



Department	Title	Dates
Research Integrity and Protection	IRB Meeting Preparation	Effective: 2/19/2018
		Approved: 1/2/2018
SOP ID		Last Revised: 10/9/2019
IRB-SOP-401		Expiration: n/a

PURPOSE

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

SCOPE

This SOP applies to all IRBs established within Ascension Wisconsin.

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), and 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.

Quorum A simple majority of the members listed on the IRB membership roster registered with the federal Office of Human Research Protections (OHRP). When the membership roster consists of an even number (N), a quorum is considered to be $(N/2)+1$.

PROCESS

- 1. RI&P staff confirms which IRB members (regular, alternate, and chairs) will be present at the meeting.**
 - 1.1.** Alternate IRB members serve the same function as other IRB members, except that if the alternate IRB member and the regular IRB member for whom the alternate member is substituting are both present only one member may vote.
 - 1.2.** If the meeting will not meet the quorum and expertise requirements, take steps to obtain the required attendance of members and consultants or cancel the meeting.

- 2. All submissions are reviewed before being placed on the agenda for a convened IRB meeting to ensure the following:**
 - 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.
 - 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).

3. Reviewer Assignment

- 3.1. IRB staff assigns a primary reviewer is assigned to each agenda item, as outlined in SOP: IRB Pre-Review. The primary reviewer is typically selected because they have the most applicable scientific expertise, 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).
- 3.2. A secondary reviewer will be assign to each new protocol on the agenda.
- 3.3. If it is determined that appropriate expertise is not available within the IRB, or should be augmented, a consultant is obtained, as outlined in SOP: Consultants, Observers and Guests.

4. Preparing and Distributing Meeting Material

- 4.1. IRB members are provided sufficient information so that each member can provide an opinion on whether the regulatory criteria for approval are met. IRB staff prepares and distribute materials at least 7 days before convened meetings, as outlined in SOP: IRB Pre-Review.
- 4.2. Urgent items
 - 4.2.1. Items requiring urgent review sometimes arrive at the IRB office after an agenda has been completed and distributed with review materials. RI&P staff use judgment (and may consult with the Chair, possible primary reviewer or the RI&P Director) to decide whether the urgent item can and should be placed on the already-distributed agenda for a pending IRB meeting.
 - 4.2.2. Materials may be distributed fewer than 7 days prior to the meeting on a case-by-case basis, if reviewers agree there is appropriate time to complete an adequate review.
 - 4.2.3. The following factors are considered:
 - Availability of appropriate expertise at the IRB
 - Availability of an appropriate primary reviewer and/or consultant
 - Number of days prior to the IRB meeting
 - Size and complexity of the late materials
 - 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, availability of subjects/resources/investigator, etc.
 - Workload for the IRB members with respect to the pending meeting

REFERNCES

45 CFR §46.108(b)
21 CFR §56.108(b)

RELATED MATERIAL

SOP: Consultants, Observers and Guests
SOP: IRB Pre-Review
SOP: Materials for Review
IRB Roster

REVISION HISTORY

Version #	Date Revised	Reason for/Brief Description of Change	Revised By
01	10/27/2017	New- Initial Integration Update	J. Blundon
02	10/9/2019	4.2.2. Clarification on time frame for urgent reviews	J. Blundon-Kirchen