From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Friday, October 14, 2005 2:54 PM
To: [Redacted]
Subject: RE: Central IRB Moving

Dear [Redacted],

I do not have a complete list of things your client will need to do. I can give you some ideas, but please understand that this is not an all-inclusive list. I encourage you to think about this yourself. The central IRB should provide information about the move, when it will occur, new contact information, etc., to all parties who use or have used the central IRB's services--this includes but is not limited to sponsors, investigators, and others, FDA, OHRP (if they have a federal wide assurance (FWA) or an agreement under an FWA), other institutions or IRBs for which the central IRB has some type of cooperative review agreement or for whom the central IRB has agreed to assume responsibility for the study, and subjects (unless phones numbers and contact information will remain the same). To the extent to which the IRB may have been identified in consent documents as a contact for answers to research related questions, if an 800 number was not previously provided, it probably ought to be provided now. With the IRB now operating in a different State, the IRB will obviously need to familiarize itself with State laws and regulations that could impact on its activities. E.g., I believe [Redacted] has a law requiring use of a subject's Bill of Rights. 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: Thursday, October 06, 2005 4:13 PM
To: gcpquestions@oc.fda.gov
Subject: Central IRB Moving

Dear FDA Representative,

One of my clients is a central IRB who is planning to move their office to another state. Can you please tell me what they will need to do and whom

they will need to notify and how to ensure they cover all of their bases relative to the FDA, sponsors, study subjects, etc.? Your input is greatly appreciated.

Thank you,
[Redacted]

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