

Guidance and Procedures Number: 69
Title: IRB Meeting and Minutes
Date of Last Revision: January 20, 2009

I. General Description

The minutes of IRB meetings will be written in sufficient detail to show attendance at the meetings, actions taken by the IRB, the vote on these actions including the number of members voting for, against and abstaining, the basis for requiring changes in or disapproving research and a written summary of the discussion of controverted issues and their resolution. IRB staff will prepare minutes that document the proceedings of each convened IRB meeting. The Board's correspondence to investigators, outlining the basis for requiring changes in or disapproving the research, will be appended to the minutes, making the IRB correspondence an official part of the minutes.

II. Information Documented

- A. **Meeting Logistics:** The minutes will document the start time, end time, date and location of the meeting.
- B. **Meeting Attendance:** The minutes will identify all individuals in attendance at the meeting, including IRB members, IRB staff, consultants, investigators and guests. The minutes will also indicate the status of each individual in attendance (e.g., Non-UCLA affiliated member, Non-scientific member, etc.) and identify the members who are prisoner representatives and other subject advocates as appropriate.

The minutes will document when a member is recused from the meeting deliberations and the vote due to a conflict of interest. All members are asked to refrain from leaving the meeting except for urgent reasons in order to ensure an appropriate and comprehensive deliberation and review. Primary and secondary reviewers will remain in attendance for the duration of the review and approval of the protocol to which they are assigned. However, if a member does leave the room, the reason will not be specified in the minutes unless it is because of a conflict of interest.

- C. **Participation of Alternate Members:** The minutes will document when an alternate member substitutes for a voting member and for whom the alternate is substituting.
- D. **Absent Members:** The minutes will indicate when an absent member's comments were read to the Board.
- E. **Protocols under Review:** The minutes will identify the IRB protocol number, principal investigator and project title of all studies under review at the meeting.

- F. **Voting:** The number of members voting for, opposing and abstaining from each motion will be recorded. Members who have been recused from a discussion and a vote due to a conflict of interest will be identified. Members who were absent from the vote for any other reason (e.g., answering a page) will be identified as “Out of Room.” The identity of a member who abstains from the vote will be documented in the minutes only upon the request of the member, in order to protect the confidentiality of members’ decisions. IRB staff will ensure that all votes are taken by a quorum of the Board, including at least one member whose primary concerns are in nonscientific areas. 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 or through video conferencing. Members may not vote by proxy, that is, without being present as described above.
- G. **Quorum:** The minutes will document the continued presence (or connection via speakerphone or through video conferencing) of a majority of the members, including at least one non-scientist. 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 and final vote by the Full Board.
- H. **Conflicts of Interest:** If a member with a conflicting interest is in attendance at the meeting, the minutes will document, by name, the member who left the room during the deliberations and voting due to a conflict of interest. If the member was 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.
- I. **Consultation:** The minutes will document when the Board requests consultant review from an expert in the field. The minutes will indicate whether a consultant is in attendance at the meeting or whether a consultant’s comments were read to the Board.
- J. **Controverted Issues:** The minutes will include a written summary of the discussion of controverted issues and their resolution.
- K. **Speakerphone or Videoconferencing Participation:** If a member is not physically present during a convened meeting, but instead participates via speakerphone or video conferencing, this will be documented in the minutes. When an IRB member participates via telephone or video conference, the minutes will document that the IRB member received all pertinent material prior to the meeting and was able to actively and equally participate in the discussion of all protocols. Such members are counted as part of the quorum and may vote on all protocols for which they are connected via speakerphone or video as long as they can actively and equally participate in the discussion.
- L. **IRB Meetings Convened via Telephone or Video Conference Call:** When an IRB meeting is conducted via telephone or video conference call, the minutes will document

that each participating IRB member received all pertinent material prior to the meeting and was able to actively and equally participate in the discussion of all protocols.

M. Actions taken by the Convened IRB: The minutes will document the IRB actions for initial review, continuing review and review of modifications to the research.

N. Specific Findings and Determinations: When the IRB is required to make specific regulatory determinations, these determinations are documented in the minutes. However, the protocol-specific information justifying each determination, when required, is included in the minutes only if that information is *not* included in the application or if the members disagree with the description rationale provided in the application.

The following regulatory determinations are documented in the minutes:

1. Justification for a waiver or alteration of informed consent [45 CFR 46.116(d)] [45 CFR 46.408].
2. Justification for a waiver of signed informed consent [45 CFR 46.117(c) and 21 CFR 56.109(c)].
3. IRB considerations of protocols involving vulnerable subjects, including:
 - a. Category(ies) of risk level for research involving children [45 CFR 46.404-407 (Subpart D) and 21 CFR 50.51 – 50.55];
 - b. Category(ies) for conducting research involving prisoners [45 CFR 46.305-306 (Subpart C)], as well as the presence of the prisoner representative;
 - c. Category(ies) for research involving pregnant women, fetuses or neonates, or the transplantation of fetal tissue [45 CFR 46.204-207 (Subpart B)]; and/or
 - d. Determinations for research involving wards of the state or other agency [45 CFR 46.409 and 21 CFR 50.56].
4. The determination of whether a device may be considered Nonsignificant Risk [21 CFR 812.3(m)].

O. Additional Determinations Documented in the Minutes as Applicable:

1. Whether protocols can be reviewed under the expedited review procedures outlined in 45 CFR 46.110 or 21 CFR 56.110 at the time of the next review;
2. The acceptability of allowing surrogate (proxy) consent including the use of a Legally Authorized Representative.
3. HIPAA Privacy Rule requirements for HIPAA authorization and/or waiver of authorization.
4. Requirements for an Investigational New Drug Exemption (IND) or Investigational Device Exemption (IDE)
5. Whether it is in the best interest of active subjects to continue participating in research interventions or interactions during a lapse in approval.

6. Justification of any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample consent document.
 7. Determinations of unanticipated problems and/or serious and/or continuing noncompliance.
- P. **Expedited Review Notification:** The minutes will include a list of all protocols, including the IRB protocol number, the name of the Principal Investigator, and the title of the study, reviewed under the expedited review procedures outside the convened meeting. The comments section for each study reviewed by expedited review will include the following information:
1. New/Continuation/renewal studies:
 - a. Expedited category citation; and
 - b. Documentation of specific findings and determinations.
 2. Addendum to previously-approved study:
 - a. Expedited category citation; and
 - b. Documentation of specific findings and determinations.
- Q. **Approval Interval:** The minutes will document the approval period for all studies; the approval period for all studies is one year minus one day from the date of the meeting, unless otherwise noted in the minutes. The minutes will indicate when a protocol requires continuing review more often than annually, as appropriate to the degree of risk.
- R. **Other Committee Business:** The following items will also be documented in the minutes:
1. Discussion of full Board reviews of any post approval reports (adverse events, violations and/or incidents, safety reports) and/or monitoring or audit reports and any related determinations of unanticipated problems and/or serious and/or continuing noncompliance;
 2. A brief description of the topic of any educational or training presentations provided at the meeting;
 3. Other miscellaneous discussions will also be documented, as applicable.

III. Approval of the Minutes

The minutes will be distributed to the IRB Chair or their designee for review. The IRB Chair or designee may approve the minutes or recommend changes. Staff will modify the minutes as requested.

IV. Distribution and Retention of the Minutes

- A. Copies of the approved minutes are forwarded on a monthly basis to the Vice Chancellor for Research or to his or her designee.
- B. Copies of approved minutes are filed in individual Committee meeting files.
- C. The minutes are retained indefinitely.
- D. Approved minutes are available for inspection by federal and state regulatory agencies, University auditors, and other authorized representatives at reasonable times and in a reasonable manner.

Regulations:

45 CFR 46.108
45 CFR 46.115(a)(2), (b)
45 CFR 46.116(d)
45 CFR 46.117(c)
45 CFR 46.204 - 207
45 CFR 46.305, 306
45 CFR 46.404 – 46.408
21 CFR 50.51 – 56
21 CFR 56.109(c)
21 CFR 56.115(a)(2)
21 CFR 812.3(m)

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: Significant Risk and Nonsignificant Risk Medical Device Studies – January 2006. <http://www.fda.gov/oc/ohrt/irbs/devrisk.pdf>
- FDA Information Sheets: Frequently Asked Questions – 1998. (<http://www.fda.gov/oc/ohrt/irbs/faqs.html>)