



DEPARTMENT OF HEALTH & HUMAN SERVICES

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March 28, 2000

TO: Division of Human Subject Protections, OPRR

FROM: Director, Division of Human Subject Protections, OPRR

SUBJECT: IRB Meetings Convened via Telephone Conference Call

As you know, Department of Health and Human Services (HHS) regulations at 45 CFR 46.108(b) require that Institutional Review Boards (IRBs) “review proposed research at convened meetings at which a majority of the members of the IRB are present”

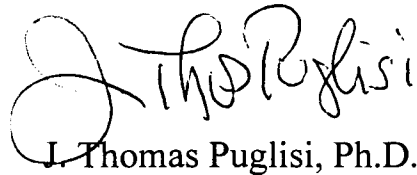
Wherever possible, OPRR strongly recommends that such meetings take place with all participating IRB members physically present. However, OPRR recognizes that circumstances sometimes warrant conducting IRB meetings via telephone conference call.

Effective immediately, OPRR will recognize as “convened” those IRB meetings conducted via telephone conference call, provided that each participating IRB member (i) has received all pertinent material prior to the meeting, and (ii) can actively and equally participate in the discussion of all protocols. Minutes of such meetings must clearly document that these two conditions have been satisfied in addition to the usual regulatory requirements (e.g., attendance, initial and continued presence of a majority of members, including at least one nonscientist member; actions taken by the IRB; the vote on such actions; discussion and resolution of controverted issues).

Recognition by OPRR of IRB meetings convened via telephone conference call is consistent with longstanding Food and Drug Administration (FDA) policy (46 FR 8967, January 27, 1981).

Conference Call IRB Meetings
March 28, 2000

The DHSP Director should be consulted should Coordinators require assistance in applying these guidelines to specific situations.



J. Thomas Puglisi, Ph.D.

Attachment

cc: Dr. Gary Ellis
Dr. Melody Lin
Ms. Michele Russell-Einhorn