From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Wednesday, March 02, 2005 4:21 PM
To: [Redacted]
Subject: RE: Attn: Bonnie Lee - Exp. vs. Full Continuing IRB Review?
Dear [Redacted],

FDA does not have comparable written guidance on Expedited Review category 8. However, the guidance offered by OHRP is consistent with our interpretation of this category.

On a separate topic, please note: FDA will be holding a public hearing in Rockville, Maryland, on March 21 to solicit views on the process by which IRBs obtain and review information on adverse events that occur during the conduct of clinical investigations. Registration to attend and/or speak at the hearing is required and can be done online at http://www.accessdata.fda.gov/scripts/oc/dockets/meetings/meetingdocket.cfm. We encourage registrants to participate as speakers. Information about the hearing is available at http://www.fda.gov/OHRMS/DOCKETS/98fr/oc04297.pdf. If you have questions or difficulty registering, we encourage you to contact Nancy L. Stanisic at 301-827-1660 or at stanisicn@cder.fda.gov.
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, March 02, 2005 2:56 PM
To: OC GCP Questions
Subject: Re: Attn: Bonnie Lee - Exp. vs. Full Continuing IRB Review?
Ms. Lee, thank you for your response. We would like to know if there is a formal FDA position regarding this question?

OHRP has specific guidance at http://www.dhhs.gov/ohrp/humansubjects/guidance/contrev2002.htm, which I have copied below. Does the FDA have similar, written guidance regarding this issue? Thank you in advance for your response.

[Redacted]

"Expedited Review Category (8):
Under Category (8), an expedited review procedure may be used for the continuing review of research previously approved by the Under Category (8), an expedited review procedure may be used for the continuing review of research previously approved by the convened IRB as follows:
(a) Where:
the research is permanently closed to the enrollment of new subjects;
all subjects have completed all research-related interventions; and 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.

Of note, category (8) identifies three situations in which research that is greater than minimal risk and has been initially reviewed by a convened IRB may undergo subsequent continuing review by the expedited review procedure.
For a multi-center protocol, an expedited review procedure may be used by the IRB at a particular site whenever the conditions of category (8)(a), (b), or (c) are satisfied for that site. However, with respect to category 8(b), while the criterion that "no subjects have been enrolled" is interpreted to mean that no subjects have ever been enrolled at a particular site, the criterion that "no additional risks have been identified" is interpreted to mean that neither the investigator nor the IRB at a particular site has identified any additional risks from any site or other relevant source."
----- Original Message -----
From: OC GCP Questions
To: [Redacted]
Sent: Tuesday, March 01, 2005 1:51 PM
Subject: RE: Attn: Bonnie Lee - Exp. vs. Full Continuing IRB Review?

Dear [Redacted],

Category 8 applies to the research at your site. Because the research that was previously approved by your IRB is the research at your site, I can't see it applying to all sites (unless you were a central IRB, responsible for all 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
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-----Original Message-----
From: [Redacted]
Sent: Tuesday, February 22, 2005 10:17 AM
To: GCP FDA Questions
Subject: Attn: Bonnie Lee - Exp. vs. Full Continuing IRB Review?
Dear Ms. Lee:
I have a question regarding Continuing IRB Review and am seeking guidance. Our institution participates in many multi-site studies that are regulated by the FDA. Although a central IRB ([Redacted]) reviews many of these studies for us, we do have some FDA-regulated studies for which our institutional IRB is the IRB of record. My question is in regards to the studies our own (local) institutional IRB reviews.
For a study that initially undergo full IRB review, may
our own (local) IRB perform Expedited Continuing Review if that study is closed to new accrual at our site, all participants have completed all protocol therapy at our site, only long-term follow-up/data collection/analysis is occurring at our site, and no additional risks have been identified at any site since the study's last review? I ask because Category 8 of the Expedited Review checklist from 63 FR 60364 (below) does not specify if (a) - (c) refer only to one's own sites or to all sites:
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.

If you could please clarify this, we would much appreciate it. Thank you.

[Redacted]