From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Tuesday, June 15, 2004 11:50 AM
To: **[Redacted]**
Subject: RE: IRB Conflicts of Interest

Dear **[Redacted]** , I am unaware of any FDA guidelines or regulations that address conflicts of interest for IRB administrators--specifically, the issue of separating safety oversight from a grant application function. I do know that it is a topic discussed in the IRB community and that generally there is a belief that the two functions ought to be separated. I'm sorry that I can't provide additional information. I don't know whether you are aware of recently issued HHS Guidance on Financial Relationships. Although this does not address the specific issue you raised, it may be of general interest. It is available on the Internet at:
http://ohrp.osophs.dhhs.gov/humansubjects/finreltn/finalguid.pdf.

I hope this 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: Wednesday, June 09, 2004 1:25 PM
To: **[Redacted]**
Subject: IRB Conflicts of Interest

I am looking for information on Conflicts of Interest for IRB administrators. I am particularly interested in requirements separating the Safety oversight of protocols, from the grant application function. Please advise.

[Redacted]