

IRB Meeting Preparation and Conduct

SOP 105
Approved: April 24, 2017

Purpose and Scope

The SOP describes the procedure to prepare for and to conduct Institutional Review Board (IRB) convened meetings.

This SOP applies to all Human Studies Program (HSP) staff, IRB members, and Investigators who are involved in the preparation and conduct of IRB meetings at the University of Hawai'i (UH).

Procedures

I. Meeting Preparation

1. The HSP Coordinator will confirm which IRB members (regular, alternate, and chairs) will be present at the meeting.

- Meeting is conducted in a reserved room located on the UH campus.
- Meeting room includes projector, laptop computer, and AV system to allow IRB members and staff access to review materials posted electronically,
- Meeting room includes teleconferencing technology (i.e., telephone, laptop computer) to allow IRB members to participate in the convened meeting as a voting member given that the member:
 - (1) has received all pertinent materials prior to the meeting, and (2) can actively and equally participate in the discussion of all protocols.
- Meeting room includes teleconferencing technology to communicate with investigators and consultants, when appropriate.

2. The HSP Coordinator will prepare an agenda for the meeting and assign reviewers.

The HSP Coordinator will:

- i. Consult the appropriate IRB Roster to be aware of the experience, expertise and representational capacity of the IRB, and to ensure that the convened IRB will include the appropriate experience and expertise to review all agenda items.
- ii. Prepare an agenda for the meeting.
- iii. Assign a primary reviewer to each agenda item
- iv. Assign a reviewer to each agenda item that has sufficient scientific/ scholarly or other professional expertise to conduct a comprehensive review on the agenda item. The primary reviewer and scientific/ scholarly reviewer may be the same individual.

- v. Along with assigning a new protocol or proposal to a primary and secondary reviewer, external expert reviewers may be asked to review to the research, when applicable (e.g., Data Governance if project involves request and use of institutional data).
- vi. If there is not at least one person on the IRB with the appropriate scientific or scholarly expertise, or other expertise or knowledge, to adequately conduct an indepth review of the research, the IRB defers the application to another meeting or to another IRB, or obtains consultation. The convened IRB can determine whether a consultant is needed.
- vii. If the scientific/scholarly reviewer is not an IRB member; determine whether the scientific/ scholarly reviewer has a conflicting interest as defined in COI: Significant Financial Interest/ Conflict of Interest Disclosure Form (non-UH). If so, assign another scientific/scholarly reviewer.

Use the “**WKSH 357: Quorum and Expertise**” to ensure that the meeting will be appropriately convened and to ensure the IRB will have the appropriate expertise for each protocol.

- i. If the meeting will not meet the quorum and expertise requirements, take steps to obtain the required attendance members and consultants or cancel the meeting.
- ii. Note any consultants who attended the meeting in the meeting minutes

Create the online agenda for IRB members and consultants.

3. Meeting Documents

All IRB meetings are held once a month and materials can be accessed via the Internet.

The agenda for the coming meeting includes:

- (1) Call to Order;
- (2) Announcements;
- (3) Verification of quorum;
 - i. Members teleconferencing into the meeting are duly noted in the meeting minutes (4)
- Educational presentations by Director, IRB Chair, or other individuals, as appropriate
- (5) General business such as approving the minutes of the prior IRB
- (6) Old business such as unfinished business or previously deferred studies;
- (7) New business, including acceptance of studies previously approved as exempt or under expedited review, review of protocol violations, unanticipated problems, initial or a continuing review of a study, or review of modification in a study;
- (8) Adjourn.

The order of events in an agenda may vary from the above list.

- New Protocol/ Proposal Applications materials include:
 - (1) Full protocol or proposal, application, or protocol summary

- (2) Consent document (including e.g., assent form, short form, debriefing)
 - (3) Recruitment Materials
 - (4) Survey instruments, questionnaires, interview guides
 - (5) Investigator Brochure, if applicable
- Amendments
 - (1) Description for requesting amendment(s)
 - (2) Protocol with proposed changes in track
 - (3) Any newly proposed consent document
 - (4) Any new study documents and/or documents with proposed changes in track
 - Continuing Review
 - (1) Full protocol or proposal, application or protocol summary
 - (2) Current consent document
 - (3) Progress report of the research
 - Protocol Violation/ Non-Compliance
 - Unanticipated Problem/ Adverse Event

4. Distribution of Materials

- a. The program will post the materials to be reviewed by IRB members before the scheduled meetings on a secure website maintained by the HSP, approximately two weekends before the meeting.
- b. IRB members have laptop computers to access review materials and reviewer worksheets during the conduct of the convened meeting. Paper copies of those materials are also available at the meeting for those who do not bring a laptop computer.
- c. Materials: The materials may contain, but are not limited to:
 - (1) agenda;
 - (2) minutes from the previous months;
 - (3) a listing of studies previously determined to be exempt or approved under expedited review;
 - (4) applications;
 - (5) protocols;
 - (6) consent forms;

- (7) assent forms if applicable;
- (8) study instruments such as questionnaires and recruitment materials;
- (9) Investigator brochures if applicable;
- (10) Responses to stipulations by Investigators, grant applications, and other supporting documents;
- (11) If the study is regulated by HHS, the HSP will also provide HHS-approved sample consent document and/or protocol, if one exists.
- (12) Reviewers can access full protocol through [myGrant](#) managed by the UH Office of Research Services. This continuing review application is provided to the expedited reviewer or to the convened IRB, as appropriate.

Meeting Conduct

1. Determining and Documenting Quorum

- The IRB Chair or designee determines whether quorum is established and the HSP staff documents quorum into minutes.

2. The Review Process at a Convened IRB Meeting

a. The IRB Chair:

- (1) Calls the meeting to order,
- (2) Asks for any correction to the minutes.
- (3) The convened IRB reviews a listing of studies previously approved under expedited review. An IRB member may request to review a study in the listing. The decisions by the convened IRB supersede those by expedited review.
- (4) Asks IRB members whether anyone has a conflicting interest in any item on the agenda. Note this on the agenda.
- (5) For each business item:
 - i. Table the item when notified by IRB staff when requirements for review of a specific item as defined in “WKSH 357: Quorum and Expertise” are not met.
 - ii. If there are IRB members with a conflicting interest, invite the IRB to ask questions of those members and then ask those members to leave for discussion and voting.
 - iii. If there is a consultant present, ask the consultant to present their review to the IRB.
 - iv. If a consultant provided written information to the IRB present at information to the IRB.
 - v. If there is a scientific review ask the scientific member to present their review to the IRB.
 - vi. Note any contingencies required by IRB staff.

- vii. Have the primary reviewer lead through the review as described below.
- viii. Open the floor for additional discussion ix. Review any modifications required by the IRB to secure approval to ensure that the IRB staff has recorded them.
- x. Entertain a motion.
- xi. Call for a vote.
 - a) Only IRB members may vote.
 - b) If a member and an alternate are both present, only one may vote.
 - c) Consultants may not vote.
- xii. For a motion to be approved, it needs the approval of more than half of the members present at the meeting. (If there are 10 or 11 members present at the meeting, 6 votes are required for approval, which is greater than 5 and 5.5. respectively.)
- xiii. Re-invite IRB members with a conflicting interest back into the meeting/
- xiv. Provide any written information provided a member or consultant to the IRB staff.

3. For each protocol requesting approval have the primary reviewer:

- a. Use the appropriate WORKSHEET (listed below) to have the convened IRB determine which regulatory criteria are met, which are not met, and which would be met if the investigator modified the protocol as requested by the IRB.
 - (1) Restate the IRB’s consensus regarding protocol specific findings justifying a determination when required by a worksheet.
 - (2) Make a motion for one of the following actions:
 - ii. Approval (with a specific continuing review interval for initial or continuing review: Made when all criteria for approval are met.
 - iii. Modifications Required to Secure Approval (with a specific continuing review interval for initial or continuing review): Made when IRB members require specific modifications such that the IRB chair can determine whether an investigator has made the required changes without judging whether a change meets the regulatory criteria for approval. When making this motion, the assigned lead reviewer restates the modifications required by the IRB members and the IRB member’s reasons for those changes.

4. Voting Requirements:

- a. If quorum is lost during the meeting, i.e., any of the above quorum requirements is not met, the IRB may not vote unless the quorum is restored. Quorum can be lost when a required member leaves the meeting room;
- b. An individual who is not on the official IRB membership roster (e.g., a consultant) may not vote;
- c. Proxy votes are not allowed;

5. Documenting Votes

- a. The HSP staff documents votes for each IRB action or determination in IRB minutes by recording the following: total number of IRB members voting, voting for, voting against; and abstaining.

6. Voting: The Chair and vice-Chair vote the same way as other members.

Materials

- WKSH 303 Non-Exempt Reviewer Worksheet
- WKSH 311 Reviewer Worksheet for Continuing Review, Modification, or Study Closure
- WKSH 314 Unanticipated Problem Reviewer Worksheet
- WKSH 315 Protocol Violation Reviewer Worksheet
- WKSH 357: Quorum and Expertise
- DOC 703 IRB Meeting Minutes Template
- DOC 704 IRB “Cheat Sheet” Placemat

References

- 45 CFR 46.108(b), 46.109, 46.116, 46.117. ○ 21 CFR 50.20, 50.25, 50.27, 56.108(b), 56.109, 56.111.
- The IRB membership permits appropriate representation at the meeting for the types of research under review, and this is reflected on the IRB roster. The IRB has one or more unaffiliated members; one or more members who represent the general perspective of participants; one or more members who do not have scientific expertise; one or more members who have scientific or scholarly expertise; and, when the IRB regularly reviews research that involves vulnerable participants, one or more members who are knowledgeable about or experienced in working with such participants. (**AAHRPP Element II.1.A**)

The IRB has and follows written policies and procedures requiring research protocols or plans to be reviewed by individuals with appropriate scientific or scholarly expertise and other expertise or knowledge as required to review the research protocol or plan. (**AAHRPP Element II.1.E**)
- The IRB has and follows written policies and procedures for conducting meetings by the convened IRB. (**AAHRPP Element II.2.C**)
- The IRB has and follows written policies and procedures to conduct reviews by the convened IRB (**AAHRPP Element II.2.D**)