

SOP: 303 C
MEETING MINUTES

1. POLICY

The IRB meeting minutes document all actions that occur during an IRB meeting. The minutes are the critical document that demonstrates appropriate review of human research.

The IRB minutes are required to document the following information by the IRB:

- Actions taken by the IRB;
- Separate deliberations for each action,
- Votes for each protocol as numbers for, against or abstaining,
- Attendance at the meeting for each action,
- When an alternate member replaces a primary member,
- The basis for requiring changes in research,
- The basis for disapproving research,
- A written summary of the discussion of controverted issues and their resolution,
- Justification of any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample consent document,
- For initial and continuing review, the approval period,
- The names of IRB members who recuse themselves from the meeting due to a conflict of interest along with the fact that a conflict of interest was the reason for the recusal,
- Determinations required by the regulations and protocol-specific findings justifying those determinations for:
 - waiver or alteration of the consent process;
 - research involving pregnant women, human fetuses and neonates;
 - research involving prisoners;
 - research involving children;
- The rationale for significant risk/non-significant risk device determinations,
- The determination of the level of risk,
- Attendance of members or alternate members who participate through videoconference or teleconference, and documentation that those members received all pertinent material before the meeting and were able to actively and equally participate in all discussions,
- The approval of research contingent on specific minor conditions by the IRB Chair or designee (to be documented in the minutes of the first IRB meeting

that takes place after the date of the approval),

- Whether protocol deviations, adverse events, and unanticipated problems involving risk to participants or others **are or are not** determined to be unanticipated problems involving risk to participants or others and are due to serious or continuing noncompliance,
- For VA research:
 - The IRB is required to provide the minutes for IRBs reviewing VA protocols to the VA Research and Development Committee.
 - Meeting minutes are required to be written and available for review by the VA Research and Development Committee within three weeks of the meeting date.

The minutes are prohibited from being altered by anyone, including a higher authority, once they are approved by the members at a subsequent IRB meeting.

Information contained in the minutes that pertains to action that must be taken by the Investigator is included in the Board action letter, which is forwarded by the IRB Staff to the Investigator.

Specific Policies

1.1 Meeting Minutes Preparation

The preparation of the meeting minutes begins with the preparation of the meeting agenda. Each item submitted to the IRB for review, either by the convened committee or the IRB Chairpersons is posted to the agenda. Refer to SOP 303A, Meeting Agenda for information pertaining to the IRB Agenda.

1.2 Information Documented

The minutes document:

- 1.2.1 Meeting Attendance: Individuals (member, alternate member, consultant, guest, etc.) attending and the status of each attendee (i.e., COI/recused, voting, non-voting).
- 1.2.2 Board Discussion & Action: Separate deliberations for each action, and the basis for requiring changes in research, the basis for disapproving research, a justification of any changes to the DHHS-approved sample consent document, the approval period for initial and continuing review; justification for a waiver of alteration of the consent process, research involving pregnant women, human fetuses and neonates, prisoners and children; and the rationale for significant risk or non-significant risk device determinations.
- 1.2.3 Review Items: Individual items of a new research project. These items may include the research protocol, investigator brochure, informed consent document, HIPAA privacy document(s), surveys, questionnaires, and advertisements.
- 1.2.4 Controverted Issues: A written summary of the discussion of the controverted issues and their resolution.
- 1.2.5 Voting for each action: Including the number of members counting toward the vote; those members who recused themselves from voting; and the number voting for, against, and abstaining from the vote. When possible, the minutes will indicate why a member abstained from voting.

- 1.2.6 The determination of the level of risk.

1.3 Information Documented As Applicable

The minutes document the following as applicable:

- 1.3.1 Device studies: Determination of whether the device is a significant risk or non-significant risk. This determination is included in the letter to the Investigator.
- 1.3.2 Inclusion of Children: The risk for children as stated in 45 CFR 46.404 - 46.407.
- 1.3.3 Inclusion of Prisoners: Seven additional findings under 45 CFR 46.305(a), as noted in SOP 501, Special Populations.
- 1.3.4 IND/IDE: Determination of whether an IND or IDE is required.
- 1.3.5 Certificate of Confidentiality: Determination of the need for an NIH Certificate of Confidentiality or an NIH Privacy Certificate
- 1.3.6 Conflict of Interest: Methods recommended by the IRB to address situations that involve a conflict of interest. (i.e., asking the Investigator to identify someone other than the Investigator to consent participants or including a statement within the consent document that the Investigator is a paid consultant of the sponsor.)
- 1.3.7 Continuing Review: Those protocols that require continuing review more often than annually, due to the degree of risk to the participants. The minutes of the IRB meetings reflect these determinations regarding risk and approval period.
- 1.3.8 Informed Consent: A consent procedure that does not include or that alters, some or all of the required elements of informed consent or when waiving the requirement to obtain informed consent. These findings are documented in the minutes of the IRB meeting, including protocol-specific information justifying each IRB finding. This procedure also applies when the convened IRB reviews research (a) involving pregnant women, human fetuses, or neonates, (b) approving research involving prisoners, and (c) approving research involving children.
- 1.3.9 Unanticipated Problems Involving Risks to Participants or Others: Whether the unanticipated problem involving risks to participants or others is or is not an unanticipated problem involving risks to participants or others.
- 1.3.10 Protocol Deviation: Whether the deviation is or is not an unanticipated problem involving risks to participants or others.
- 1.3.11 Adverse Events: Whether the Adverse Event is or is not an unanticipated problem involving risks to participants or others.

1.4 Other Information

The following information originally documented on the meeting agenda is automatically reflected in the meeting minutes:

- 1.4.1 Old Business Items
- 1.4.2 New Business Items – review of previous meeting's minutes and miscellaneous items
- 1.4.3 Corrections
- 1.4.4 Protocol Items

- 1.4.5 Board-Requested Revisions
- 1.4.6 Protocols, Continuing Reviews, Amendments, Local Adverse Events, External Adverse Events, Protocol Deviations, and/or Unanticipated Problems Involving Risks to Participants or Others.

2. SCOPE

These policies and procedures apply to all other SOPs.

3. RESPONSIBILITY

The IRB Administrator must attend the IRB meetings and record the meeting minutes and actions of the IRB.

The IRB Administrator must complete, review, and present the meeting minutes to the HRPP Director or Assistant Director within 2 weeks of the meeting.

The IRB Administrator must present the meeting minutes to the IRB at the next scheduled meeting.

The IRB members shall review, recommend changes, and approve the meeting minutes.

The IRB Chair shall provide guidance and assistance to the IRB staff in the development of the minutes as needed and sign the approved meeting minutes.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46

21 CFR 56

OHRP Guidance on Written IRB Procedures, July 11, 2002

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 303-A, IRB Meeting Agenda

SOP 501, Special Populations

6. ATTACHMENTS

303C-A Minutes Review Checklist

303C-B Meeting Minutes Template

7. PROCESS OVERVIEW

7.1 During the Meeting – Meeting Minutes Documentation

7.1.1 The IRB Administrator begins the documentation process by bringing to the meeting a recorder and blank tapes, a laptop computer, and paper for handwritten notes in order to record meeting discussion.

7.1.2 When possible, two IRB Administrators attend each IRB meeting. One IRB Administrator shall record electronic notes during the meeting; the second IRB Administrator shall take handwritten notes.

7.2 Post Meeting – Meeting Minutes Development

7.2.1 The IRB Administrator gathers all notes from the meeting and utilizes these notes to prepare the Board minutes.

- 7.2.2 Phase One – Correspondence: The first phase of IRB meeting minutes begins with the IRB Administrator writing all action letters regarding new research projects, continuing reviews, amendments, and adverse events. All IRB-requested changes are addressed in this letter, which is forwarded to the Investigator. All information documented in the letter is also included in the meeting minutes.
- 7.2.3 IRB action letters are expected to be completed on or before the third business day following the meeting. The IRB Administrator forwards the IRB action letters to the HRPP Director or designee for review. Following this review, the IRB Administrator forwards the letters to the IRB Chair for signature.
- 7.2.4 Phase Two – Meeting Minutes: The second phase of IRB meeting minutes involves completing the minutes by recording all deliberations, decisions, IRB actions, controverted issues, and votes. This information is not included in the correspondence to the Investigator.
- 7.2.5 The minutes are expected to be completed on or before the 10 business days from the meeting date. The IRB Administrator proofreads the draft version for accuracy using the Minutes Review Checklist. Items in the minutes correspond with items reflected on the meeting agenda. The minutes are presented to the HRPP Director or designee for review.
- 7.2.6 The IRB Administrator prepares the final version of the minutes for review at the next appropriate IRB meeting and adds the item for review to the next meeting agenda.
- 7.2.7 Once the minutes are approved, all notes from the meeting that are used to develop the minutes are retained for a period of one year. Following that time period, they are shredded

7.3 Meeting Minutes Approval

- 7.3.1 The minutes are presented at the next appropriate convened IRB meeting for review/approval. The IRB Staff copies the minutes and includes them in the packages for distribution to the IRB members.
- 7.3.2 Following approval by the convened IRB, the IRB Administrator obtains the signature of the IRB Chair on the minutes and files them in the IRB meeting minutes notebook.
- 7.3.3 When the minutes are contingently approved because of revisions noted by the IRB members, the IRB Administrator makes the revisions, presents the revised minutes to the IRB Chair for signature, and records the approval of the minutes by the IRB Chair on the next appropriate agenda.
- 7.3.4 Completed and signed IRB meeting minutes are presented to the Institutional Official at the HSC campus and the Norman campus.

7.4 Summary of Expectations

- 7.4.1 Meeting Week – The expectation is that all Board action letters are to be completed 3 business days after the meeting. All board action letters are forwarded to the HRPP Director or designee for review.

- 7.4.2 Meeting Week – The expectation is that all Board action letters will be reviewed by the HRPP Director or designee and, once all requested revisions have been completed, the IRB action letters are forwarded to the IRB Chair for review and signature.
- 7.4.3 Following signature by the IRB Chair or designee, the Board action letters are immediately forwarded to each investigator.
- 7.4.4 Week following meeting – The expectation is that a completed version of the minutes are forwarded to the HRPP Director or designee for review 10 business days after the meeting.

APPROVED BY: _____ **DATE:** 09/01/2009

NEXT ESTABLISHED REVIEW DATE: MAY 2012