From: Lee, Bonnie
Sent: Wednesday, June 11, 2003 12:04 PM
To: [Redacted]
Subject: RE: FDA question

Dear [Redacted],

I am responding to your e-mail question (below). As you know the case history for each individual subject needs to document that informed consent was obtained prior to participation in the study (see 21 CFR 312.62(b)). In the situation you have described, both the medical chart and the sponsor-provided source document would be part of the case history, therefore either or both would serve to comply with this requirement. Although we usually encourage sponsors to use the established practices of the site as much as possible, rather than introducing new record keeping practices, you should check with the sponsor to determine whether the sponsor would agree to having the medical chart serve as the source record for the informed consent process. If the sponsor requires use of their form, then you may decide to simply indicate on the medical chart that the consent process is documented on the sponsor's form (and maintain a copy of it) in order to avoid duplication of effort. Basically (ignoring the preference or requirements of the sponsor) you could use the medical record or use the sponsor sheet; you do not need to use both.

In addition to the items that you listed, FDA also looks at the information provided to subjects (the informed consent form) to ensure that it conforms to 21 CFR part 50, particularly, whether it contains the elements of informed consent required by 21 CFR 50.25. Depending upon the nature of the study, or the individual subjects, we may also examine how competency was judged (e.g, in a study involving subjects who may be incompetent); if the subject(s) speak a different language, whether the consent information was provided in that language; etc. I do, however, think that you have covered the basic questions. I hope this information is helpful to you.

Sincerely,

Bonnie
Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, HF-34, 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.

-----Original Message-----
From: [Redacted]
Sent: Wednesday, June 04, 2003 3:16 PM
To: 'OC Webmail'
Subject: RE: FDA question

I have read these documents thoroughly and did not find a satisfactory answer to my questions. Could you please answer this specifically?

Thanks, [Redacted]

-----Original Message-----
From: OC Webmail [mailto:wmail@OC.FDA.GOV]
Sent: Wednesday, June 04, 2003 1:01 PM
To: [Redacted]
Subject: RE: FDA question

See:
http://www.fda.gov/oc/ohrt/IRBS/

-----Original Message-----
From: [Redacted]
Sent: Wednesday, June 04, 2003 2:44 PM
To: wmail@oc.fda.gov
Subject: FDA question

Name: [Redacted]

E-Mail: [Redacted]

Address: [Redacted]
Phone: [Redacted]
URL:

Comments: I am a CCRC practicing in a private cardiology clinic. Our department would appreciate some clarification concerning the informed consent process. What precise documentation does the FDA look for when reviewing the informed consent process? We are in compliance with the informed consent form, my concern is how we document the process. As a seasoned coordinator, I document the process on the source document provided by the sponsor and I also document the process in the patient's medical record. Am I unnecessarily double documenting. Is it appropriate to refer to the research source document for information about the informed consent process? Our research source document includes statements that the patient has an opportunity to ask questions, the questions were answered, the subject read the informed consent form, the subject signed the informed consent prior to study related activities, the date & time and the subject recieved a signed copy of the informed conse!
nt form. Is this inclusive? If not what other information does the FDA examine? Does this need to be found in the subjects permament medical record?
Thanks so much for your time.
[Redacted]