From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Tuesday, September 07, 2004 2:24 PM
To: [Redacted]
Cc: CDER DRUGINFO
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Dear Ms. [Redacted]:

Your question regarding who should maintain a copy of the final consent form approved by a Central IRB was forwarded to me for a response. I apologize for the delay in responding to you.

FDA's regulations pertaining to the conduct of clinical studies do not specifically require sponsors to retain a copy of the informed consent form template.

The best guidance that FDA has on the good clinical practice, including which records should be retained and by whom, is the ICH E-6, Good Clinical Practice: Consolidated Guideline. Pertinent to your question, Chapter 8, "Essential Documents for the Conduct of a Clinical Trial," Section 8.3.3, states:

"Dated, documented approval/favorable opinion of institutional review board (IRB)/independent ethics committee (IEC) of the following: ...- Revision(s) of Informed consent form..." should be maintained in the Investigator's and Sponsor's files, to "document that the amendment(s) and or revision(s) have been subject to IRB/IEC review and were given approval/favorable opinion and to identify the version number and date of the document(s)."

Although not required by FDA's regulations, maintaining a copy of the informed consent document by the sponsor and investigator is clearly identified in the ICH guidance as a good clinical practice.

I hope this is helpful.

Sincerely,

Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
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Rockville, MD 20857

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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: CDER DRUGINFO
Sent: Wednesday, August 04, 2004 2:17 AM
To: OC GCP Questions
Subject: FW: DrugInfo Comment Form FDA/CDER Site

-----Original Message-----
From: [Redacted]
Sent: Tuesday, August 03, 2004 1:49 PM
To: druginfo@cder.fda.gov
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [Redacted]

E-Mail: [Redacted]

Comments: Regulatory Policy Question - In regard to retention of required documents by a Sponsor - When using a Central IRB for a study, should a Sponsor retain (in their central files) the final informed consent template that was mutually agreed upon by the Central IRB and the Sponsor?