From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Monday, June 20, 2005 12:01 PM
To: [Redacted]
Cc: CDER DRUGINFO
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Dear Ms. [Redacted]:

Your question to the CDER DRUGINFO e-mail account was forwarded to me for a response. You asked, "For sponsored studies, does the sponsor need their own IRB approval? If yes, do the individual sites' IRBs need to see that approval? Or, do the sponsors rely on the individual sites' IRBs' approvals?" You did not state whether the study in question involves a drug/biological product or a medical device, so I will address both possibilities in my response.

IRB review is required for all studies involving FDA regulated products. Who is responsible for securing that review may vary, however; see below. In answer to your question, regardless of who obtains IRB review, ALL parties (i.e., clinical investigator, sponsor, monitor, CRO) should be informed of the IRB that is responsible for initial and continuing review of the study.

In general, for drug/biologic studies, securing review by an IRB is typically the responsibility of the investigator. 21 CFR 312.53(c) describes the "Statement of Investigator" (Form FDA 1572), which contains various commitments as to how the investigator will conduct the study. The form is signed by the investigator and provided to the sponsor.

21 CFR 312.53(c)(1)(vii) includes "[a] commitment by the investigator that, for an investigation subject to an institutional review requirement under part 56, an IRB that complies with the requirements of that part will be responsible for the initial and continuing review and approval of the clinical investigation and that the investigator will promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others and will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to the human subjects."

This is reiterated in 21 CFR 312.66, which states: "An investigator shall assure that an IRB that complies with the requirements set forth in part 56 will be responsible for the initial and continuing review and approval of the proposed clinical study..."

For device studies, the requirements in FDA's device regulations are slightly different. 21 CFR 812.40 states, "Sponsors are responsible for...ensuring that IRB review and approval are obtained...and ensuring that any reviewing IRB and FDA are promptly informed of significant new information about an investigation..."

There has recently been interest, particularly for multi-site trials, in allowing the use of a centralized IRB to review a study protocol and thus reduce or even eliminate multiple reviews by local IRBs at each site. If a centralized IRB review process is used, it should be coordinated with any local IRBs that may have jurisdiction over a study. It should also be clearly documented in writing so that all parties are aware of the things that each party is responsible for.

FDA recently issued a draft guidance on "Using a Centralized IRB Review Process in Multicenter Clinical Trials," that may be of interest to you. It may be viewed on FDA's Good Clinical Practice website (http://www.fda.gov/oc/gcp; here is a specific link to the guidance:

http://www.fda.gov/OHRMS/DOCKETS/98fr/05d-0103-gdl0001.pdf

You may also be interested to know that FDA's official guidance, the ICH E6 "Good Clinical Practice: Consolidated Guidance," states that both the clinical investigator and the sponsor should maintain a copy in their respective files, of the "Dated, documented approval/favorable opinion of the IRB/IEC of the ... protocol and any amendments, CRF (if applicable), informed consent form(s)..." etc. [See ICH E6, section 8.2.7.]

The complete text of FDA's regulations and the ICH E6 guidance may also be viewed on FDA's GCP website, shown above.

I hope this answers your question.

Sincerely,

Carolyn Hommel
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Good Clinical Practice Program
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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: Monday, June 13, 2005 2:21 PM
To: OC GCP Questions
Subject: FW: DrugInfo Comment Form FDA/CDER Site

-----Original Message-----
From: [Redacted]
Sent: Monday, June 13, 2005 12:05 PM
To: druginfo@cder.fda.gov
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [Redacted]

E-Mail: [Redacted]

Comments: We are having a heated disagreement here. For sponsored studies, does the sponsor need their own IRB approval? If yes, do the individual sites'IRBs need to see that approval?
Or, do the sponsors rely on the individual sites' IRBs' approvals?

Thank you for your time in aiding us.
[Redacted]