From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Sunday, November 27, 2005 2:22 PM
To: [Redacted]
Subject: RE: IRB Review of Phase IV Studies

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
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: 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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