From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Wednesday, December 29, 2004 12:58 PM
To: [Redacted]
Subject: RE: Convened meetings
Dear [Redacted] , I apologize for the delay in responding to your questions below. 21 CFR 56.108 allows for meetings where members can have real-time discussion and conversation; this would be in convened meetings, and where necessary, supplemented by teleconferencing for those members who would not otherwise be able to participate in the meeting from a remote site. On-line discussions that do not permit real-time discussion would not substitute for a convened meeting. The basic rule, if you want to call it that, is that the membership must be able to (as you have stated) consider, interact, deliberate, question and vote in real time. I would suggest that for those who are concerned about intimidation that there are likely other things wrong with the IRB's membership that ought to be fixed. I hope this is helpful to you and that you have a happy new year.

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, November 30, 2004 3:17 PM
To: 'gcpquestions@oc.fda.gov'
Subject:
Thank you in advance for considering this question.
21 CFR 56.108 requires that "except when an expedited review procedure is used, [an IRB must] review proposed research at convened meetings at which a majority of the members of the IRB are present...." Does this requirement preclude IRBs reviewing protocols on line--for example, in an on-line discussion via messages posted to a secure IRB members-only message board (i.e., not a real-time discussion)? Can a meeting be considered "convened" if some/all of the necessary members are not present, but are participating via telecon, videocon, or a real-time on-line discussion (real time chat room)? In 21 CFR 56.108, what are FDA's rules for "present" (is physically present required?) and "convened" (must members be physically present, or can they be located elsewhere, provided they can consider, interact, deliberate, question and vote in real time?)?
Note: Some non-FDA commentators have pointed out that on-line discussion can be helpful to prepare for, but cannot replace, a convened meeting. Others have said that face-to-face deliverations may not be advantageous in all ways-intellectual intimidation of nonscientific members, for example.
Thanks,
[Redacted]