From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Wednesday, August 31, 2005 4:19 PM
To: [Redacted]
Subject: RE: IRB composition and related procedures

Dear [Redacted],

I cannot tell whether your IRB's constitution and documentation meet our requirements. It does appear that you have tried to address in the following email a number of FDA's regulatory requirements for IRBs. However, without an inspection to track one or more studies through the review process, a review of the IRB's written procedures (which are not mentioned), a determination as to whether those procedures are compliant with our regulations and being followed, if they are, there is no way to determine whether your procedures are in line with GCP. I'm sorry that I can't be more helpful.

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, August 29, 2005 1:26 PM
To: gcpquestions@oc.fda.gov
Subject: IRB composition and related procedures

I am working in an upcoming Clinical Research Organization to conduct Bioequivalence studies for US. Please suggest that the following IRB constitution and documentation is as per your expectations and meets the GCP requirements.

Our IRB full board consists of 7 members (Chairperson, Member Secretary and five members). 5 members are independent and 2 members are dependent and two members are non-scientific. The chairperson is independent of the institution and the member secretary is dependent (QA & RA in-charge).

IRB meetings are conducted when the quorum (more than 50% of the full board and presence of at least one non-scientific member) is established. Clinical Investigator shall present the study details to the full board and leave the conference hall.

The IRB members shall review the study documents and vote on the study. The IRB minutes are prepared by the member secretary and approved the chairperson.

Once the study is approved, the member secretary on behalf of the IRB shall stamp and sign and date on each page of the protocol, Informed Consent and other documents and forward to the clinical investigator by keeping a photocopy of all the documents as proof of the operation.

The IRB documents such as IRB Roster, Minutes, IRB member's details and training records, study documents are maintained by the member secretary.

Please suggest that the above procedure is in line with GCP. If not please suggest.

Waiting for your reply

Regards
[Redacted]