From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Friday, April 15, 2005 3:04 PM
To: [Redacted]
Subject: FW: IRB

Dear [Redacted], There is nothing in FDA's IRB regulations that addresses the issue of acknowledgement. Generally, the regulations address the IRB's responsibility for having the authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by the regulations. See 21 CFR 56.109. 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: CDER DRUGINFO
Sent: Tuesday, April 05, 2005 1:22 PM
To: OC GCP Questions
Subject: FW: IRB

Hi,

Can you please help me with the question below?
I looked through 21 CFR Part 56 and saw Part 56.111 which spoke about "approval", but I didn't see anything on "acknowledge".

Thanks
Brenda Stodart
DDI

-----Original Message-----
From: [Redacted]
Sent: Thursday, March 31, 2005 1:56 PM
To: CDER DRUGINFO
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [Redacted]

E-Mail: [Redacted]

Comments: Hello,

Are there any guidelines for what items are to be "approved" by an IRB and what items can be "acknowledged"?

Thanks for your help.

[Redacted]