

UC San Diego INSTITUTIONAL REVIEW BOARD ADMINISTRATION	OIA-041 SOP: IRB Meeting Conduct				
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1 PURPOSE

- 1.1 This procedure establishes the process to conduct convened IRB meetings.
- 1.2 The process begins when the IRB members gather for a convened meeting.
- 1.3 The process ends when the meeting is adjourned.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None.

3 REQUIREMENTS

- 3.1 The IRB reviews research in accordance with the applicable regulatory criteria for approval.
- 3.2 The IRB meetings may be held in-person, virtually, or hybrid .
- 3.3 If quorum is lost during a meeting, the IRB cannot take votes until the quorum is restored.
- 3.4 When the IRB determines that more information and/or additional conditions for approval are required:
 - 3.4.1 If there are substantive changes or requirements, requests for more information for IRB consideration, or when the IRB is unable to specify changes that would cause the study to satisfy the regulatory criteria for approval, convened IRB review of the response is required.
 - 3.4.2 If the response to the IRB includes, unsolicited by the IRB, substantive changes or requirements, or other issues related to the regulatory criteria for approval, convened IRB review of the response is required.
 - 3.4.3 Minor, administrative, or prescriptive changes or requirements may be reviewed for approval by the IRB chair, a designated reviewer, or a designated Office of IRB Administration (OIA) staff member.
 - 3.4.4 If the research expires before the conditions are reviewed and approved, all research activities must stop until approval is obtained.
- 3.5 The list of protocols approved using expedited procedures (initial reviews, continuing reviews, reviews of modifications to previously approved research, and study closures), including worksheets and checklists described in *OIA-301 WORKSHEET: Review Materials*, or equivalent, and listed below in "Section 6: MATERIALS," are provided to IRB members, either via email or the electronic submission system, in advance of meetings per *OIA-040 SOP: IRB Meeting Preparation*. The materials are used to conduct meetings and meet regulatory requirements.

4 RESPONSIBILITIES

- 4.1 The IRB chair, with assistance of the OIA staff, ensures these procedures are carried out.
- 4.2 Primary reviewers lead the convened IRB members through consideration of the regulatory approval criteria for relevant IRB agenda items.


5 PROCEDURE

- 5.1 Call the meeting to order.
- 5.2 Ask IRB members whether anyone present has a conflicting interest, which has not been identified in the agenda assignment process, for any item on the agenda. Note the responses, and take any steps necessary to mitigate the conflict, such as reassigning the item to another member or to another agenda.
- 5.3 For each agenda item involving review of a protocol:
 - 5.3.1 Table the item when notified by OIA staff that review requirements for a specific item, as defined in *OIA-305 WORKSHEET: Evaluation of Quorum and Expertise*, or equivalent, are not met.¹
 - 5.3.2 If there are IRB members with a conflicting interest, invite the IRB to ask questions of those members during the relevant agenda item review. The member(s) with conflicting interest will be asked to leave the meeting during discussion and voting. If the member(s) with conflicting interest is/are present by teleconference, they will be placed on hold or will disconnect for discussion and voting on any items for which they have a conflicting interest.
 - 5.3.3 If a consultant is present, ask the consultant to present their review to the IRB.
 - 5.3.4 If a consultant provided written information to the IRB, or if there is documentation of comments delivered orally from consultant to OIA staff, present that information to the IRB.

¹ "Tabled" is not an action of the IRB, but is a status based on the inability of the IRB to take an action because of reasons of quorum or expertise. This action may also be taken by the IRB when it is prudent for an item to be reviewed as part of a different agenda.

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- 5.3.5 Ask the scientific or scholarly reviewer or primary reviewer to present the scientific or scholarly review to the IRB. See *OIA-320 WORKSHEET: Scientific or Scholarly Review*, or equivalent.
- 5.3.6 Ask the primary reviewer to lead the convened IRB through a discussion of the criteria in the *OIA-314 WORKSHEET: Criteria for Approval and Additional Considerations*, or equivalent; *OIA-322 WORKSHEET: Emergency Use*, or equivalent; or *OIA-323 WORKSHEET: Criteria for Approval and Additional Considerations HUD*, or equivalent; and all applicable referenced checklists (listed in "Section 6: MATERIALS" below) to have the convened IRB determine which regulatory criteria are met (or continue to be met), which are not met (or are no longer met), and which would be met if the investigator modified the protocol as requested by the IRB.
- 5.3.7 Ask the secondary reviewer, if assigned, to lead the convened IRB through a discussion of any additional concerns they identified.
- 5.3.8 For reportable events (unanticipated problem involving risks to subjects or others/unanticipated problem report, serious or continuing non-compliance, or suspension or termination of IRB approval) ask the primary reviewer to use the *OIA-321 WORKSHEET: Review of Reportable Events*, or equivalent, to lead the convened IRB through a discussion of what actions, if any, are needed to protect human subjects.
- 5.3.9 For continuing review of research, the IRB determines:
- 5.3.9.1 Whether the IRB needs verification from sources other than the researchers that no material changes have occurred since previous IRB review.
- 5.3.9.2 Whether the current consent document is still accurate and complete.
- 5.3.9.3 Whether any significant new findings arising from the review process that might relate to participants' willingness to continue participation will be provided to participants.
- 5.3.10 Restate the reviewers' recommended determinations regarding any protocol specific findings justifying a determination when required by a checklist, or equivalent, that were not previously determined and documented.
- 5.3.11 Make a motion for one of the following actions:
- 5.3.11.1 Approve: Made when all criteria for approval are met. Include in motions for initial and continuing review, the period of approval or a statement that no continuing review is required, as well as the level of risk. When making this motion, ask the primary reviewer to use the *OIA-319 WORKSHEET: Approval Period*, or equivalent, to lead the convened IRB through a discussion of the appropriate approval period.
- 5.3.11.2 Approve pending: Made when IRB members require specific modifications such that an OIA staff member, IRB chair, or a designated reviewer can determine whether an investigator has made the required changes without judging whether a change meets the regulatory criteria for approval. When making this motion, the assigned primary reviewer restates the modifications required by the IRB members, the reasons for those changes, the level of risk, and the approval period or a statement that no continuing review is required. When making this motion, ask the primary reviewer to use the *OIA-319 WORKSHEET: Approval Period*, or equivalent, to lead the convened IRB through a discussion of the appropriate approval period.
- 5.3.11.3 Defer: Made when the research does not yet qualify for approval or approval pending and the IRB has recommendations that might make the protocol approvable. When making this motion, the assigned primary reviewer identifies the regulatory criteria for approval that are not satisfied and describes recommendations to make the research approvable.
- 5.3.11.4 Disapprove: Made when the research does not qualify for approval, approval pending, or deferral and the IRB has no recommendations that might make the protocol approvable. When making this motion, the assigned primary reviewer describes the regulatory criteria for approval that are not satisfied.
- 5.3.11.5 Suspension or termination of IRB approval: Made when reportable event(s) about currently approved research has/have been submitted to the IRB which

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indicates that the study, in whole or in part, should not continue temporarily or permanently. This may include, but is not limited to, instances in which the research is not being conducted in accordance with regulatory requirements, the IRB's requirements, or has been associated with unexpected serious harm to participants. When making this motion, ask the primary reviewer to use the *OIA-321 WORKSHEET: Review of Reportable Events*, or equivalent, to lead the convened IRB through a discussion of what actions are needed, if any, to protect human subjects. The assigned primary reviewer describes the IRB member's reasons for the decision.

- 5.3.11.6 Unanticipated problem involving risks to subjects or others/unanticipated problem report: Made when an event occurs that meets the definition in *OIA-001 SOP: Definitions*.
- 5.3.11.7 Serious and/or continuing non-compliance: Made when a report discloses information that satisfies the definitions of serious and/or continuing non-compliance.
- 5.3.11.8 Open the floor for additional discussion.
- 5.3.12 Review any approve pending stipulations to ensure that the OIA staff has recorded them.
 - 5.3.12.1 Ensure that the required modifications include all final contingencies on *OIA-401 CHECKLIST: Pre-Review*, or equivalent.
- 5.3.13 When a financial conflict of interest is reported, the IRB will review the reported related financial interest as outlined in *OIA-055-SOP: Financial Conflicts of Interest*.
- 5.3.14 Call for a vote.
 - 5.3.14.1 Only IRB members may vote.
 - 5.3.14.2 The IRB chair votes as a regular member.
 - 5.3.14.3 If a member and an alternate are both present, only one vote is recorded.
 - 5.3.14.4 Consultants may not vote.
 - 5.3.14.5 For a motion to be approved, the approval of more than half of the voting members present at the meeting is required. (For example, if there are 10 or 11 members present at the meeting, 6 votes are required for approval, which is greater than 5 and 5.5, respectively.)
- 5.3.15 Re-invite IRB members with a conflicting interest back into the meeting.
- 5.3.16 Provide any written information provided by a member or consultant to the OIA staff.
- 5.4 Adjourn the meeting when notified by OIA staff that quorum has been lost or when there is no further business.

6 MATERIALS

- 6.1 *OIA-001 SOP: Definitions*
- 6.2 *OIA-040 SOP: IRB Meeting Preparation*
- 6.3 *OIA-055-SOP: Financial Conflicts of Interest*
- 6.4 *OIA-301 WORKSHEET: Review Materials*
- 6.5 *OIA-305 WORKSHEET: Evaluation of Quorum and Expertise*
- 6.6 *OIA-306 WORKSHEET: Drugs*
- 6.7 *OIA-307 WORKSHEET: Devices*
- 6.8 *OIA-314 WORKSHEET: Criteria for Approval and Additional Considerations*
- 6.9 *OIA-314B WORKSHEET: Requirements for Informed Consent*
- 6.10 *OIA-315 WORKSHEET: Advertisements*
- 6.11 *OIA-316 WORKSHEET: Payments*
- 6.12 *OIA-317 WORKSHEET: Short Form of Consent Documentation*
- 6.13 *OIA-318 WORKSHEET: Additional Federal Criteria*
- 6.14 *OIA-319 WORKSHEET: Approval Period*
- 6.15 *OIA-320 WORKSHEET: Scientific or Scholarly Review*
- 6.16 *OIA-321 WORKSHEET: Review of Reportable Events*
- 6.17 *OIA-322 WORKSHEET: Emergency Use*
- 6.18 *OIA-323 WORKSHEET: Criteria for Approval and Additional Considerations HUD*
- 6.19 *OIA-401 CHECKLIST: Pre-Review*
- 6.20 *OIA-410 CHECKLIST: Waiver or Alteration of the Consent Process*

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- 6.21 OIA-411 CHECKLIST: *Waiver of Written Documentation of Consent*
- 6.22 OIA-412 CHECKLIST: *Pregnant Subjects*
- 6.23 OIA-413 CHECKLIST: *Non-Viable Neonates*
- 6.24 OIA-414 CHECKLIST: *Neonates of Uncertain Viability*
- 6.25 OIA-415 CHECKLIST: *Prisoners*
- 6.26 OIA-416 CHECKLIST: *Children*
- 6.27 OIA-417 CHECKLIST: *Cognitively Impaired Adults*
- 6.28 OIA-418 CHECKLIST: *Non-Significant Risk Device*
- 6.29 OIA-419 CHECKLIST: *Waiver of the Consent Process for Emergency Research*
- 6.30 OIA-441 CHECKLIST: *HIPAA Waiver of Authorization*

7 REFERENCES

- 7.1 [21 CFR 50.20](#)
- 7.2 [21 CFR 50.25](#)
- 7.3 [21 CFR 50.27](#)
- 7.4 [21 CFR 56.109](#)
- 7.5 [21 CFR 56.111](#)
- 7.6 [45 CFR 46.109](#)
- 7.7 [45 CFR 46.111](#)
- 7.8 [45 CFR 46.116](#)
- 7.9 [45 CFR 46.117](#)