From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Thursday, December 02, 2004 8:49 AM
To: **[Redacted]**
Cc: CDER DRUGINFO
Subject: RE: IRB violation?

Dear Ms. **[Redacted]** :

Your question to FDA's CDER DRUGINFO e-mail account was forwarded to me for a response.

Yes, a new IEC meeting would be needed (with lay members present) to confirm the favorable opinion.

FDA's regulations state that "In order to fulfill the requirements of these regulations, each IRB shall...review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas..." See 21 CFR 56.108(c).

My understanding is that a non-scientific member must be present at the convened meeting for the IEC to be able to review research that does not qualify for expedited review. Thus, because no non-scientific member was present, the requirements set forth in 21 CFR 56.108(c) were not met.

Sincerely,

Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program (HF-34)
Office for Science and Health Coordination
Office of the Commissioner
US Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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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: Tuesday, November 30, 2004 10:14 AM
To: druginfo@cder.fda.gov
Subject: DrugInfo Comment Form FDA/CDER Site

Name: **[Redacted]**

E-Mail: **[Redacted]**

Comments: Dear Sirs,I am involved in int.'l clinical trials in **[Redacted]** as trial manager. In a study carried out under an IND, **[Redacted]** Ethics Committee, properly constituted as per ICH GCP (16 members of either sex, scientific and non scientific, employed by, and independent of, the Institution , etc.) issued a favourable opinion for the above mentioned study. It happens though that on that IEC meeting date both lay members were absent for different reasons. It has to be noted that they had had access, anyway, to the documentation submitted to the IEC secretariat three weeks in advance.
I am discussing with my QA manager on this issue and the questions are: would this be considered by in spectors a major violation (i.e., non compliance with the 21 CFR part 56) even if the lay members, after reading the docs submitted did not raise any evident objection in the weeks preceding the meeting? Is a new IEC meeting needed (with lay members present) to confirm the opinion?
Many thanks in advance for your help and kind regards,
[Redacted]