From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Monday, February 28, 2005 10:35 AM
To: [Redacted]
Subject: RE: Conflict of interest question

Dear [Redacted],

There is no regulation that dictates whether individuals involved in a protocol either should be present or should be absent during an IRB's discussion and vote on a protocol. It is really up to the IRB. On the one hand, some IRBs may feel that their conversation is inhibited by the presence of such individuals. Other IRBs may feel comfortable discussing anything regardless of who is in the room.

Years ago, when I managed our IRB, I know that we encouraged investigators to be present during our discussion of their protocols. We felt that they gained a better understanding of the committee's concerns by hearing the discussions; were available to the committee if members had additional questions that needed clarification; and were, as a result more responsive to changes requested by the committee. The quality of their protocol submissions also improved as they gained a better understanding of the IRB expectations by attending IRB meetings. Therefore, if you go by my experience (and I don't know if it's typical or not), attendance at meetings during the discussion and vote may make the work of the individuals you describe easier and more responsive to concerns raised by the committee.

If these individuals were allowed to participate in the deliberations of the IRB, then I may be concerned about a potential conflict of interest; but you didn't mention that role for them.

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

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, February 24, 2005 12:20 PM
To: GCPQuestions@OC.FDA.GOV
Subject: Conflict of interest question

Good afternoon:

We have an unusual situation and I would appreciate some guidance. We have a [Redacted] that assists investigators in preparing their IRB packets (writing the consent documents, completing forms, etc.). They

are not listed as research team members. They have requested to attend the IRB meetings and we have agreed to their presence at the meeting. They will also provide assistance to the investigators with any required changes/clarifications. Should they exit the room during the discussion and vote of those protocols?

The IRB members are not aware of the individuals' role on the study submission process. To me there is a potential conflict of interest.

Thank you for your time.

[Redacted]