



UNIVERSITY OF
SOUTH ALABAMA

IRB SOP 303
Meeting Procedures and IRB Actions

Purpose

This Standard Operating Procedure (SOP) describes the procedures followed during a meeting of the full convened Institutional Review Board (IRB).

Definitions

Quorum: A simple majority of the members listed on the IRB membership roster registered with the federal Office of Human Research Protections (OHRP). A quorum is considered to be half plus one of the members present at a convened IRB meeting.

Primary reviewer: The IRB member with the most appropriate expertise for reviewing a specific item.

- Provides a brief summary of the item to the IRB.
- Leads a discussion of the criteria for approval with respect to the item, including the identification of any concerns.
- Usually makes the first motion proposing specific IRB actions (for example, approval).
- May assist in writing or reviewing the correspondence to the investigator that communicates the IRB's decisions, requirements, and questions.
- May assist in verifying that the investigator's responses to a Conditional Approval outcome satisfactorily meet the IRB's conditions.

Secondary reviewer: An IRB member who fulfills the same responsibilities as the primary reviewer on a given item, and who is chosen to ensure an appropriate balance of scientific and/or non-scientific expertise for a specific item. Secondary reviewers are not a required part of the USA IRB review process for expedited reviews.

Recusal: An IRB member's absence from the IRB meeting due to a conflict of interest with respect to the item under consideration. The member no longer counts towards the quorum. Recusals are indicated in the minutes as "Recusal". The USA IRB allows all members to be present during the convened meeting. Therefore, members who recuse themselves have a non-voting status.

Policy

1.0 Frequency of Meetings

Each convened meeting of the IRB meets once a month.

1.1 *Biomedical Research – IRB*

1.1.1 This committee meets the second Tuesday of each month

1.2 *Educational Behavioral Research –IRB*

1.2.1 This committee meets every third week.

2.0 Voting

In order for research to be approved, it shall receive the approval of a majority of the members (i.e., half plus one) present at the meeting provided a quorum exists. At least one member participating must have primary concerns in a nonscientific area (i.e. a non-scientist). The voting process proceeds as follows: The chair may entertain a motion (which usually comes from a primary reviewer) and a second that the IRB take a certain action regarding a given protocol. The actions the IRB may take are outlined below under Procedures section, 3.0 "Motion Proposing IRB Action". After a motion has been made and seconded, there should be an opportunity for discussion before a vote is taken. Those members present for the vote should be recorded as either voting for, opposed or abstained. Members who have a real conflict of interest must recuse themselves from the vote.

3.0 Recusal of members with a conflict of interest

When an IRB member has a conflict of interest that requires him/her to recuse himself/herself from discussion of and voting on a particular protocol, that member may not participate in the discussion unless asked to address questions raised by other members. If the member's recusal causes a loss of quorum, the vote must be deferred to another meeting. For this reason, IRB members should notify the chair prior to the meeting if they have a conflict of interest related to a specific protocol slated for review at the meeting, and every effort should be made to ensure adequate members in attendance. Additionally, members and guests sign a confidentiality agreement.

4.0 Attendance by investigators

The USA IRB does not require investigators to attend IRB meetings at which their materials will be reviewed. However, on occasion the IRB may require an investigator's presence to answer specific questions and provide information. In addition, investigators may ask to attend a meeting. The IRB Chair and/or Office of Research Compliance and Assurance make the decision about whether such attendance would be appropriate and helpful. Investigators only attend the portion of the IRB meeting at which their protocol is discussed.

5.0 Attendance by guests

The USA IRB meetings are not considered "public meetings". However, the IRB allows guests and observers at convened IRB meetings, at the discretion of the IRB Chair and the supporting staff. The IRB may permit guests to attend a meeting, for example, in order for them to learn about the IRB process. Members should be alerted to the presence of guests and their reason for attending. Guests should sign the confidentiality agreement prior to the start of their attendance at the meeting.

6.0 Teleconference/videoconferencing

On occasion, meetings may be convened via telephone or video call conferencing. For example, if the agenda is brief and only includes review of continuing review and/or amendments. In some cases, teleconferencing and/or videoconferencing may be necessary in order to have a quorum for a meeting, or to ensure that a protocol is reviewed by someone with a proper level of expertise. When the IRB makes use of this technology, all other normal meeting requirements apply. Additionally, whenever teleconferencing and/or videoconferencing is used, special care must be taken to ensure the security of the data transmissions so that the privacy of researchers and IRB members are protected.

Procedures

1.0 Opening business

- 1.1 The Chair calls the meeting to order.
- 1.2 The Chair introduces any observers or guests.
- 1.3 The Chair asks the members for any corrections or revisions to any minutes from previous meetings (if provided). A motion is made, and voted upon, to accept, accept with corrections, or not accept the minutes. Voting is not restricted to those members who were present at the meeting described by the minutes.

- 1.4 The Chair asks the members for any comments or questions regarding Adverse Event reviews or expedited reviews (if any). A motion is made, and voted upon, to accept, accept with corrections, or not accept the report.
- 1.5 The Chair facilitates the conduct of any other business, including education and training activities, announcements, etc.

2.0 Reviewing items

2.1 Information presentation

The Chair performs the following actions, in a sequence that is appropriate to the item and circumstances.

- 2.1.1 Asks the primary reviewer to provide a short descriptive summary of the item.
 - 2.1.2 If the investigator or a member of the research team will be present or available by phone: invites him/her to present information and/or to answer questions from the members.
 - 2.1.3 If a member has a conflict of interest: Invites the IRB to ask questions of the member.
- ### **2.2 Discussion of criteria for approval, and required determinations.**
- 2.2.1 The primary reviewer leads a discussion of the criteria for approval, referring as needed to the IRB Reviewer Sheet
 - 2.2.2 The primary reviewer also leads a discussion of any determinations that the IRB is required to make (examples: waiver of consent; device risk determination)
 - 2.2.3 Experienced IRB/Research Compliance staff provide regulatory clarification and guidance
 - 2.2.4 Guests, observers, etc., may not participate in the discussion unless specifically requested to do so.
 - 2.2.5 Any member with a conflict of interest must recuse himself/herself. Members who abstain during voting counts toward quorum.

3.0 Motion proposing IRB Actions

An IRB member (typically the primary reviewer) makes a motion recommending specific IRB actions. The IRB administrative staff shall provide written notification of its determinations to investigators. If a submitted project is incomplete or requires revisions for greater than 90 days the IRB administrative staff will close the project and notify the Investigator by publishing a decision letter in IRBNet.

IRB actions, upon review of research, include the following:

3.1 Approved

In the case of an approval with no changes, the research may begin once the investigator receives written documentation of IRB approval.

Unless otherwise specified, the approval period for research approved without changes is one year from the date of the meeting at which approval was granted.

3.2 Modifications Required

The IRB may determine that a study may be approved with minor changes or clarifications. Minor changes are those changes that do not involve potential for increased risk or decreased benefit to the human subjects. For minor changes, the IRB administrative staff ensures that the investigator makes the appropriate changes to the research protocol. The research may proceed after the required changes are verified and the investigator receives IRB letter of approval.

3.3 Information Required

The primary reviewer and/or secondary reviewer is responsible for reviewing the changes to ensure that the changes are adequately addressed. The IRB protocol receives final approval when all required changes have been submitted and approved by the reviewer(s).

Unless otherwise specified, the approval period for research for which minor changes were stipulated is one year from the date of the last convened meeting at which the protocol was reviewed.

3.4 Pending follow-up of receipt and review of serious adverse event

All outstanding serious adverse event(s) pending review and/or response from the investigator during review of a renewal or amendment submission at the convened meeting will not be granted approval until the adverse event(s) is resolved.

3.5 Deferral

Deferral is used to describe the situation in which the IRB determines that substantive changes must be made before approval may be granted. The investigator's response, including any amended materials, must be reviewed at the next convened IRB meeting.

Subject to IRB discretion, a proposal may be withdrawn if the investigator does not respond to a deferral within a reasonable amount of time. If the investigator wishes to

conduct a study that has been withdrawn, he/she must submit a new application, addressing concerns from the prior IRB review.

Unless otherwise specified, the approval period for research protocols that are deferred is one year from the date of the last convened meeting at which approval was granted or minor changes were stipulated.

3.6 Disapproval

If the IRB determines that the research cannot be conducted at USA or by employees or agents of the University or otherwise under the auspices of the University, the project, as proposed, is disapproved and may not go forward. Disapproval usually indicates that a proposal requires major changes not likely to be feasible without a complete reassessment of the protocol by the investigator and/or sponsor. Disapproval is not permissible through the expedited review mechanism and can only be given by a majority vote at a convened meeting of the IRB.

3.7 Suspension and Termination of Research Study by IRB

The chair of the IRB or the convened IRB may suspend a study at any time if it is determined that the study requires further review or evaluation. This determination may be made due to an adverse event, noncompliance or other danger to human subjects. Once a study has been suspended, the convened IRB should review the study and either requires changes to the protocol, allow the study to restart, or terminate the study.

Though the chair may suspend a study, only the convened IRB can make the decision to terminate a study. When a study is suspended or terminated, the IRB notifies the Institutional Official. If the suspended or terminated study is externally funded, the IRB will notify the Office of Sponsored Programs. The Institutional Official is responsible for all required reports to federal agencies.

3.9 Closed – Expired

IRBNet automatically generates a notification of expiration via email if a study is not closed or renewed by the date of expiration. An expiration document is published in IRBNet and the project status is changed to closed-expired.

3.10 Closed – Project Complete

Upon receipt of a IRB closure form the IRB Office administratively closes the research project. The researcher will not be permitted to have any further interaction with subjects or their data in ways that would require ongoing IRB approval. If the

investigator wishes to enroll new subjects for the study or engage in human subject's research he/she must reactivate the protocol with the IRB Office. The researcher may close a study when he/she is no longer accruing subjects, using research interventions on existing subjects, collection data (including follow-up data), or performing any other tasks identified as part of the IRB approved research study. However, a researcher may continue to analyze aggregate de-identified data sets beyond study closure.

3.11 Closed

Project closure that is not affiliated with project completion or expiration, as it does not meet the criteria defined in sections 3.9 or 3.10 above. Examples include sponsor withdrawal, Investigator withdrawal, study not initiated due to funding.

3.12 Administrative Review and Changes

An administrative review includes a pre-review by IRB staff to assess a protocol's completeness and determination for exempt, limited review, expedited, full board review or request for external IRB review.

Additionally, the IRB may administratively review, in which it considers administrative changes, where one of the following criteria is met: 1) the proposed change has no impact on human subject protection, or 2) the proposed change is necessary to clarify or provide only editorial updates to the protocol and/or consent form. These changes can be reviewed and approved by IRB staff and in consultation with the IRB Chair, as necessary. Examples of administrative changes may include: changes in telephone numbers, general updates to study personnel, correction of typographical errors, or minor administrative changes in the protocol by the sponsor.

4.0 Notification of IRB Actions

Investigators receive automated notifications via IRBNet of the IRB's decision and any changes required. Summaries of actions taken are provided to the Institutional Official in the form of meeting minutes. Final approval is not granted until all required changes have been made and submitted for review and approval. The IRB attempts to retain approval periods constant from year to year throughout the life of each project. Therefore, when materials are submitted far enough in advance that the IRB performs the continuing review within 30 days before the current approval period expires, the IRB retains the original anniversary date as the date for the new approval period to begin. That is, the calendar need not be reset if review occurs within thirty days of the original anniversary date. This notification process applies to all levels of review. The IRB Chair does not sign approval letters generated in IRBNet. Federal regulations do not specify the procedure the IRBs must use regarding signatures of IRB approval documents. USA IRB does not require signature of approval letters by the Chair.

5.0 Appeal of IRB Decisions

Investigators may appeal IRB requirements for specific changes in the protocol and/or consent document(s). At the discretion of the chair, the investigator may make such an appeal in writing to the IRB. At the IRB's discretion, the investigator may be invited to the IRB meeting at which his or her appeal will be considered.

If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision, and give the investigator an opportunity to respond in person and/or in writing. An appeal of a disapproved research project must be reviewed at a convened meeting.

Other university officials may, in certain cases, decide that a research study may not be conducted despite IRB approval. One example could be a circumstance in which a certain project or area of research is deemed to be inappropriate or underfunded. In the case of a decision by the IRB to disapprove, suspend, or terminate a project, only the Institutional Official may request that the IRB reevaluate a project because of procedural questions related to the IRB review. However, the IRB decision to disapprove, suspend, or terminate a project may not be reversed by the any officer or agency of the University of South Alabama, state government or federal government

University Related Documents

[SOP 301: IRB Meeting Preparation](#)

[SOP 401: IRB Meeting Agenda](#)

[SOP 501: IRB Review](#)

History:

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Responsible Office:

Office of Research Compliance and Assurance