**From:** Lee, Bonnie on behalf of OC GCP Questions
**Sent:** Wednesday, June 30, 2004 10:06 AM
**To:** [Redacted]
**Cc:** [Redacted]
**Subject:** FW: IRB meetings convened via teleconference

Dear [Redacted] , Although we have addressed this question in our Frequently Asked Questions information sheet, which is undergoing revision at this time, I would encourage you to rely on the statement in the preamble to the 1981 regulations. That is available at: http://www.fda.gov/oc/gcp/preambles/46fr8958.html, in comment 67 and states:

67. Several comments stated that FDA should allow meetings to take place by conference calls. These comments argued that effective dialogue can occur between IRB members on conference calls without forcing the members to be physically present in one room.

Although FDA, like HHS, encourages meetings to take place with members physically present in the room, FDA also recognizes that in some cases time and commuting expense would favor conference calls. As long as each IRB member can actively participate in any discussion of a protocol and has all pertinent material before the call, FDA has no objection to allowing meetings to occur in such a fashion and will consider meetings that take place by conference call to be "convened" meetings. These meetings must follow the same requirements (minutes, etc.) as meetings with members physically present.

I hope that this information is helpful to you.

Sincerely,

Bonnie

Bonnie M. Lee

Associate Director for Human Subject Protection Policy

Good Clinical Practice Program, FDA

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-----Original Message-----
**From:** [Redacted]
**Sent:** Tuesday, June 15, 2004 10:17 AM
**To:** disclosure@oc.fda.gov
**Subject:** IRB meetings convened via teleconference

There is an apparent long-standing FDA policy (46 FR 8967, January 27, 1981) regarding IRB meetings convened via teleconference. Is there a link to this document, or perhaps a statement that can summarize when this mechanism of communication is acceptable? I've been put in charge of developing a SOP for our IRB regarding this phenomenon. I have contacted a repository library in my general vicinity but would like

to know if there has been any recent coverage of this particular topic since 1981. Any information/direction you can provide would be most helpful.

Thank you,

[Redacted]