From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Monday, February 28, 2005 11:44 AM
To: [Redacted]
Subject: RE: Conflict of interest question

Dear [Redacted], Actually, perhaps I wasn't clear. My comments covered both the discussion as well as the vote. If the members feel comfortable voting with an audience present (even with some people in the audience, involved in the research), then there is nothing in the regulations that would prevent this practice. Some IRBs may prefer to vote in private; others may not care. The regulations are silent on the issue. Thus, it is really up to the IRB to decide.

Bonnie

Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA

-----Original Message-----
From: [Redacted]
Sent: Monday, February 28, 2005 10:40 AM
To: GCPQuestions@OC.FDA.GOV
Subject: RE: Conflict of interest question

Hi Bonnie:

Thanks for the information - I guess that I was not clear. I am asking should they leave the room during the vote by the IRB members?

[Redacted]