SOP 12.02 – IRB Minutes

1. Objective

To describe the preparation and maintenance of the minutes of fully convened Institutional Review Board (IRB) meetings.

2. General Description

In conformance with 45 CFR 46.115 (a)(2), minutes of IRB meetings shall be 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.

3. Roles & Responsibilities

Execution of SOP: Office of Research Integrity –Human Subjects (ORI-HS) Staff and the IRB

4. Procedures

Preparation

The ORI-HS staff member(s) who attend the convened IRB meeting takes notes regarding IRB discussions and determinations. These notes are then written using a template for minutes. The content of minutes may include, but are not limited to the following:

Content for Minutes

- The times at which the meeting is called to order and adjourned;
- The name of the person who called the meeting to order;
- A list of attendees, including members, alternates (including the name of the person they are serving as alternate for), IRB staff, guests and consultants;
- Initial and continued quorum including at least one nonscientist
- When a member leaves the room or leaves the meeting and whether quorum is maintained
- If applicable, the names of all members who attended via teleconference or video conference;
- Descriptions of educational activities/training/materials;
- Statement indicating any member conflict of interest with agenda items;
- Reports to the board, including protocol deviations, adverse events, unanticipated problems involving risks to participants or others, audit reports, details of disciplinary actions, etc. (if applicable); acknowledgement of or changes to minutes from previous meetings; and comments, if any, on reports of expedited and exempt activities provided with the meeting agenda.

Content for Each Protocol

Minute entries should capture the content of discussions and include all required findings and requests made of Principal Investigators (PI). Documentation for each protocol must include, at a minimum:

- The title of the protocol, the protocol number, the name of the PI;
- Actions taken on each protocol, including votes for and against and abstentions or recusals;
- The name of a member that did not participate in the discussion or vote due to late arrival or early departure;
- For recusals, a comment indicating that a named member recused and the reason for recusal (e.g. personal or financial conflict of interest);
- A statement that the protocol satisfies regulatory criteria for IRB approval of research;
- Summaries of discussions and resolution of concerns and questions;
- Level of Risk;
- Length of approval time;
- If revisions are required to secure approval, whether they may be reviewed by the chair or co-chair, or whether they need to be reviewed by the full board;
- Grounds for disapproving or deferring approval of protocols; and
- The attendance and participation of consultants or researchers, if applicable.

Optional elements may include

- Acknowledgment and management of conflicts of interest disclosed by study personnel;
- Additional safeguards required for the involvement of other vulnerable subjects;
- Documentation that all appropriate elements of informed consent are present;
- Consultants' or cultural consultant' statements;
- Waiver of or alteration to HIPAA authorization;
- Noncompliance must be recorded in the minutes and must include:
    - The determination of whether the noncompliance is serious and/or continuing; and
    - Any committee actions including research oversight, remedial action or termination or suspension of research.
- Adverse Reactions and Unexpected Events must be documented in the meeting minutes and must include:
    - The report of the adverse reaction or unexpected event; The IRB's determination on necessary and/or remedial action; and
    - A report of any emergency or preliminary action taken prior to the IRB meeting.

Specific Findings

When the IRB makes specific findings at convened meetings, ORI-HS staffs document these findings in the minutes of the meeting and include protocol-specific information justifying each finding. Examples of specific findings include, but are not limited to:

- Alteration or Waiver of the Informed Consent Process in Non FDA Requested Research: When the convened IRB reviews a procedure that alters or waives the requirements of informed consent, the minutes document the IRB's determinations required by the federal regulations (45 CFR 46.116).
- Waiver of Documentation of Informed Consent: When the convened IRB reviews a procedure that waives the requirements for obtaining a signed informed consent document, the minutes document that the IRB made the findings in accordance with federal regulations (45 CFR 46.117 and/or 21 CFR 56.109).

- Research Involving Deception: When the convened IRB reviews research involving deception, the minutes document that the IRB made the findings in accordance with 45 CFR 46.116.
- Research Involving Prisoners: When the IRB reviews research involving prisoners, the minutes indicate that the research meets the findings required by 45 CFR 46.305(a) and represents one of the categories of research permissible under Health and Human Services (HHS) regulations required by HHS 45 CFR 46.306(a).
    - At least one member of the IRB is a prisoner or a prisoner representative with appropriate background and experience to serve in that capacity.
    - In cases where more than one IRB reviews a particular research project, only one IRB need satisfy this requirement.
- Research Involving Children: When the IRB reviews research involving children, the minutes document that the IRB made the findings in accordance with IRB policy and federal regulations (HHS 45 CFR 46 Subpart D 46.404-46.407 and/or FDA 21 CFR Subpart D 50.50-50.55).
- Wards of the State or Other Agency: When the IRB reviews research involving children who are wards of the state or any other agency, institution, or entity, the minutes document that the IRB made the findings in accordance with federal regulations (45 CFR 46.409 and/or 21 CFR 50.56).
- Research Involving Pregnant Women, Human Fetuses and Neonates: When the IRB reviews research involving pregnant women, human fetuses, and neonates, the minutes must document that the IRB made the findings in accordance with federal regulations (45 CFR 46 Subpart B).
- Research Involving Individuals with Impaired Consent Capacity: When the IRB reviews research involving individuals who are cognitively impaired and/or lack consent capacity, the minutes document that the IRB made the findings in accordance with federal regulations [45 CFR 46.111(b) and/or 21 CFR 56.111(b)], and local policy.
- Investigational New Devices: The minutes document the IRB's determination of significant or non-significant risk for Investigational New Devices and the rationale for that decision, in accordance with federal regulations [(21 CFR 812.3(m)].

Acknowledgement and Retention

Draft versions of meeting minutes will be prepared by the ORI-HS staff for review, correction, and acknowledgment by the IRB. The minutes are written impersonally and do not contribute opinions expressed by members of the IRB. The minutes will only identify members when they recuse or abstain from a vote, enter a meeting after it has been called to order or leave prior to the meeting being adjourned. Acknowledgment of minutes by the IRB shall be indicated in the meeting minutes, and hard copies shall be retained by ORI-HS in binders. The acknowledged version shall constitute the official record of proceedings. IRB minutes, which are an official record of research review and approval, shall be retained for at least 3 years after completion of the research. IRB Minutes can be destroyed 3 years after completion of the research, and a log is maintained marking the destruction date.

Storage and Access

A copy of the IRB-acknowledged minutes for each IRB meeting is made available to the Institutional Official.

The IRB minutes, once acknowledged, may not be altered by anyone except by the IRB Chairperson with the concurrence and approval of the convened IRB (e.g. to correct factual errors). The IRB delegates to ORI-HS staff the authorization to correct administrative errors as appropriate (e.g, typographical/grammatical errors). All approved minutes shall be accessible for inspection and copying by authorized persons or groups.

5. References

45 CFR 46.107

45 CFR 46.108
45 CFR 46.111
45 CFR 46.115 (a)(2)
45 CFR 46.116
45 CFR 46.117
45 CFR 46.409
21 CFR 812.3(m)
21 CFR 50.23
21 CFR 50.24
21 CFR 50.56