From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Wednesday, March 02, 2005 9:27 AM
To: [Redacted]
Subject: RE: IRB/Ethics annual review

Dear [Redacted],

FDA's IRB regulations state, in part, that "An IRB shall conduct continuing review of research covered by these regulations at intervals appropriate to the degree of risk, but not less than once per year..." See 21 CFR 56.109(f).

Several scenarios for determining the date of continuing review apply for protocols reviewed by the IRB at a convened meeting. To determine the date by which continuing review must occur, focus on the date of the convened meeting at which IRB approval occurs. (These examples presume the IRB has determined that it will conduct continuing review no sooner than within 1 year).

Scenario 1: The IRB reviews and approves a protocol without any conditions at a convened meeting on October 1, 2002. Continuing review must occur within 1 year of the date of the meeting, that is, by October 1, 2003.

Scenario 2: The IRB reviews a protocol at a convened meeting on October 1, 2002, and approves the protocol contingent on specific minor conditions the IRB chair or his/her designee can verify. On October 31, 2002, the IRB chair or designee confirms that the required minor changes were made. Continuing review must occur within 1 year of the date of the convened IRB meeting at which the IRB reviewed and approved the protocol, that is, by October 1, 2003.

Scenario 3: The IRB reviews a study at a convened meeting on October 1, 2002, and has serious concerns or lacks significant information that requires IRB review of the study at subsequent convened meetings on October 15 and October 29, 2002. At their October 29, 2002 meeting, the IRB completes its review and approves the study. Continuing review must occur within 1 year of the date of the convened meeting at which the IRB reviewed and approved the protocol, that is, by October 29, 2003.

For a study approved under expedited review, continuing review must occur within 1 year of the date the IRB Chair or IRB member(s) designated by the Chair gives final approval to the protocol.

Review of a change in a protocol ordinarily does not alter the date by which continuing review must occur. This is because continuing review is review of the full protocol, not simply a change to it.

When continuing review occurs annually and the IRB performs continuing review within 30 days before the IRB approval period expires, the IRB may retain the anniversary date as the date by which the continuing review must occur. This would be, for example, October 1, 2003, in the above Scenarios 1 and 2, and October 29, 2003, in Scenario 3, even if the continuing reviews took place up to 30 days prior to these dates.

The key to picking the date for continuing review is to ensure that no more than one year will elapse between reviews (assuming the interval for review has been set for yearly). Therefore, in response to your question, it would be the most recent review date (assuming that's review of the whole study--continuing review--and not just a change to it).

I hope this information is helpful to you.

On a separate 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. The Federal Register document also describes how interested individuals can submit written comments in lieu of attending the hearing.

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: Wednesday, March 02, 2005 1:53 AM
To: gcpquestions@oc.fda.gov
Subject: IRB/Ethics annual review

Dear GCP help desk,

We are sending out reminders to our sites regarding obtaining IRB/Ethics annual reviews.

[Redacted] Is there any US FDA title 21 regulations to review?

Question?
Does the date of review go back to the original approval date, if it is different from the last annual review date given by Ethics or is it the from the most resent date from the last annual review?

For example, A site might have been late in submitting progress reports to Ethics in the past, therefore the approval date now is inconsistent with the original date of approval. Do we use this new date or go back to the orginal date for tracking future progress reports?

Your response would be most appreciated,

[Redacted]

##
####################################

IMPORTANT NOTICE: This e-mail and any attachment to it are intended only to be read or used by the named addressee.
It is confidential and may contain legally privileged information. No confidentiality or privilege is waived or lost
by any mistaken transmission to you. The [Redacted] is not responsible for any unauthorised alterations to this e-mail or
attachment to it. Views expressed in this message are those of the individual sender, and are not necessarily the
views of the [Redacted]. If you receive this e-mail in error, please immediately delete it and notify the sender. You must
not disclose, copy or use any part of this e-mail if you are not the intended recipient.

##
#####################################