OFFICE OF THE INSTITUTIONAL REVIEW BOARD

Standard Operating Procedures		
SOP #104.6 Revision 6	**TITLE: IRB Meeting Minutes**	Effective Date: 5/8/2022
Approved By: OIRB Director	Signature Linda Mayo	Date 5/2/2022
Approved By: IRB Chair	Signature	Date 5/2/2022

PURPOSE

To describe policies and procedures for completing the minutes of the convened meetings of the University of New Mexico (UNM) Institutional Review Board (IRB).

REVISIONS FROM PREVIOUS VERSION

Updated references to electronic research administration (ERA) system

POLICY

The federal policies for the protection of human participants (45 CFR 46.115(a)(2) and 21 CFR 56.115(a)(2)) require that "Minutes of IRB meetings shall be in sufficient detail to show attendance at the meeting; 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."

Good minutes enable a reader who was not present at the meeting to determine exactly how and with what justification the IRB arrived at its decisions. They also provide the IRB itself with sufficient detail to help it reconstruct its discussions at a later date, if necessary. Comprehensive minutes also demonstrate respect for the participants in research. Meeting minutes do not have to contain information provided in protocols the IRB has previously approved. This process assumes that if IRB members do not discuss a particular issue, the IRB deems the issue acceptable.

RESPONSIBILITIES

Execution of SOP: OIRB Staff, OIRB Director, IRB.

PROCEDURE

Minutes Preparation

1. The OIRB staff member attending the convened IRB meeting drafts detailed notes to document IRB discussions and determinations. OIRB staff uses the OIRB minutes template as a guide in drafting minutes. Examples of the type of information included in the minutes are as follows:
    - The location of the meeting and the time the IRB the meeting was convened and adjourned;
    - Announcements and continuing education activities presented to the IRB;
    - Documentation of attendance to include:
        - Initial and continued presence of a majority of members (i.e. quorum), including at least one nonscientist (See IRB Meeting Conduct SOP for definition of a quorum.);
        - Whether an alternate is voting and for whom they are voting;
        - When a member leaves the room or leaves the meeting; and
        - Name of researchers and others attending the meeting, if appropriate.

- Minutes on the review of each submission include the following:
  - The names of any IRB member(s) recused from the meeting due to a conflict of interest during the discussion and vote of the submission;
  - Separate deliberations for each action taken by the IRB;
  - A summary of the discussion of any controverted issues and their resolutions;
  - Determination that all criteria for approval are met or what modifications are need in order for them to be met;
  - Specific findings with justifications when needed (see below);
  - The vote on these actions, including the number of voting "for," "opposed," or "abstaining";
  - The IRB's determination on frequency of continuation review (based on the degree of risk or the risk/benefit ratio);
  - The basis for requiring changes in the research;
  - The level of risk determined by the IRB;

2. When the IRB disapproves a submission, OIRB staff documents the basis for the disapproval in the minutes and documents discussion of the controverted issues.
3. Minutes will include a justification for projects that involve procedures listed in categories for expedited review but are determined to be greater than minimal risk.
4. OIRB staff writes IRB meeting minutes impersonally and do not attribute opinions expressed by IRB members. Typically, the minutes only identify members by name when they recuse themselves from a particular review due to conflict of interest or leave the meeting for any reason.
5. The IRB considers written comments and/or information provided by ad hoc or cultural consultants in the review process. Consultants may provide comments or recommendations in writing to the IRB prior to the meeting or attend the convened meeting to participate in the review. IRB staff maintain documentation of written comments or reports with review records for the submission. Meeting minutes include that a consultant was participating or provided a written review.

Alternates

1. IRB meeting minutes document when an alternate IRB member replaces a voting IRB member and for whom the alternate is substituting.
2. When alternates substitute for a primary member, the alternate member receives and reviews the same materials that the primary reviewer received or would have received.

Specific Findings

1. When the IRB makes specific findings at convened meetings, OIRB staff documents these findings in the minutes of the meeting and include protocol-specific information justifying each finding, when appropriate. Examples of specific findings include, but are not limited to:
   - Alteration or Waiver of the Informed Consent Process: 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, 21 CFR 56.109(c)(1)).
   - 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 requirements at 45 CFR 46.305(a) and represents one of the categories of research permissible under Health and Human Services (HHS) regulations required by 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.
  - A majority of the IRB (exclusive of the prisoner representative) have no association with the prison involved, apart from their membership on the IRB.
  - 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 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 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 who are Cognitively Impaired: When the IRB reviews research involving individuals who are determined to be 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), 21 CFR 56.111(b)), and local policy.
- Investigational Devices: The minutes document the IRB's determination of significant or nonsignificant risk for Investigational New Devices and the rationale for that decision, in accordance with federal regulations (21 CFR 812.3(m)).

Department of Health and Human Services (DHHS) Approved Sample Consent Documents (e.g., NIH-Supported Multi-Center Clinical Trials)

1. When the IRB reviews DHHS-approved informed consent documents (e.g., NIH-supported multi-center clinical trials), the minutes include justification for any instance in which the IRB requested or approved the researcher's deletions or substantive modifications of information concerning risks or alternative procedures contained in the DHHS-approved sample informed consent document.

Tele/Videoconference Participation

1. At a meeting in which IRB members participate via telephone or other virtual meeting means, meeting minutes document which members participated via an alternative mechanism and the time they joined and left the meeting .

Distribution of Minutes

1. OIRB staff completes a draft of the IRB meeting minutes that is reviewed by the OIRB Director or Specialist.
2. Once finalized, minutes are made available in the ERA system to all reviewers.
3. A list of IRB initial, continuing and amendment reviews conducted outside of meeting published monthly in the ERA system.

4. Each IRB member present during the convened meeting reviews the minutes and forwards any necessary revisions to the appropriate OIRB staff member. The IRB delegates to OIRB staff the authority to correct administrative errors in meeting minutes as appropriate.
5. The minutes are made available to the Institutional Official and others as deemed appropriate by the OIRB or the IRB.

Record Keeping

1. OIRB staff maintain an electronic copy in a secure OIRB directory indefinitely.

REFERENCES

45CFR 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