From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Wednesday, March 02, 2005 10:42 AM
To: [Redacted]
Subject: RE: A separate Q' regarding GCP
Dear [Redacted],

FDA's regulations do not contain any requirements regarding the amount of time it "should" take an IRB to review protocols or amendments. FDA's guidance documents are also silent on this issue.

You are correct that the amount of time it takes would depend on how frequently the IRB meets, and also, whether the attendance at the meetings is sufficient for the IRB to actually conduct business. 21 CFR 108(c) requires that "...a majority of the members of the IRB [be] present, including at least one member whose primary concerns are in nonscientific areas... " If a majority is not present, or the non-scientific member is absent, the IRB would not be able to complete any reviews. Another thing that may affect "majority" is whether any of the IRB members would be unable to vote, due to a conflict of interest related to the study.

Another thing to consider is that during the review, issues may be raised that would require additional information from the clinical investigator, in which case, the actual voting on the study protocol may be delayed until the identified issues are resolved. Thus, it may take more than one meeting for the IRB to have sufficient members present to conduct business, and in addition, to ensure that any concerns raised by IRB members about the study protocol are fully discussed and resolved.

With respect to IRB approval of amendments to a study protocol, are you aware that minor amendments may be eligible for review through an expedited process, which would mean that the review would not have to wait for a convened meeting of the IRB? See 21 CFR 56.110(b): "An IRB may use the expedited review procedure to review either or both of the following:...(2) minor changes in previously approved research during the period (of 1 year or less) for which approval is authorized. Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the IRB chairperson from among the members of the IRB..."

[You may view the complete text of our regulations through a link on our website: http://www.fda.gov/oc/gcp; once at the site, click on "Good Clinical Practice/Clinical Trials Regulations" in the center column.)

I hope this answers your question.

Carolyn

Carolyn Hommel
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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.

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 8:19 AM
To: OC GCP Questions; carolyn.hommel@fda.hhs.gov
Subject: A separate Q' regarding GCP
Importance: High
Dear Carolyn,

I've been reading the GCP's Guideline regarding the functions and operations of IRB's. However specifics as to

- how long do the IRB's take for approval of a protocol and
- how long do they take to approve an amendment to a known protocol

are questions not addressed in the booklet I have. Should I use my common sense to say that the IRB per se, would have its own schedule of meetings. Or in your experience is there something standard to go by with these Institutional Review Boards for the questions above?

Please advice,

Thanks,

[Redacted]