

Ensure Sound Study Design and Minimize Risk

SOP 104
Approved: December 18, 2015

Purpose and Scope

The SOP documents the requirement by the University of Hawai'i (UH) Human Studies Program (the Program) to ensure each study has a sound study design. The Institutional Review Board (IRB) is required to evaluate the study design to ensure potential risks to participants are minimized and that potential benefits justify the potential risks.

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

Procedures

Scientific and Scholarly Validity Review

When evaluating the scientific and scholarly validity of a protocol, the IRB relies on the review provided by different non-UH entities, as follows:

- For federally sponsored research, the peer review process by the sponsoring agency (e.g., NIH, NCI) provides scientific and scholarly review.
- For research subject to FDA review, the FDA conducts a rigorous scientific design review during IND or IDE evaluation. Most industry-sponsored research falls within this category. An important exception is Non-Significant Risk (NSR) device research, where the IRB serves, in a sense, as the FDA's surrogate with respect to review and approval of NSR studies.

For research that has departmental funding, gift funding or no funding, or that has not otherwise gone through a scientific and scholarly review, a UH scientific review committee (see next section) or the UH IRB will be responsible for such review. UH IRB review will only focus on the validity as it pertains to the risk of participants.

If the IRB Chair has a conflicting interest with a study under review by the IRB, the person may not chair the meeting during the discussion and vote on the study.

1. The IRB Chair must be absent from the room during the discussion and vote on the study with which the chair has a conflicting interest.
2. If the IRB Chair recuses from participation in the review and vote on a study, the chair will appoint a temporary IRB Chair from among the participating members of the IRB.

3. The meeting minutes will reflect the IRB Chair did not chair the meeting or participate in the discussion and vote for the study due to a conflict of interest. The minutes will record the name of the temporary Chair.

Parties Responsible for Scientific and Scholarly Validity

1. For **all** research conducted by students, including student research that may undergo scientific review by an awarding entity, this confirmation is provided by the Faculty Advisor who is responsible for the scientific review. Faculty advisor signature provided on the IRB application confirms that the protocol has been reviewed for soundness of the research design and the ability of the research to achieve its aims.
2. The Cancer Center Scientific Review Committee (SRC) provides a peer review of local and national research protocols involving cancer patients treated at the UH Cancer Center. The review primarily focuses on the scientific merit of the study and applies to all phases of clinical therapeutic intervention, behavioral clinical trials, tissue and body fluid research, and diagnostic trials, which impact medical decision making for the treatment of cancer patients. The process is described in the SRC [website](#). All cancer studies are required to undergo SRC review with the exception of prospective biospecimen studies that are not investigating a scientific hypothesis and compassionate use studies for a single patient.
3. For research that has departmental funding, gift funding or no funding, or that has not otherwise gone through a scientific review as described above, the IRB will review those studies following the procedures provided below.

UH IRB Review

The procedures for Cooperative studies deviate from those for the Biomedical and Social & Behavioral Sciences studies because the former studies are federal-funded, and therefore are already reviewed by the sponsor's scientific review committee.

Procedures for scientific and scholarly review by the [UH Biomedical](#) and the [UH Social Behavioral Sciences IRBs](#) are as follows:

1. The primary and secondary, if any, IRB reviewers will review the application based on scientific review questions provided in the reviewer worksheet.
 - a. Reviewers may consult the investigator or seek outside consultants with competence in the specialty if the primary or secondary reviewer lacks the scientific or scholarly expertise.
2. The IRB reviewers will provide documentation of their review to the Human Studies Program (HSP) staff.
 - a. IRB reviewer worksheet will note if an outside consultant was sought for the scientific review.
 - b. Consultants may provide comments in writing. The written comments are retained in the study files.
3. Reviewer documentation of scientific and scholarly review will be filed with the study application.

4. The IRB will review the study during a convened-IRB meeting.
 - a. Consultants may be invited to attend a convened IRB meeting to provide additional information to the IRB regarding a particular study. Consultants are excused before the vote and may not vote or be counted towards a quorum.

Studies to be reviewed by the UH Cooperative IRB are federally funded. Before being funded, they have been reviewed and approved for scientific validity by the funding agency. The IRB need not repeat the scientific review. So, for these studies, the procedures for scientific review are as follows:

1. The reviewers are *encouraged* to review the application for scientific validity using the reviewer worksheet.
 - a. The primary, and alternate if any, reviewers may skip the questions on scientific review in the worksheets.
2. The IRB reviewers will forward the completed worksheets to HSP staff. HSP staff will include the worksheets in the study package.
3. The IRB will further review the study during a convened-IRB meeting.
 - a. Consultants may be invited to attend a convened IRB meeting to provide additional information to the IRB regarding a particular study. Consultants are excused before the vote and may not vote or be counted towards a quorum.

Materials

- APP 04 New Research Protocol/ Proposal for Initial Approval – Non-Exempt
- WKSH 303 Non-Exempt Reviewer Worksheet
- GUIDE 604 Developing a Clinical Research Protocol
- GUIDE 605 Developing a Social & Behavioral Sciences Research Project Description

References

- The Organization has and follows written policies and procedures for reviewing the scientific or scholarly validity of a proposed research study. Such procedures are coordinated with the ethics review process (AAHRPP Element I.1.F.)
- Researchers employ sound design in accordance with the standards of their discipline. Researchers design studies in a manner that minimizes risks to participants. (AAHRPP Element III.1.C.)