



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.

The process ends when the minutes are approved by the IRB Chair, HRPP Director or designee.

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.

Minutes are officially approved on behalf of the IRB by the IRB Chair, HRPP Director or designee.

- 3.3 The IRB staff compose minutes and make them available for review 5 business days before the meeting date.
- 3.4 IRB members may make corrections to minutes at the convened meeting before approval by the Committee.

Minutes are made available to the Institutional Official (IO) or designee, HRPP Quality Assurance & Evaluation (QA&E) Team, and, when applicable, to cooperative research institutions.

- 3.5 Any proposed changes to approved minutes must be returned to the convened IRB for approval.

4 RESPONSIBILITIES

- 4.1 IRB staff members carry out these procedures.

5 PROCEDURE

Use **5.301 (HRP-501b) – TEMPLATE – Minutes in eIRB+** to record observations at meetings.

- 5.1 Under “Attendance Table” record each voting member (regular members and alternates) present at the meeting at any time: (Do not record non-voting members under “Attendance Table.”)
 - 5.1.1 Name
 - 5.1.2 Status: E.g., chair, vice chair, scientific member, non-scientific member, unaffiliated member, representative of vulnerable population (specify), prisoner representative, or alternate member
 - 5.1.3 For alternate members who are substituting for a regular member, indicate the name of the regular member for whom the alternate member is substituting.
 - 5.1.4 Whether the member was present by telephone or videoconferencing.
- 5.2 Record the total number of members on the IRB Committee Member Roster. Exclude alternate members in this count.
- 5.3 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 IRB Roster, then $10/2 = 5$ and the next whole number is 6. If there 11 IRB members on the IRB Roster, then $11/2=5.5$ and the next whole number is 6.
- 5.4 Indicate whether members present by telephone or videoconferencing received all pertinent material before the meeting and were able to actively and equally participate in all discussions.
- 5.5 Record the meeting start time.
- 5.6 Record a summary of each business item that was discussed.
- 5.7 For each protocol reviewed record:
 - 5.7.1 Type(s) of review: Initial review, continuing review, review of modifications to previously approved research, or review of Unanticipated Problem Involving Risks to



NUMBER	DATE	PAGE
5.004 (HRP-043)	4/29/2024	2 of 3

Subjects or Others, Serious Non-Compliance, Continuing Non-Compliance, Suspension of IRB Approval, Termination of IRB Approval

- 5.7.2 Protocol Title
- 5.7.3 Investigator name
- 5.7.4 IRB identification number
- 5.7.5 Funding Agency (indicate “none” if none)
- 5.7.6 Grant Title (indicate “none” if none)
- 5.7.7 Grant ID (indicate “none” if none)
- 5.7.8 IND or IDE (indicate “none” if none)
- 5.7.9 Documents reviewed
- 5.7.10 Notes: Summarize issues useful to understand the agenda item. For example, a brief history of recent IRB actions

Consultant report: Summarize the key information provided by the consultant. Delete if there was no consultant.

- 5.7.11 Controverted issues and their resolution. 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.”

Motion: Approved, Approved with Stipulations, Conditions Pending for Approval, Disapproved, Tabled, Tabled Assistance, or Terminated. For initial or continuing review add the period of approval to the motion. If the protocol was tabled, indicate this.

- 5.7.12 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.
 - 5.7.12.1 For: Voting for the motion
 - 5.7.12.2 Against: Voting against the motion
 - 5.7.12.3 Abstain: Present for the vote, but not voting “For” or “Against”
 - 5.7.12.4 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”
 - 5.7.12.5 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”
 - 5.7.12.6 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)”
- 5.7.13 Level of risk determined by the convened IRB: Minimal Risk or more than Minimal Risk
- 5.7.14 Determinations and findings that require documentation: If the research involves waiver or alteration of consent, waiver of written documentation of consent, children, pregnant women, neonates, Prisoners, or cognitively impaired adults, include one of more of the “Determination/Protocol Specific Findings” tables in **5.301 (HRP-501b) – TEMPLATE – Minutes in eIRB+** or enter “See IRB records for this protocol” and



ensure that the corresponding completed checklist is in the IRB records. Otherwise delete.

- 5.7.15 Rationale for a significant/non-significant device determination: Describe the rationale for the determination. Otherwise delete.
- 5.7.16 Modifications required to secure approval: If this is the motion, document the required changes and corresponding reasons. Otherwise, delete.
- 5.7.17 Deferral/disapproval reasons and recommended changes: If this is the motion, document the recommendations and corresponding reasons. Otherwise, delete.
- 5.7.18 Suspension/termination reasons and recommended changes: If this is the motion, document the recommendations and corresponding reasons. Otherwise, delete.
- 5.7.19 Tabled reason: If the protocol was tabled, provide the reasons. Otherwise, delete.
- 5.8 Record the meeting end time.
- 5.9 Within 2 business days revise minutes for accuracy and provide them to the IRB Chair, HRPP Director or designee for review and approval.
- 5.10 Once approved by the IRB chair, HRPP Director or designee, make them available to:
 - 5.10.1 IO or designee (in eIRB+)
 - 5.10.2 IRB members (in eIRB+)
 - 5.10.3 HRPP QA&E Team (in eIRB+)
 - 5.10.4 Cooperative research institutions, when applicable (via correspondence)
 - 5.10.5 Authorized representatives of Federal Departments or Agencies
- 5.11 IRB members have 5 business days before the convened meeting to review the minutes.
- 5.12 Attach the following documents to the approved minutes:
 - 5.12.1 List of protocols granted approval using the expedited procedure

6 MATERIALS

- 6.1 5.301 (HRP-501b) – TEMPLATE – Minutes in eIRB+

7 REFERENCES

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