From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Wednesday, August 31, 2005 2:53 PM
To: [Redacted]
Subject: RE: Phase IV clinical trials

Dear [Redacted],

Your email (below) was forwarded to me for response.

Under FDA regulations, institutions involved in multi-institutional studies may use joint review, reliance upon the review of another qualified IRB, or similar arrangements aimed at avoidance of duplication of effort. See 21 CFR 56.114. The information sheet on Cooperative Research at the following address: http://www.fda.gov/oc/ohrt/irbs/research.html provides our expectations when a central IRB is used. At a minimum, the central IRB needs to be aware of each site participating in the study and the qualifications of each investigator. Thus, you should submit your information to the IRB.

It appeared from your email that you didn't want us to pursue this further (e.g., with the review division or [Redacted]. If I misunderstood your intentions, please let me know. I hope this information is helpful to you.

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, August 22, 2005 2:03 PM
To: 'pharrell@'
Subject: Phase IV clinical trials

Dear Phyliss
I am writing to follow up on our conversation. I have been told by a sponsor- [Redacted] that the following clinical trial is a phase IV, it has been IRB approved by a Central IRB, [Redacted] and that I do not need to submit to the IRB as a site. After reviewing the FDA guidelines on what is exempt from IRB approval, I called you.The Informed Consent and Title read-[Redacted].
Thank You
[Redacted]

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reserve the right to monitor all e-mail communications through our network.
Thank you.

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Thank you.