for example, progress notes of the physician, the individual's hospital chart(s), and nurses' notes." In other words, by reviewing the various documents that comprise the case history for each subject, one should be able to determine that consent was obtained from the subject before any study-related procedure is performed. FDA deliberately did not mandate how sites should accomplish this because the agency wanted to afford sites some flexibility in their approaches.

You might find the discussion of this topic in the final rule (published in the Federal Register on November 5, 1996 [vol. 61, pp. 57278- 57280, Comment #1] to be helpful. I have attached a copy for your convenience.

I hope this is helpful.

Sincerely,

Carolyn Hommel
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Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
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-----Original Message-----
From: [Redacted]
Sent: Friday, February 28, 2003 7:10 PM
To: gcpquestions@oc.fda.gov
Subject: ICF source documentation

> I am trying to find the guideline that states that an investigative site must document the informed consent process in their source documentation. I've looked in the GCP and ICH guidelines and have been unable to locate this. Is this

actually mandatory? I am a CCRA and have a site that is refusing to do this unless I can prove to them that it is mandatory.

Thank you for your help!
[Redacted]