From: Lepay, David on behalf of OC GCP Questions
Sent: Wednesday, January 28, 2004 8:13 PM
To: **[Redacted]**
Subject: RE: IRB approval notices

Dear Mr. **[Redacted]** :
There are actually two facets to your question:

The first relates to clinical investigator responsibilities under FDA regulations (see Title 21 Code of Federal Regulations Part 312.66; this can be accessed from our GCP website www.fda.gov/oc/gcp through the link to Regulations and hence to Part 312). In particular "An investigator shall assure that an IRB that complies with the requirements set forth in Part 56 will be responsible for the initial and continuing review and approval of the proposed clinical study." That is, the clinical investigator has responsibility to assure that review is conducted by an IRB compliant with FDA regulations. To do this, the investigator clearly needs to know that the IRB is properly constituted, and for this, it may be necessary for the investigator to know something of the membership/representative capacity of those on the IRB. This need not necessarily include a listing of names of each member present --- but at least some knowledge that membership and representative capacity is compliant with FDA regulations.

The second facet more directly answers your question: FDA IRB regulations under 21 CFR Part 56 (in particular 56.109(e)) require that "An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity." The regulation does not specify an inclusion in this notification of any signature requirement or listing of names/credentials of IRB members present at the meeting --- although such written notification is typically signed by the IRB Chair.

FDA would expect, however, that the IRB's minutes would capture the attendance and representative capacity of members present at any meeting and voting on any given protocol. 21 CFR 56.115 (a) [IRB Records] requires that the institution or IRB prepare and maintain adequate documentation of IRB activities, including: "minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

I hope the above helps in answer to your query.

Sincerely,

David A. Lepay, MD PhD
Senior Advisor for Clinical Science and
Director, Good Clinical Practice Programs,
OSHC, Office of the Commissioner, US FDA

-----Original Message-----
From: **[Redacted]**
Sent: Wednesday, January 28, 2004 9:45 AM
To: 'gcpquestions@oc.fda.gov'
Subject: IRB approval notices

Greetings,

I have been newly assigned to attend to administrative functions for the **[Redacted]** Institutional Review Board. I'm entirely new to the process, but most of the HHS and FDA guidance has been very clear and easy to follow.

I do have a question regarding approval notices:

Does the FDA require that IRB notices of approval (or disapproval) to the investigator of a clinical trial include the names and credentials of the IRB members present at the meeting? If so, please advise as to what IRB membership and meeting participation details are required for notices. If you can point me to the regulation document that addresses this, that would be most helpful.

I appreciate your attention and consideration.

[Redacted]