Collaborative Research

SOP 120.2
Revised: December 18, 2015

Purpose and Scope

This document covers procedures for establishing IRB coverage of collaborative research in which the University of Hawai`i is engaged in the research.

This SOP applies to all UH Investigators conducting collaborative research, non-UH Investigators conducting research in which UH is engaged, and HRPP administrators involved in establishing IRB agreements.

Definitions

- **Collaborative research:** research that involves more than one institution.[1] It is also called cooperative research, multi-center research, or multi-site research.
- **Lead institution**: with collaborative research, the institution that holds the initial award from the funding sponsor
- **Lead investigator**: with collaborative research, the principal investigator of the lead institution. If there are multiple investigators from the lead institution, the lead investigator that is listed as the Principal Investigator in the initial award. There may be more than one lead investigator in a project.
- **To Cede Authority**: one institution allows the IRB of another institution to review and oversee collaborative research in which both institutions are engaged and accepts the decisions by that IRB on the research.
- **IRB Authorization Agreement** (IAA): a written agreement between two institutions that allows one institution (institution A) to rely on the IRB of another institution (institution B) to review and oversee human subjects research in which this institution (institution A) is engaged. An IAA can cover all research, a defined set of studies, or a particular study conducted at an institution. The detailed terms of the IAA are often set forth in a memorandum of understanding (MOU) or memorandum of agreement (MOA).
- **Data and Safety Management Plan** (DSMP): a plan to monitor research progress and safety of participants.

Procedures

1. **Determining Whether UH Is Engaged.** When an investigator of a collaborative study contacts the Human Studies Program (the Program) about whether the study must be reviewed by the UH IRB, the Program will need to first determine whether UH is engaged in the study.

[1] 45 C.F.R. § 46.114 (2013).

1.1. **Engagement.** To determine whether an institution is engaged in the study, see **SOP 103: When Must a Non-UH Investigator Seek Review by the UH IRB? – The Issue of Engagement**.

1.1.1. **If Not Engaged.** If the Program determines that UH is not engaged, the Program informs the investigator that UH is not engaged and the study is not required to be reviewed by the UH IRB.

1.1.2. **If Engaged.** If the Program determines that UH is engaged, the Program inquires whether there is a UH investigator in the study.

1.1.2.1. If there is not a UH investigator in the study, the non-UH investigator must find a UH investigator who is willing to be a co-investigator for the study. If the UH investigator agrees to do so, the UH investigator is listed as a co-Investigator in the protocol/ proposal IRB application submission for initial approval.

2. **Determining whether the non-UH Institution Has an IRB.** The Program inquires and determines whether the non-UH institution has an IRB under a current Federalwide Assurance (FWA). If the non-UH institution does not have an IRB and the non-UH investigator wishes to designate the UH IRB as the IRB of record, the Program will follow the procedures described under the section: Designating the UH IRB to Serve as the IRB of Record..

3. **Determining Whether the Study Is Covered Under an IAA.** The Program determines whether the study is covered under an existing IAA entered by UH and the non-UH institution (institutional IAA).
   3.1. **If Under an IAA.** If the study is covered under an institutional IAA, the Program follows the terms described in institutional IAA and supplemental Memorandum of Agreement or Understanding (MOA/MOU), which can be that UH relies on the IRB of the non-UH institution or the non-UH institution relies on the UH IRB.
   3.2. **If Not Under an IAA.** If the study is not covered under an IAA, the Program will inquire whether the non-UH investigator or the non-UH institution is interested in entering into a research-specific IAA. If so, the Program will follow the procedures on Creating an IAA, detailed in this document.

4. **Reviewing.**
   4.1. **If the Study Is Not Covered Under an IAA or an IAA Will Not Be Created,** the study is reviewed separately by the IRBs of the institutions involved in the study.
   4.2. **If the Study Is Covered Under an IAA**, review of the study will follow the terms of the IAA.
   4.3. **When Reviewed By the UH IRB.** If the study will be reviewed by a UH IRB, the Director of the Program (the Director) will designate the study to one of the UH IRBs for oversight based on the research topic and sources of funding.

5. **After Reviewing.** It is the responsibility of the investigators to communicate the IRB decisions to the other institutions engaged in the study. If UH cedes authority to a non-UH IRB, the investigator should follow the procedures on Reporting the Non-UH IRB's Decisions to the Program if UH Relies on a Non-UH IRB, detailed in this document.

Creating an IAA

1. **Subject Matter of an IAA.** An IAA can cover a particular study (research-specific IAA), a defined set of studies, or all research performed by one institution (institutional IAA).

2. **If the IAA Is to Cover a Particular Study.**
   2.1. **Communicating Ceding Arrangement.** All communication concerning ceding authority for human subjects protection on a particular study must be between the Program and a UH investigator. It is not appropriate for a representative of a non-UH IRB to contact the Program directly to request a ceding arrangement on a particular study.

2.2. **Ceding to a non-UH IRB.**

2.2.1. **The UH Investigator.** The UH investigator must provide a legitimate justification for ceding IRB oversight to a non-UH IRB.

2.2.2. **The non-UH IRB.** The non-UH institution must have a legitimate role in the study; the role cannot be just as a sponsor of the study or as an agent of the sponsor.

2.2.3. **If a Study Is Conducting Under the Approval of a UH IRB** and the investigator of that study communicates the preference for UH to cede authority to a non-UH IRB, the ceding request must be reviewed by the UH IRB that has approved the study. Also, this request must be reviewed by a convened IRB, not under an expedited review procedure. The convened IRB will decide whether UH will cede authority on the study. This decision will be documented in the meeting minutes.

2.2.4. **If the Study Has Not Been Submitted to a UH IRB for Approval**, the decision to cede authority to a non-UH IRB can be made by the HSP Director, in consultation with the IRB Chair as appropriate, and the Institutional Official.

2.3. **Ceding to the UH IRB.** If a non-UH investigator wishes the non-UH institution to cede its authority to a UH IRB, the Director, in consultation with the IRB Chair as appropriate, has the authority to approve this ceding arrangement. That authority should not be delegated. Typically, before accepting the ceding arrangement UH must have a role in the study.

3. **If the IAA Is to Cover a Set of or All Studies Conducted in an Institution.** IAAs on a set of or all studies conducted in an institution are often negotiated at the institutional level. Generally, such IAAs require a Memorandum of Agreement or Memorandum of Understanding to specify the terms of the agreement between the institutions involved. The UH Office of the General Counsel may be consulted with regards to the terms of the IAA and the MOU/MOA.

4. **Criteria for Approving Request for UH to Cede authority to a non-UH IRB.** Before approving the ceding of authority to a non-UH IRB, the Director or the IRB should have confidence in the capacity and compliance of the non-UH IRB.

4.1. The Director or the IRB will consider the knowledge of and respect for the other institution and its IRB.

4.2. If UH is asked to cede human subjects authority to an IRB that is unknown to the Program, the Director or the IRB will:

4.2.1. ask for a copy of that institution's policies and procedures on human subjects protection;

4.2.2. check the Office for Human Research Protections (OHRP) website for determination letters regarding that institution;

4.2.3. through the OHRP website, verify that institution has a current FWA.

4.3. If there is no information on the non-UH IRB's competence and compliance, UH will not cede authority to the non-UH IRB and enter into an IAA on this regard.

5. **The Terms.** During negotiation, both IRBs may agree to maintain communication throughout the study. For example, the IRB that has accepted IRB oversight authority may agree to submit relevant meeting minutes to the IRB that has ceded authority. Such terms should be documented in writing.

6. **Entering into an IAA.** If UH agrees to cede authority to a non-UH IRB or to accept authority ceded by another institution, the Program must facilitate the drafting and execution of an IAA between the two institutions.

7. **Signing the IAA.** The IAA must be signed by the Institutional Officials (IOs) of both institutions.

8. **Sending the Signed IAA to the Investigator.** The Program will send the signed IAA to the UH investigator. It is the responsibility of the investigators to send the IAA to the non-UH institution.

9. **Updating UH FWA if UH Cedes Authority to a non-UH IRB.** If UH cedes authority to a non-UH IRB, the Program will update the UH FWA by including the non-UH IRB as a designated IRB.

10. **Keeping the Record.** A signed IAA must be kept on file at both institutions and provided to OHRP upon request.

Designating the UH IRB to Serve as the IRB of Record

This section covers the procedures when a non-UH investigator wants a UH IRB to review and oversee the investigator's study.

1. **Designating a UH Investigator.** If there is not a UH investigator in a collaborative study, the non-UH investigator must designate a UH investigator on the study.

2. **The UH Investigator.** To request the designation of the UH IRB as the IRB of record, the UH investigator must provide a signed letter to the Human Studies Program Director with justification for this request and include the following information:
   2.1. the title of the study;
   2.2. name and contact information of the UH investigator;
   2.3. if appropriate, funding source of the study and the primary awardee;
   2.4. the name of the institution requesting to rely on the UH IRB;
   2.5. whether the non-UH institution has an IRB;
   2.6. the name and role of the collaborating non-UH investigator.

3. **The Program.**
   3.1. **Confirming.** The Program will confirm that the collaborating institution is engaged in the research.
   3.2. **Communicating the Program's Decision.** The Program will communicate with the UH investigator its decision whether to serve as the IRB of record for the study.
   3.3. **Providing an Agreement Template.** The Program will provide a template of an IAA between UH and non-UH institution. The agreement will specify that UH IRB will provide the IRB review and the non-UH institution will rely on the review.

4. **The Non-UH Investigator.**
   4.1. The UH investigator will return the completed, signed IAA to the Program.
   4.2. The non-UH investigator should ask the non-UH institution to obtain an FWA or update the existing FWA, identifying the UH IRB as a designated IRB.

Reporting the Non-UH IRB's Decisions to the Program if UH Relies on a non-UH IRB

This section covers the procedures for an investigator to report to the Program decisions and findings by a non-UH IRB if UH relies on the non-UH IRB.

After Approval During Initial Review.

1.1. No later than one month after approval of a research protocol by a non-UH IRB, the UH investigator must provide the following information to the Program:
   1.1.1. name of the institution to which human subjects authority is ceded;
   1.1.2. full title of the research protocol;
   1.1.3. the name of the sponsor, if applicable;

1.1.4. sponsor's protocol number, if applicable;
1.1.5. sites where the research is conducted;
1.1.6. the UH investigator's name and contact information; and
1.1.7. protocol abstract or draft consent form.

1.2. This information should be submitted by email to the uhirb@hawaii.edu.

The Program. The Program will
1.1. assign a protocol number,
1.2. record the protocol in its database,
1.3. store the submitted information according to its policies and procedures on document maintenance,
1.4. protect the confidentiality of the research, as required by law, and
1.5. provide letter to PI acknowledging their receipt.

Continuing Duties. The UH investigator must continue fulfilling the following duties:
1.1. **Continuing Review or Modification Requests.** The UH investigator should provide a copy of notice of approval on continuing review and modification requests by the non-UH IRB, no later than one month after the approval. The investigator should also include a copy of all materials submitted to the non-UH IRB for the continuing review or modification requests.

1.2. Noncompliance or Unanticipated Problems. The UH investigator should provide the Program a copy of reports on noncompliance or unanticipated problems submitted to the non-UH IRB. The investigator should also provide the Program a copy of decisions by the non-UH IRB on the noncompliance or unanticipated problems.
1.3. **Suspension, Termination, or Completion.** The UH investigator should notify the Program when the research protocol is completed, or when it is suspended or terminated by the non-UH IRB.

No "Forum Shopping." If research has been disapproved by a UH IRB, the research must not be conducted at UH, and UH will not recognize any approval on the research by a non-UH IRB.

UH Cooperative IRB (Coop IRB)

1. **Research Reviewed by This IRB. To minimize duplicated efforts,** this IRB reviews federally-funded collaborative research by an investigator from institutions that have signed the MOU (Coop MOU), detailing the Coop IRB. Here, the institutions that have signed the Coop MOU are referred to as participating institutions.
   1.1. **Note on the Studies by UH Investigators utilizing research resources from Queen's.** UH and Queen's Medical Center (Queen's) have entered into an IAA covering studies not under the Coop MOU. The terms of that IAA are detailed in an MOU. Internally, studies covered under that MOU are referred to as Queen's MOU Studies. Authority on those studies is ceded to the Queen's IRB.

2. **Submitting Studies to Be Reviewed by the Coop IRB.**
   2.1. **Must Be from a Participating Institution.** An investigator must be from a participating institution before the investigator may submit an application for review by the Coop IRB.

   2.2. **The IRB of the Participating Institution Must Have Approved a Request to Be Reviewed by an External IRB.** Before the investigator may submit an application for review by the Coop IRB, the investigator also must have approval from the IRB of the participating institution,

allowing the investigator to seek review on the investigator's study by an IRB external to the participating institution.

3. **How to Become a Participating Institution.** If a non-participating institution wishes to have the studies conducted by its investigators reviewed by the Coop IRB, the institution may petition the Coop IRB with a request. The Coop IRB will review the request and notify the requesting institution of its decision. Once the Coop IRB approves the request and IOs of UH and the institution sign the Coop MOU, the institution becomes a participating institution and must abide by the policies and procedures of the Program and the terms of the Coop MOU.

4. **After Review by the Cooperative IRB.** After review by the Coop IRB, the IRBs of the participating institutions are free to conduct review on the studies, but the IRBs may not reverse any disapproval by the Coop IRB.

Data Safety Monitoring Plan (DSMP)

1. **Information on the DSMP.** If the UH investigator is the lead investigator of a collaborative study, the UH investigator must provide information on the DSMP of the study, specifically, information on how the investigator manages the following:
   1.1. Unanticipated problems involving risks to participants or others;
   1.2. interim results; and
   1.3. modifications.

2. **Reviewing the Information.** The information will become a part of the study file and be provided to the IRB for review. The IRB will determine whether the DSMP is adequate to protect participants.

Materials

- Collaborative Research Procedural Flowchart – Procedures for Handling Collaborative Research (see Appendix below)
- DOC 725 IRB Authorization Agreement Template – UH as the Ceding IRB
- DOC 726 IRB Authorization Agreement Template – UH as the Relying IRB

References

- The IRB has and follows policies and procedures for managing multi-site research by defining the responsibilities of participating sites that are relevant to the protection of research participants, such as reporting of unanticipated problems or interim results. (**AAHRPP Element II.2.H**.)

Appendix

The following flowchart depicts the procedures that the Program follows in handling collaborative research.