From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Thursday, March 04, 2004 3:43 PM
To: [Redacted]
Subject: RE: IRB approval status
Dear Ms. [Redacted] :

I apologize for the delay in responding to your e-mail question as to whether the site was operating with IRB approval for the period between acknowledgement of the Study Closure Notification and the date that the IRB reviewed and re-approved the study. FDA's regulations and guidance do not specifically address the situation that you described.

Because the situation is rather complicated and ambiguous, I would recommend simply that you document what occurred and outline the steps you have taken, or are taking (e.g., modifications in procedures, appropriate training for staff), to prevent similar mixups in the future.

I hope this is helpful.

Sincerely,

Carolyn Hommel

Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
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Rockville, MD 20857

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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, February 18, 2004 11:02 AM
To: FDA
Subject: IRB approval status

[Redacted] had been notified by a principal investigator that a sponsor was terminating a study, however, currently enrolled subjects were to continue to be followed to completion. This notification was misinterpreted by [Redacted] staff member as requiring a final report to the

IRB. Although the investigator's site director did not agree, a Study Closure Notification was submitted and received by [Redacted] . The report, accompanied by a copy of the sponsor letter to the investigator was reviewed and processed by one of our Co-chairs and the [Redacted] study file was inactivated. The investigator received acknowledgement of the review of the Study Closure Notification form and immediately contacted our office to explain that the study was not closed. Per our SOPs the study was resubmitted for board review and approval.

The issue is whether or not the site operated under IRB approval during the acknowledgement of the Study Closure Notification and the re-review and approval of the board. Because the initial IRB approval was granted [Redacted] my position is that the site did operate with IRB approval.

Please advise.

Regards,

[Redacted]