



UNIVERSITY OF
SOUTH ALABAMA

IRB SOP 402
IRB Meeting Minutes

Purpose

This Standard Operating Procedure (SOP) describes the policies and procedures for creating minutes of the IRB.

Scope

This SOP applies to IRB staff and other compliance designees.

Policy

The IRB meets at least once a month on a regularly scheduled day. Scheduled meetings may be cancelled by the IRB Administrator due to the inability to secure a quorum for attendance, or other reasons as may arise that make a scheduled meeting unnecessary or otherwise inappropriate. The IRB Office maintains an electronic IRB address book used to notify members of meetings and other pertinent IRB information.

One week prior to the convened meeting, all members of the IRB shall be provided with detailed initial review materials describing the research to facilitate discussion of the protocol adequately and determine the appropriate action during the convened meeting. All members of the IRB are expected to familiarize themselves with meeting materials in order to contribute to the IRB's deliberations.

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.

1.0 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 research project 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 documents
- 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 research project-specific findings justifying those determinations for:
 - o waiver or alteration of the consent process
 - o research involving pregnant women, human fetuses, and neonates
 - o research involving prisoners
 - o research involving children
 - o research involving participants with diminished capacity to consent
- 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

The approval of research contingent on specific minor conditions by the IRB Chair or IRB Chair's designee (to be documented in the minutes of the first IRB meeting that takes place after the date of the approval)

Whether reports of protocol deviations and unanticipated problems involving risk to participants or others (1) **are or are not** determined to be unanticipated problems involving risk to participants or others and (2) are or are not due to serious or continuing noncompliance

- Information that pertains to action that must be taken by the Investigator

2.0 Meeting Minutes Preparation

The preparation of the meeting minutes begins with the preparation of the meeting agenda. Each submitted item to the IRB for review is posted to the agenda. Refer to *IRB SOP 401: IRB Agenda*.

3.0 Information Documented

The minutes of IRB meetings shall be compiled by the IRB Administrator, following the IRB meeting minutes template. The following specific information shall be recorded in the meeting minutes:

1. Attendance recorded by name
2. Approval of previous minutes
3. Adverse Events action
4. Protocol Deviations
5. List of closed/expired protocols
6. List of approved exempt and expedited approved protocols and specific citation for the category of expedited review.
7. Actions taken by the IRB on initial, amendments, and continuing review applications. If applicable, specific measures taken to protect vulnerable populations and request for waiver of informed consent.
 - Votes on these actions
 - Basis for requiring changes in or disapproving research
 - Summary of controverted issues
 - Required IRB findings and determinations
8. Information/Education
9. Research Compliance
10. Quality Assurance and Quality Improvement
11. Old/New Business
12. WCG Submissions
13. NCI CIRB Submissions
14. Other External IRB Submissions

The minutes shall record when a member either enters/leaves the convened meeting as evidence of proper quorum. The minutes shall record any presence of conflict of interest or abstention

3.1 Information Documents as Applicable

The minutes document the following as applicable:

1. Device Studies
2. Inclusion of Children
3. Inclusion of Prisoners
4. Certificate of Confidentiality
5. Conflict of Interest

Procedures

1.0 Development of IRB Meeting Minutes

The IRB Administrator identifies all reviews and comments from the meeting and utilizes this information to prepare the Board minutes.

2.0 Meeting Minutes Approval

The minutes are presented at the next appropriate convened IRB meeting for review and approval. The IRB Office posts minutes in IRBNet for review in advance of the Board meeting. The chair leads the meeting of the convened IRB. This includes calling the meeting to order, leading the IRB through the agenda, and calling for motions and votes. The chair ensures that all members have an opportunity to express their opinions and concerns on the research under review.

Regulated Documentation

45 CFR 46; 21 CFR 56

[DHHS Office of Human Research Protections: Guidance on Written IRB Procedures](#)

University Related Documents

[SOP 301: IRB Meeting Preparation](#)

[SOP 401: IRB Meeting Agenda](#)

History:

Effective Date:

Revisions: October, 2018

Responsible Office:

Office of Research Compliance and Assurance