From: Lepay, David
Sent: Tuesday, August 09, 2005 4:23 PM
To: [Redacted]
Subject: RE: Protocol Disapproved

Dear [Redacted]:
The two pertinent sections of FDA's IRB regulations are:

21 CFR 56.109 IRB Review of Research --- and in particular 21 CFR 56.109(e) which describes the requirement of an IRB to notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity --- and in the case of a decision to disapprove, to include in its written notification a statement of the reasons for the decision and provision for the investigator to respond in person or in writing. There is no requirement under 56.109(e) for reporting to FDA.

21 CFR 56.113 Suspension or termination of IRB approval of research. This requires reporting to the investigator, appropriate institutional officials, AND the FDA when an IRB suspends or terminates approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.

It would seem that the provisions of 56.109 are those in question given circumstances as you describe. If so, reporting to FDA is not required.

Should you want to review the precise wording of these two regulations, they can be accessed from www.fda.gov/oc/gcp through the link to "Good Clinical Practice/Clinical Trial Regulations" and hence to 21 CFR Part 56.

I hope this is the information you seek.

Regards, Dave

David A. Lepay, MD PhD
Senior Advisor for Clinical Science and
Director, GCP Programs,
OSHC, Office of the Commissioner, US 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, August 09, 2005 1:23 PM
To: David.lepay@fda.hhs.gov
Subject: Fwd: Protocol Disapproved

Sorry. Resending

[Redacted]

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