



TITLE: **IRB Meeting Preparation**

PURPOSE: Prepare for a convened IRB meeting

RESPONSIBILITIES: HSPP Staff
IRB Committee Members

PROCEDURES:

Committee Members

Using “W305 - Evaluation of Quorum and Expertise” as a guide, ensure that the meeting will be appropriately convened and to ensure the IRB will have the appropriate expertise for each protocol.

- When the IRB requests that a consultant assist in the review of any agenda items, follow the procedures in SOP-021: Consultation to the IRB. Note any consultants on the agenda.
- When a project involves prisoners, at least one IRB member or consultant knowledgeable about or experienced in working with such subjects must be present at the meeting.
- When a project involves other vulnerable subjects, at least at least one IRB member or consultant knowledgeable about or experienced in working with such subjects will be present at or will provide consultation for the meeting.
- Alternate members serve the same function as regular members. If a regular member and alternate member are both present, only one member may vote.

If the meeting will not meet the quorum and expertise requirements, take steps to obtain the required members and consultants or reschedule the meeting.

Materials and Agenda

The agenda is closed approximately two weeks before each convened IRB meeting. Materials must be complete at least one week before each meeting to ensure a spot on the agenda. If a project is complete and the agenda is full or a reviewer is not available, the project will be placed on the next available agenda.

Review all submissions for the convened IRB meeting for completeness.

- Assign a primary reviewer to each agenda item.
- As appropriate, assign a secondary reviewer to each agenda item whose primary responsibility is to review the consenting materials.
- Prepare agenda and agenda packets for IRB members and consultants using “W301 – Agenda Packet Contents” as guidance for the meeting.
- Upload IRB meeting agenda packets to a University web-based document portal for all IRB members and consultants per instructions in the "Operations Manual." Materials are provided to members approximately one week before each convened meeting.
- Place a copy of all materials in the protocol file.

MATERIALS:

- SOP-021: Consultation to the IRB



- Operations Manual
- W305 - Evaluation of Quorum and Expertise

REFERENCES:

- 45 CFR §46.108(b)
- 21 CFR §56.108(b)

REVIEW/REVISIONS:

From 10/01/2010 version: Indicated that secondary reviewers are necessary only "as appropriate."

From 08/01/2011 version: Added reference to Operations Manual.

From 10/2014 version: Renumbered from P&P-040; References to P&P-051 revised to SOP-021 to reflect new numbering system.