From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Tuesday, November 29, 2005 12:31 PM
To: [Redacted]
Subject: RE: IRB Review of Phase IV Studies

Dear [Redacted], It's always difficult to answer these questions in the abstract. You could certainly look at the regulations, specifically, the definition of a "clinical investigation", the requirements for when an IND is required (21 CFR 312.2). It is important to note that even when an IND is not required, IRB review is one of the conditions that makes the clinical investigation exempt from the IND requirements. Because it is likely that any Phase IV study may yield results that could be used to change the labeling (if submitted and approved by FDA), I would suspect that IRB review would be required by us. That would be the regulatory answer to your question. As to what constitutes good clinical practice, I would argue that IRB is a norm that provides protections to the subjects participating in the activity. Therefore, whether federal regulations require IRB review or not, it ought to be obtained.

I hope this information is helpful to you.

Sincerely,

Bonnie

Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, 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: Monday, November 28, 2005 8:54 AM
To: OC GCP Questions
Subject: RE: IRB Review of Phase IV Studies

Bonnie,

Thank you for the information provided below. What about Phase IV studies that are not imposed upon companies by the FDA as a condition of approval [e.g., registries, marketing studies, and other post-approval studies using approved product for approved indication to additional gather data)? What are the FDA's expectations of an IRB for review of these?

Thank you,

[Redacted]

"OC GCP Questions" <GCPQuestions@OC.
To FDA.GOV> [Redacted]

Sent by: "Lee, [Redacted] Bonnie"
cc <BLee@OC.FDA.GOV>
Subject RE: IRB Review of Phase IV Studies 11/27/2005 11:21 AM

Dear [Redacted],

Generally, Phase 4 studies are post-marketing studies that are imposed upon a pharmaceutical or device firm as a condition for drug or device approval. Because the results of those studies are required to be submitted to FDA, they are subject to IRB review. The IRB review responsibilities are the same for Phase 4 studies as they are for other studies regulated by FDA. I hope this information is helpful to you.

Sincerely,

Bonnie

Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA
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-----Original Message-----
From: [Redacted]
Sent: Tuesday, November 22, 2005 4:24 PM
To: gcpquestions@oc.fda.gov
Subject: IRB Review of Phase IV Studies

Dear FDA Representative,

Can you please tell me what the FDA's expectations are of an IRB regarding review of Phase IV studies?

Thank you,

[Redacted]
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