From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Wednesday, September 07, 2005 2:12 PM
To: [Redacted]
Subject: RE: Guidance
Dear [Redacted] ,

I can't say whether you are meeting the intent of the regulation. In many respects I think it would depend upon what you do with the information you receive and the extent to which it may influence your actions on a protocol. I think I would also be more impressed if you had indicated that you may consult with individuals from a community in special situations--and that you had done that.

If auditors comment on this issue, you could respond with a description of what you do to consider the ethical standards of the local community. I appreciate your clarification of the title of 56.114; I mentioned this section because its content deals with multi-institutional studies and can apply to the activities of an independent IRB as well.

I hope this is helpful to you.

My warmest regards to you as well,

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: Tuesday, September 06, 2005 3:49 PM
To: 'OC GCP Questions'
Subject: RE: Guidance
Good morning Bonnie,

Thank you for your response.

The reason I asked the question was due to a comment in an audit report that noted, "There are no members who are specifically oriented to determine community attitudes, and no consultants are used for this purpose in any area where studies they review are conducted." I agree with you that obtaining knowledge of community attitudes is doable, however, the mechanism utilized by most independent IRBs does not include having a member of consultant provide the information. Therefore, my concern regarding the enforceability of the regulation addressed in Title 21, CFR 56.107(a). Auditors often comment on this issue. How do we respond to these types of comments from auditors?

Our submission form requires each investigator to provide information regarding demographics, population, and community attitudes toward research. Are we meeting the intent of the regulation?

In paragraph three of your response you reference the preamble to the 1981 rule as well as CFR 56.114. CFR 56.114 pertains to cooperative research, which we have yet to be involved in.

Bonnie, your responses are always very helpful and I greatly appreciate what you do.

Warm regards,

[Redacted]