From: [Redacted]
Sent: Friday, May 13, 2005 11:23 AM
To: OC GCP Questions
Subject: RE: Board composition question
Bonnie,

Your response is helpful; I shall speak to the sponsor directly to assess their concerns.

Best wishes,

[Redacted]
-----Original Message-----
From: Lee, Bonnie [mailto:BLee@OC.FDA.GOV]On Behalf Of OC GCP Questions
Sent: Friday, May 13, 2005 9:58 AM
To: [Redacted]
Subject: RE: Board composition question
[Redacted] the intent of the regulations is to have membership that can adequately review the research and in order to take action we have said that at a minimum the IRB needs to have at least 5 members with varied background, without conflicts, and a majority of those voting for the research. As I pointed out in my first email to you, there may be some aspects of your membership that may be causing the sponsor to pause.... (I know you rejected that; but I do wonder whether you adequately considered it.). Anyway, no, if we said you had to have 5 members on the IRB and five members present to transact business, we would have said that--but we didn't.

I hope this helps.

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: Thursday, May 12, 2005 6:01 PM
To: OC GCP Questions
Subject: RE: Board composition question
Importance: High
Bonnie,

The confusion seems to be whether the intent of the regulation is to always have five members present. Since we only had four of our seven-member board present they have a concern. Is this a legitimate concern?

I greatly appreciate your time and attention to this matter.

Warm regards,
[Redacted]

-----Original Message-----
From: Lee, Bonnie [mailto:BLee@OC.FDA.GOV]On Behalf Of OC GCP Questions
Sent: Thursday, May 12, 2005 3:57 PM
To: [Redacted]
Subject: RE: Board composition question
[Redacted] It seems to me that if that's their concern, the regulations are pretty clear....you need at least 5 members and you need a majority of them saying yes (as in 3 out of 5, or in your case 4 out of 7). Perhaps we're both missing something?

My best,

Bonnie
Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA
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-----Original Message-----
From: [Redacted]
Sent: Thursday, May 12, 2005 4:47 PM
To: OC GCP Questions
Subject: RE: Board composition question
Importance: High
Hi Bonnie,

Thank you for the kind thought. I hope you are doing well also.

Thank you for your thorough response. I apologize for not providing more clarity in my message.

All four members voted to approve the PI. The scientific member who possessed the expertise was present during the initial review of the study, as were the other three members. Two non-scientist members were present; neither of them [Redacted] employees.

I believe the sponsor issue is the fact that less than five board members reviewed/approved the PI. Although we explained our SOP to the sponsor, they feel are we non-compliant with federal regulations.

Regards,

[Redacted]

-----Original Message-----
From: Lee, Bonnie [mailto:BLee@OC.FDA.GOV]On Behalf Of OC GCP Questions
Sent: Thursday, May 12, 2005 3:23 PM
To: [Redacted]
Subject: RE: Board composition question
Dear [Redacted] ,

I hope that this email finds you well. In reading your email below, I wonder whether the sponsor's concern has been adequately articulated. As you know, FDA regulations require, among other things, each IRB to have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. See 21 CFR 56.107(a). No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. See 21 CFR 56.107(e). The regulations also state that except when an expedited review procedure is used, the IRB is to review proposed research at a convened meeting at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved it shall receive the approval of a majority of those members present at the meeting. See 21 CFR 56.108(c).

From your description (below), it is not clear whether all 4 members (a majority) voted for the review of "this PI"....you only state that they voted. I know that some (many?) IRBs have expressed concern about having an administrative staff person from an independent or other IRB serve as an IRB member due to the potential for a conflict of interest. While we leave those determinations to each IRB, I do think this is something your IRB needs to consider and discuss. It is also not at all clear who the individual member might be whose primary concerns are in nonscientific areas. You also don't describe the qualifications of other members present at the meeting and whether any of these possessed the necessary scientific expertise.... I can understand why the sponsor may have additional questions and suggest that you consider providing greater specificity to the sponsor.

I hope this information is helpful to you.

Sincerely,

Bonnie
Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA
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-----Original Message-----
From: [Redacted]
Sent: Thursday, May 12, 2005 11:36 AM
To: FDA
Cc: [Redacted]
Subject: Board composition question
Importance: High
A sponsor has voiced concern to [Redacted] via a CRO regarding the appropriateness of our board composition for the review of the addition of an investigator to a previously approved study. The board is comprised of seven members; however, only four members were present and voted on the review of this PI. The sponsor's concern is that only four voting members reviewed the PI information. [Redacted] 's SOP states in part,

A. All board members, as well as alternate members, reviewing the study documents will have full voting rights, including those members attending by conference call, as long as the member(s) was involved during the discussion period. No votes by proxy will be allowed. The membership will reflect the following:
* A minimum of five board members, one of which is a representative of the administrative staff
> Fifty-one percent of the voting members constitute a quorum
? One member will be sufficiently qualified through experience and expertise to review an investigational new drug or device study
? One member of each board will be designated as Chairman as reflected on the membership roster
? One member of the administrative staff will be designated as Co-Chairman as reflected on the membership roster
We have conveyed this information; however, the sponsor finds it unacceptable. Therefore, your comments are appreciated.
Regards,
[Redacted]