

UC San Diego <small>INSTITUTIONAL REVIEW BOARD ADMINISTRATION</small>	OIA-043 SOP: IRB Meeting Minutes				
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1 PURPOSE

- 1.1 This procedure establishes the process to record minutes for convened meetings.
- 1.2 The process begins when the meeting is called to order.
- 1.3 The process ends when the minutes are approved by the Office of IRB Administration (OIA) director or assistant director.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None.

3 REQUIREMENTS

- 3.1 Minutes are to comply with regulatory and guidance¹ requirements.
- 3.2 Minutes are to record separate deliberations for each IRB action.
- 3.3 Minutes are officially approved on behalf of the IRB by the OIA director or assistant director.
- 3.4 IRB members may make corrections to the minutes.
- 3.5 The OIA staff write minutes and make them available for review within 35 business days following the meeting date.
- 3.6 Approved minutes may be amended with approval of the OIA Director or assistant director. The original approved minutes must be retained, the amended version(s) labeled as such, and a note-to-file documenting the change(s) and their rationale created and retained with the original and amended minutes. The person completing the quality improvement assessment in section 5.12 below and the person approving the minutes in section 5.14 below cannot be the same person.


4 RESPONSIBILITIES

- 4.1 OIA staff and IRB members carry out these procedures.

5 PROCEDURE

- 5.1 Use the *OIA-501 TEMPLATE: Minutes*, or equivalent, to record activities at meetings.
- 5.2 Under “attendance table,” or equivalent, record information for each voting member (regular members and alternates) present at the meeting at any time.
 - 5.2.1 Alternates serving as voting members for that meeting should be listed with the voting members, and the regular member in whose place they are serving that day should be recorded.
 - 5.2.2 List as “absent” in the attendance table the regular/core members who are both not present and do not have an alternate serving in their place that meeting.
- 5.3 Record any guests in attendance at the meeting.
- 5.4 Record any consultants in attendance at the meeting.
- 5.5 Record announcements or other business.
 - 5.5.1 The chair’s solicitation of conflicting interest prior to any deliberations should be noted, and any affirmative responses recorded.
 - 5.5.2 Provision of the list of protocols granted approval using the expedited procedure, and the period in which these approvals were granted, should be noted.
 - 5.5.3 Whether or not continuing education/training was given should be noted. If given, the topic should be noted.
- 5.6 Record the total number of core/regular members on *OIA-601 DATABASE: IRB Roster*, or equivalent. Exclude alternate members in this count.
- 5.7 Record the number of members required for quorum, using *OIA-305 WORKSHEET: Evaluation of Quorum and Expertise*, or equivalent.
- 5.8 Record the meeting start and end time.
- 5.9 List each business item that was discussed.
- 5.10 For each protocol reviewed, record:
 - 5.10.1 Type of review
 - 5.10.2 IRB identification number
 - 5.10.3 Principal investigator name
 - 5.10.4 Protocol title
 - 5.10.5 Sponsor/Funding agency (indicate “none” if none)
 - 5.10.6 Investigational new drug (IND) or investigational device exemption (IDE) (indicate “none” if none)

¹ [Minutes of Institutional Review Board \(IRB\) Meetings: Guidance for Institutions and IRBs](#)

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- 5.10.7 Consultant report: Summarize the key information provided by the consultant. Indicate “none” if none or delete if no consultant participated.
- 5.10.8 Notes: Summarize issues useful to understand the agenda item, for example, administrative comments or additional comments on reportable events provided to the researchers.
- 5.10.9 Controverted issues and their resolution: Summarize the issues in which IRB members expressed a difference of opinion. For each issue, indicate the resolution or indicate that there was none. If no controverted issues, indicate “none.”
- 5.10.10 For new projects or continuing reviews, or when new information and/or changes alter the prior determination, document level of risk determined by the convened IRB: minimal risk or greater than minimal risk.
- 5.10.11 Motion: approved, approved pending, deferred, disapproved, suspended, or terminated. For initial or continuing review, add the period of approval to the motion. If new information and/or changes require modification of the approval period, record the updated approval period. If the protocol was tabled, indicate this.
- 5.10.12 Vote: For each agenda item, record as the number of members voting for, against, abstaining, absent, recused, or other. List the names of IRB members who abstained, were absent, or were recused. Consultants may not vote. The total number voting may never exceed the total number of core/regular members on the roster.²
 - 5.10.12.1 Attendance total: total number of voting members taken from the attendance table.
 - 5.10.12.2 Vote total: total number of voting members present for the discussion and vote on this protocol.
 - 5.10.12.2.1 For: voting for the motion.
 - 5.10.12.2.2 Against: voting against the motion.
 - 5.10.12.2.3 Abstain: present for the vote, but not voting “for” or “against.” List the names of abstaining members in the vote.
 - 5.10.12.3 Non-Voting:
 - 5.10.12.3.1 Absent: listed as voting on the attendance table but not present for the discussion and vote on this protocol for reasons other than a conflicting interest. List the names of absent members.
 - 5.10.12.3.2 Recused: listed as voting on the attendance table but not present for the discussion and vote on this protocol because of a conflicting interest. List the names of recused members.
 - 5.10.12.3.3 Other: listed as voting on the attendance table but not voting on this protocol either because an alternate member is substituting for a regular member, or for any other reason.
 - 5.10.12.4 Substitutions: When an alternate(s) is listed as non-voting but present on the attendance table, and the alternate member substitutes as voting in place of another member for a given agenda item, identify the name of the alternate to indicate which individual is serving as the voting member for this vote. Indicate “none” if there are no substitutions.
 - 5.10.12.5 Record the names of the non-voting members present for the deliberation and vote of the given agenda item, or indicate none if there is none present.
- 5.11 Document any required determinations and findings. These may include but are not limited to:
 - 5.11.1 If the criteria for approval have been met
 - 5.11.2 The research involves a conflict of interest management plan
 - 5.11.3 Waiver or alteration of consent
 - 5.11.4 Waiver of written documentation of consent
 - 5.11.5 Children
 - 5.11.6 Pregnant subjects

² When an alternate member is present at the given meeting but not listed as voting that day, if the alternate member was primary or secondary reviewer of a protocol, the alternate member should vote and be counted for that item, substituting for a member who was listed as voting that day in the attendance table but was not a primary or secondary reviewer for the given protocol.

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- 5.11.7 Neonates
 - 5.11.8 Prisoners
 - 5.11.9 Cognitively impaired adults
 - 5.11.10 Rationale for a significant/non-significant risk device determination
 - 5.11.11 Rationale for an IND exemption determination
 - 5.11.12 Approve pending: If this is the motion, complete the entry for the agenda item with the required changes and corresponding reasons.
 - 5.11.13 Deferral/disapproval reasons and recommended changes: If this is the motion, complete the entry for the agenda item with the recommendations and corresponding reasons.
 - 5.11.14 Suspension/termination of IRB approval reasons and recommended changes: If this is the motion, complete the entry for the agenda item with the recommendations and corresponding reasons.
 - 5.11.15 Tabled reason: If the protocol was tabled, provide the reason(s).
 - 5.11.16 For reportable events: when made, document the IRB's determination and rationale regarding whether the event(s) in question constitutes an unanticipated problem involving risks to subjects or others/unanticipated problem report (UPR) or serious and/or continuing non-compliance, as applicable.
 - 5.11.17 Any other actions taken by the IRB to protect human subjects, such as instituting an enrollment hold or requiring changes to the protocol or consent document, should be recorded.
 - 5.12 Provide minutes to the quality assurance/quality improvement lead or other OIA staff member responsible for performing a quality improvement assessment, using *OIA-335 WORKSHEET: Minutes Quality Improvement Assessment*, or equivalent.
 - 5.13 Provide minutes to IRB chair, or vice chair if chair was not in attendance, for review, allowing for a period for comment.
 - 5.14 Revise minutes for accuracy and provide them to the OIA director or assistant director for review and approval.
- 6 MATERIALS**
- 6.1 *OIA-001 SOP: Definitions*
 - 6.2 *OIA-335 WORKSHEET: Minutes Quality Improvement Assessment*
 - 6.3 *OIA-501 TEMPLATE: Minutes*
 - 6.4 *OIA-601 DATABASE: IRB Roster*
- 7 REFERENCES**
- 7.1 [21 CFR 56.115\(a\)\(2\)](#)
 - 7.2 [45 CFR 46.115\(a\)\(2\)](#)
 - 7.3 [Minutes of Institutional Review Board \(IRB\) Meetings: Guidance for Institutions and IRBs](#)