From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Wednesday, December 21, 2005 12:54 PM
To: [Redacted]
Subject: RE: Kind Atten: Bonnie M. Lee
Dear [Redacted],

There is nothing in FDA's IRB regulations that addresses your question. Assuming that the head of your QA is serving as IRB staff (as a secretary) and not as a member and assuming he/she would have no role in trying to influence the outcome of your IRB (other than to point out regulatory requirements, as needed), I see no reason why he/she could not serve as a secretary to the IRB.

I hope this information is helpful to you. Happy holidays.

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: Friday, December 09, 2005 5:28 AM
To: GCPQuestions@OC.FDA.GOV
Subject: Kind Atten: Bonnie M. Lee
Dear Bonnie M. Lee

We are establishing a bioequivalence center, where QA reports to the top management and indepdent of the Principal investigator and other study personnel.

We are establishing an Institutional Review Board (IRB)with seven scientific and non - scintific background members as per ICH E6.

Does the Head - QA in our bioequivalence center can act as Secretary of IRB to assist IRB on procedures and regulatory requirements?

Your suggestion is very helpful to us.

Regards
[Redacted]