

SOP: IRB Meeting Minutes				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-043	12/6/18	T. Bechert	G. Ostrander	1 of 3

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 IRB chair or IRB Manager.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None.

3 POLICY

- 3.1 Minutes are to comply with regulatory and guidance requirements.
- 3.2 Minutes are to record separate deliberations for each action.
- 3.3 Minutes are officially approved on behalf of the IRB by the IRB chair or IRB manager.
- 3.4 IRB members may make corrections to minutes.
- 3.5 The IRB writes minutes and makes them available for review within 21 days of the meeting date.
- 3.6 Minutes may not be altered by anyone including a higher authority once accepted by the convened IRB.

4 RESPONSIBILITIES

- 4.1 IRB staff members carry out these procedures.

5 PROCEDURE

- 5.1 Execute the “Convene Meeting” activity
- 5.2 Record each voting member (regular members and alternates) present at the meeting at any time: (Do not record non-voting members under “Attendance Table.”)
 - 5.2.1 Name.
 - 5.2.2 Status: E.g., chair, vice chair, scientific member, non-scientific member, unaffiliated member, representative of vulnerable population (specify), prisoner representative, Veterans Administration (VA) representative, or alternate member.
 - 5.2.3 For alternate members who are substituting for a regular member, indicate the name of the regular member for whom the alternate member is substituting.
 - 5.2.4 Whether the member was present by teleconference.
- 5.3 Record the total number of members on “DATABASE: IRB Roster (HRP-601).” Exclude alternate members in this count.
- 5.4 Record the number of members required for quorum. Divide the number of members by two and select the next whole number. For example, if there are 10 IRB members on the “DATABASE: IRB Roster (HRP-601),” then $10/2 = 5$ and the next whole number is 6. If there are 11 IRB members on the “DATABASE: IRB Roster (HRP-601),” then $11/2=5.5$ and the next whole number is 6.
- 5.5 Indicate whether members present by teleconference received all pertinent material before the meeting and were able to actively and equally participate in all discussions. Delete if no members were present by teleconference.
- 5.6 Record the meeting start time.
- 5.7 For each submission reviewed record in the “Submit Committee Review” activity or “Submit RNI Committee Review” activity, as appropriate:
 - 5.7.1 Motion: Approved, Approved with Modifications, Deferred, Disapproved, Suspended, or Terminated. For initial or continuing review add the period of approval to the motion.
 - 5.7.2 Risk Level: Minimal Risk or more than Minimal Risk.
 - 5.7.3 Last Day of Approval Period: Record the study expiration date.
 - 5.7.4 Recommended Changes and Reasons: If the motion is Modifications required to secure approval or deferral/disapproval, complete the table with the required changes and corresponding reasons. If no recommended changes, indicate “None.”

SOP: IRB Meeting Minutes				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-043	12/6/18	T. Bechert	G. Ostrander	2 of 3

- 5.7.5 Controverted Issues and their Resolutions: Summarize the issues where 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.”
- 5.7.6 Determinations and findings that require documentation: If the research involves waiver or alteration of consent, waiver of written documentation of consent, children, pregnant women, Prisoners, or cognitively impaired adults, enter “See attached Supporting Documents” and ensure that the corresponding completed checklist is uploaded as a supporting document. If no determinations that require documentation, indicate “None.”
- 5.7.7 RNI Determinations: Record the determination of unanticipated problem involving risks to subjects or others, suspension or termination of IRB approval, serious non-compliance, continuing non-compliance, non-compliance that is neither serious nor continuing, allegation of non-compliance with no basis in fact, or none of the above.
- 5.7.8 RNI Considerations: Record requirements determined by the IRB, for example modification to the protocol or ask subjects to re-consent.
- 5.7.9 Additional Information and Notes: Summarize issues useful to understand the agenda item. For example, a brief history of recent IRB actions
- 5.7.10 Supporting documents: For any determinations that require documentation, upload the appropriate checklist(s), or any other appropriate supporting documents.
- 5.7.11 Vote: Record as the number of members for, against, abstaining, absent, or recused. List the names of IRB members who were absent or recused. Do not count votes of consultants. If both a regular IRB member and the alternate IRB member are present at the meeting record the vote of just one.
 - 5.7.11.1 For: Voting for the motion.
 - 5.7.11.2 Against: Voting against the motion.
 - 5.7.11.3 Abstain: Present for the vote, but not voting “For” or “Against.”
 - 5.7.11.4 Absent: Listed under “Members Present” but not present for the discussion and vote on this protocol for reasons other than a Conflicting Interest. List the names of absent members in the vote. For example: “For: 7 Against: 3 Abstain: 2 Absent: 2 (Alice Baker, Charlie Delta) Recused: 0 Substitutions: 0”
 - 5.7.11.5 Recused: Listed under “Members Present” but not present for the discussion and vote on this protocol for because of a Conflicting Interest. List the names of recused members in the vote. For example: “For: 7 Against: 3 Abstain: 2 Absent: 0 Recused: 2 (Evelyn Foxtrot, George India) Substitutions: 0”
 - 5.7.11.6 Substitutions: Listed under “Members Present” When regular members and their alternate(s) are listed under “Members Present” and an alternate member substitutes for the regulator member, identify the name of the alternate to indicate which individual is serving as the voting member for this vote. May be deleted if there are no substitutions. For example: “For: 7 Against: 3 Abstain: 2 Absent: 0 Recused: 0 Substitutions: 1 (Evelyn Foxtrot substituted for George India)”
- 5.7.12 For an Unanticipated Problem Involving Risks to Subjects or Others, in the “Submit RNI Committee Review,” document the IRB’s determination as to whether a protocol or consent document modification is warranted, and if so, document the IRB’s determination as to whether previously enrolled subjects must be notified of the modification and, if so, when such notification must take place and how such notification must be documented.
- 5.8 Record the meeting end time.
- 5.9 Execute the “Prepare Minutes” activity and combine the attendee information with the generated submission-specific determinations.

SOP: IRB Meeting Minutes				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-043	12/6/18	T. Bechert	G. Ostrander	3 of 3

- 5.10 Within 2 business days revise minutes for accuracy and notify the IRB chair or IRB manager for review and approval.
 - 5.10.1 For minutes of Veterans Administration (VA) research have the IRB chair or a qualified voting member of the IRB designated by the IRB chair sign the minutes and upload signed version into the meeting workspace
- 5.11 Once approved by the IRB chair or IRB manager, and execute the “Close Meeting” activity. Email minutes to:
 - 5.11.1 Veterans Administration (VA) Research and Development Committee
 - 5.11.2 When an affiliate IRB is the IRB of Record, the affiliate may either:
 - 5.11.2.1 Provide VA with unredacted copies of meeting minutes, or
 - 5.11.2.2 Provide VA with redacted copies of meeting minutes and permit relevant VA personnel (including, but not limited to, ORO staff, local VA Research Office staff, local RCOs, and R&D Committee members) to review the unredacted meeting minutes within two business days of a written request from VA. Such review may occur at the affiliate site during normal business hours, or as otherwise mutually acceptable to VA and the affiliate.
- 5.12 IRB members have 7 days to review the minutes.
- 5.13 Attach the following documents to the meeting workspace:
 - 5.13.1 List of protocols granted approval using the expedited procedure.
- 5.14 Execute the “Approve Minutes” activity

6 MATERIALS

- 6.1 TEMPLATE VA MINUTES SUPPLEMENT (HRP-509)

7 REFERENCES

- 7.1 21 CFR §56.115(a)(2)
- 7.2 45 CFR §46.115(a)(2)