

Policy Number: 68
Title: IRB Meeting Administration
Date of Last Revision: July 5, 2007

I. General Description

Except when an exempt or expedited review procedure is used, the IRB will review proposed research at a convened meeting at which a quorum is present. Each IRB will meet biweekly, or at some other frequency as determined by the IRB Chair and the OPRS Director.

II. Quorum

A majority of the IRB members must be present (or connected via speakerphone), including at least one member whose primary concerns are in nonscientific areas. The IRB staff in attendance at the meeting will be responsible for ensuring: (1) that a quorum is met when all votes are taken, (2) the presence of a nonscientist for all votes and (3) the presence of members and/or the comments of consultants with the appropriate expertise to review the research, including the presence of a physician member when FDA-regulated research is reviewed. In order for a motion to pass, it must receive the approval of a majority of those members present at the meeting (including members connected via speakerphone). Members may not vote by proxy.

Should the quorum fail during a meeting (e.g., loss of a majority through recusal of members with conflicting interests or early departures, or absence of a nonscientist member), the IRB may not take further actions or votes unless the quorum can be restored.

Should the IRB experience a loss of quorum during a convened meeting, discussion of protocols may continue, but the IRB may not vote on a protocol until quorum has been restored. Once quorum has been lost for the duration of the meeting, the Board can consider whether to meet as a Sub-Committee. If the Board determines to review protocols as a Sub-Committee, the determinations and votes made on all protocols by the Sub-Committee will be returned to the following convened meeting for review by the Full Board.

III. Conflicts of Interest

The minutes will identify when a regular or alternate member has a conflict of interest on a protocol that has been identified by staff. IRB members and others present at the meeting (e.g. guests, consultants) should identify any additional conflicts not already identified on the agenda by staff. If a member with a conflicting interest is in attendance at the meeting, the minutes will

document that the member has been recused from the discussion and the vote due to a conflict of interest on a protocol. If the member is asked to provide information to the Board, the minutes will note that the member remained in the room to provide information at the request of the IRB, but was recused prior to the discussion and the vote.

IV. Speakerphone Participation

If a member is not able to be physically present during a convened meeting, but is available by telephone, the member can participate in the meeting via speakerphone. Members who were connected via speakerphone will be identified as such in the minutes. Members who are connected via speakerphone are provided the same materials the other members are given. Such members are counted as part of the quorum and may vote on all protocols for which they are connected via speakerphone as long as they can actively and equally participate in the discussion.

V. IRB Meetings Convened via Telephone Conference Call

Whenever possible, meetings will be conducted with all participating IRB members physically present. However, circumstances may warrant conducting IRB meetings via telephone conference call. When an IRB meeting is conducted via telephone conference call, each participating IRB member will have received all pertinent material prior to the meeting and will be able to actively and equally participate in the discussion of all protocols.

Regulations:

45 CFR 46.10745 CFR 46.108

45 CFR 46.115(a)(2), (b)

21 CFR 56.107

21 CFR 56.108(c)

21 CFR 56.115(a)(2)

References:

OHRP Guidance on Written IRB Procedures – January 15, 2007.
(<http://www.hhs.gov/ohrp/humansubjects/guidance/irbgd107.pdf>)

OHRP Compliance Oversight Activities: Significant Findings and Concerns of Non-Compliance– October 12, 2005.
(<http://hhs.gov/ohrp/compliance/findings.pdf>)

OHRP Guidance on IRB Meetings Convened via Telephone Conference Call – March 28, 2000
(<http://hhs.gov/ohrp/references/irbtel.pdf>)

FDA Information Sheets: Frequently Asked Questions – 1998.
(<http://www.fda.gov/oc/ohrt/irbs/faqs.html>)