From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Thursday, May 12, 2005 10:47 AM
To: [Redacted]
Subject: RE: Question relating to Continuing Review

Dear [Redacted],

In response to your question below, continuing review is required. If you look at our list of procedures that can be reviewed through the expedited review process, the 8th includes this category; the 9th also covers continuing review. See: http://www.fda.gov/oc/ohrt/irbs/expeditedreview.html Specifically, 8 and 9 state that the IRB can use the expedited review procedures to review some or all of the research appearing on the expedited review list and found by the reviewer(s) to involve no more than minimal risk for:
(8) Continuing review of research previously approved by the convened IRB as follows:
(a) Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
(b) Where no subjects have been enrolled and no additional risks have been identified; or
(c) Where the remaining research activities are limited to data analysis. [This explicitly is your situation.]
(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

It sounds as though you will need to change your procedures.

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: Monday, May 09, 2005 11:11 AM
To: FDA
Subject: FW: Question relating to Continuing Review

Please see question below. Thanks.

-----Original Message-----
From: [Redacted]
Sent: Tuesday, May 03, 2005 1:43 PM
To: FDA
Subject: Question relating to Continuing Review

Does the FDA require Continuing Review for studies where the remaining research activites are limited to data analysis?

Currently our procedures allow Investigators to submit a Final Report when the above is true. Please advise.

Thank you.
[Redacted]