



UNIVERSITY OF
SOUTH ALABAMA

IRB SOP 301
IRB Meeting Preparation

Purpose

This document describes the procedures used to prepare for a meeting of the full convened IRB.

Definitions

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

- 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 correspondence to the investigator that communicates the IRB's decisions, requirements, and questions

Secondary reviewer: An IRB member who fulfills the same responsibilities as the primary reviewer 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 routine part of the UW IRB review process.

A secondary review is NOT required for review of expedited studies at a convened meeting.

Quorum: A simple majority of the members listed on the IRB membership roster registered with the federal Office of Human Research Protections (OHRP). Quorum consists of half plus one voting IRB members.

Policy

- 1.0 When creating the agenda for an IRB meeting, IRB Office ensures that:
 - 1.1 Items are assigned to an agenda only when the IRB members who will attend can provide sufficient expertise to determine whether the applicable criteria for IRB approval are met. This expertise may be supplemented by the involvement of an external consultant.
 - 1.2 Items involving vulnerable populations will be placed on the agenda only when at least one individual (IRB member or consultant) who is knowledgeable about or experienced in working with the population will participate in the meeting (or a consultant has been obtained).
- 2.0 An IRB member is identified as the primary reviewer for each item that will be reviewed. The primary reviewer is typically the person with the most applicable scientific expertise for the item, though in some cases the most appropriate primary reviewer may be someone with expertise in some other aspect of the research (for example, the particular subject population being studied).
- 3.0 External consultants may be asked to provide information and expertise, as needed to ensure an appropriate review. Consultation may be provided in-person at an IRB meeting or through a consultant's written comments distributed to the IRB.
- 4.0 IRB members are provided with sufficient information so that each member can provide an opinion on whether the applicable regulatory criteria for approval are met.
- 5.0 Review materials are provided to all IRB members at least 5 days before meetings, except in special circumstances (described below).
- 6.0 A meeting will be re-scheduled or canceled if it becomes apparent that meeting requirements (quorum, sufficient expertise, participation of a non-scientist member) will not be met.

Procedures

1.0 IRB Meeting Schedule

The IRB Office establishes the IRB meeting schedule for the **Biomedical Research –IRB** a year in advance and the **Educational and Behavioral Research – IRB** each semester, considering holidays, the academic calendar, and special circumstances. Additional meetings may be scheduled on an *ad hoc* basis. The schedule is distributed to all IRB members, clinical research sites, and posted on the Human Subject's website.

2.0 Meeting Requirements

In advance of each meeting, the IRB Office confirms which IRB members will be present.

Referring to the IRB Membership Roster, the IRB Office verifies that the following regulatory requirements for an IRB meeting will be met:

- 2.1 Quorum. A quorum of members will be present (or participating by teleconference or videoconference).
- 2.2 Non-scientist member. At least one member who is identified as a “non-scientist” on the membership roster will be present.
- 2.3 Sufficient expertise. The members in attendance have sufficient expertise to determine whether the applicable criteria for approval have been met. This includes, when relevant, expertise with a vulnerable population involved in the research.

3.0 Preparation of the meeting agenda- IRB Staff:

3.1 Select the items for the agenda.

3.1.1 In all cases, the availability of sufficient expertise is the primary consideration for the selection of items.

3.2 Assign a primary reviewer. The member with the most appropriate expertise is assigned as the primary *reviewer*. *The IRB Chair or others may be consulted about the assignment.*

3.2.1 If it is determined that appropriate expertise is not available within the IRB, or should be augmented, a consultant will be considered.

3.2.2 A secondary reviewer may also be assigned to an item. A secondary reviewer is typically assigned when the items begin reviewed involves: high risks for subjects; an exceptionally vulnerable population; a high complex study; or significant technical issues.

3.2.3 It is not necessary to document the specific rationale for selecting the primary reviewer

3.2.4 Vulnerable populations. If expertise with a specific vulnerable population is needed but not available from the IRB members, a consultant may be obtained for expertise

3.2.5 The agenda document. The agenda document is prepared as described in the *SOP 401: Meeting Agenda*.

4.0 Prepare meeting materials. The IRB Office prepares the materials for IRB members, referring to the *SOP 302: Materials for Review* to ensure that all appropriate materials are provided, according to the individual's roles (i.e., primary review, other members, Chair, etc)

5.0 The IRB Office delivers review materials via IRBNet online management system.

6.0 Urgent items. Items requiring urgent review may be provided to the IRB Office after an agenda has been completed and distributed with review materials. The IRB Office will use judgment (and may consult with the Chair, possible primary reviewer, or Office of Research Compliance and Assurance) to decide whether the urgent item can and should be placed on the already-distributed agenda for a pending IRB meeting. The following factors are considered:

- 6.1 Availability of an appropriate primary reviewer and/or consultant
- 6.2 Number of days prior to the IRB meeting
- 6.3 Size and complexity of the late materials
- 6.4 Urgency of the issue. Examples of urgent issues include but are not limited to:
 - Subject welfare and safety
 - Funding considerations
 - Timing and dependency of research procedures on factors such as a school year, availability of subjects/resources/investigator, etc.
- 6.5 Workload for the IRB members with respect to the pending meeting

7.0 Make teleconference arrangements, as needed.

University Related Documents

[SOP 302: Materials for Review](#)

[SOP 401: Meeting Agenda](#)

References

45 CFR 46.107 and 21 CFR 56.107

45 CFR 46.108(b) and 21 CFR 56.108(c)

History:

Effective Date:

Revisions: October, 2018

Responsible Office:

Office of Research Compliance and Assurance