From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Monday, June 27, 2005 3:08 PM
To: [Redacted]
Subject: Pharmacists and Conflicts of Interest

Dear [Redacted],

The preamble to our regulations is very specific that it is up to the IRB or institution to determine what constitutes a conflict of interest--not the study coordinator. In fact, it is common for pharmacists to serve as voting IRB members and they should be valued in that role. Except in those instances where there really is a direct conflict (as you note, such as being paid per subject in a study or other direct involvement in the study that is beyond your expected responsibilities as a pharmacist), we believe that pharmacists fill an important knowledge base for the IRB and should be allowed to serve as voting IRB members. Where the pharmacist, IRB, or institution determines that conflicts exist, then the pharmacist IRB member (as with any other conflicted member) should limit their involvement to providing information requested by the IRB. 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: CDER DRUGINFO
Sent: Thursday, June 16, 2005 12:29 PM
To: OC GCP Questions
Subject: FW: DrugInfo Comment Form FDA/CDER Site

-----Original Message-----
From: [Redacted]
Sent: Thursday, June 16, 2005 11:47 AM
To: druginfo@cder.fda.gov
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [Redacted]

E-Mail: [Redacted]

Comments: I need to know who to contact with a question regarding IRB conflict of interest. I am a research pharmacist at [Redacted] and a member of our IRB. A study coordinator is now telling me that I cannot vote on any protocol that I am involved with even if it is a dispensing role only. She states that the fact that I dispense study drugs means that I have a conflict of interest. (I do not have a financial conflict of interest because my job will still exists if research halts at my institution, and I am not paid based on patient enrollment or # of studies.) I need to know where the FDA stands on this matter because I know that plenty of research pharmacists are voting members of IRBs. Please email me or feel free to call me at [Redacted]. Thanks!

[Redacted]