From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Wednesday, March 24, 2004 11:35 AM
To: [Redacted]
Cc: CDER DRUGINFO
Subject: RE: IRB's continuing review

Dear Mr. [Redacted]:

Your question to the CDER DrugInfo e-mail account was forwarded to me for a response. I apologize for the delay in responding to you.

You asked what to do if an investigator fails to notify the IRB about a study's status, and in the interim the IRB's approval for the study expires, but eventually the IRB reapproves the study.

Because the situation is rather complicated and ambiguous, I would recommend simply that both the CI and the IRB carefully document what occurred and outline the steps that both have taken, or are taking (e.g., modifications in operating procedures, appropriate training for staff), to prevent similar mixups and problems in the future.

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: [Redacted]
Sent: Thursday, February 26, 2004 10:08 AM
To: druginfo@cder.fda.gov
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [Redacted]

E-Mail: [Redacted]

Comments: My inquiry is concerning continuing review by an IRB related to 21 CFR 312.66, 56.103, 56.108, and 56.109. Have also reviewed the relevant FDA Information Sheet Guidances.

In the event an investigator fails to notify the IRB of the status of his/her study and the one-year expiration has occurred (IRB approval expired), in an instance whereby the current informed consent form does not require any revisions or alterations, what should be done regarding 'research' activities, if any, that occurred during the time the expiration lapsed and when reapproval granted ?
Is there any guidance on specific recommendations an IRB should partake when there was not IRB oversight during this time frame, such as disallowing any data collected, recommendation of discontinuing the participation of any subjects that may have been enrolled, or termination of the study project.
Thank you in advance for your assistance regarding this question.