From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Tuesday, November 01, 2005 3:50 PM
To: [Redacted]
Subject: RE: Change in IRB
Dear [Redacted], You can wait until your next clinical study report to report the change in the identity of the IRB at one of your investigational sites. I hope this 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: Wednesday, October 26, 2005 2:43 PM
To: gcpquestions@oc.fda.gov
Subject: Change in IRB
Hello:

Are we required to submit an intermim report to FDA if there is a change in the IRB at one of our investigational sites? Or can we indicate the change in our next clinical study report (e.g. Annual or List of Current Invesitgators reports)

Thank you for your reply.
[Redacted]

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