When Must a Non-UH Investigator Seek Review by the UH IRB?—the Issue of Engagement

SOP 103
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Purpose and Scope

The question of whether a non-UH investigator must seek review from the UH IRB is often called the question of "engagement," i.e., whether UH is engaged in the research conducted by the non-UH investigator. The research conducted by the non-UH investigator is referred to as "the research" in this document. If UH is engaged in the research at issue, the non-UH investigator must seek review by the UH IRB before initiating research activities.

This document provides guidance and the procedures for determining whether a non-UH investigator must seek review from the institutional review board (IRB) of University of Hawaii (UH) before initiating research activities. This document only applies to non-UH investigators, who are not students, faculty, staff, or members in the board of regents at UH.

Definitions

Criteria for Engagement of an Institution

An institution is engaged in the research at issue if:

1. the institution receives a grant or contract under which the research at issue is conducted or
2. the institution's employees for the purpose of the research are obtaining
   (a) data about research subjects through intervention or interaction with them;
   (b) identifiable private information about the research subjects; or
   (c) informed consent of the research participants.[1]

Examples of Scenarios That UH Is Likely Engaged

1. **Grant or Contract.** UH has received a grant or contract under which the research is conducted.

2. **Obtaining Informed Consent.** UH employees obtain the informed consent of participants for the research.

3. **Intervention or Interaction.**
   (a) UH employees intervene for research purposes with participants of the research by performing invasive or noninvasive procedures.

   Examples of invasive or noninvasive procedures include

[1] Guidance on Engagement of Institutions in Human Subjects Research, U.S. Dep't of Health and Human Servs. (HHS), III (Oct. 16, 2008), http://www.hhs.gov/ohrp/policy/engage08.html.

- drawing blood;
- collecting buccal mucosa cells using a cotton swab;
- administering individual or group counseling or psychotherapy;
- administering drugs or other treatments;
- surgically implanting medical devices;
- using physical sensors; and
- using other measurement procedures.

(b) UH employees intervene for research purposes with participants of the research by manipulating the environment.

Examples of manipulating the environment include
- controlling environmental light, sound, or temperature;
- presenting sensory stimuli; and
- orchestrating environmental events or social interactions.

(c) UH employees interact for research purposes with participants of the research.

Examples of interacting include
- engaging in protocol-dictated communication or interpersonal contact;
- asking someone to provide a specimen by voiding or spitting into a specimen container; and
- conducting research interviews or administering questionnaires.

4. **Obtaining Identifiable Private Information.** UH employees obtain for research purposes identifiable private information or identifiable biological specimens from any source for the research at issue. In this scenario, it is important to distinguish "obtain" and "release."[2] cf. Example 4 below, "releasing identifiable private information".

Note:
(a) Private information or biospecimens are individually identifiable if they can be linked to specific individuals by the investigator directly or indirectly through coding systems.

(b) This scenario applies even if the UH employees do not directly interact or intervene with human subjects. In general, obtaining identifiable private information or identifiable biospecimens includes, but is not limited to,
(i) observing or recording private behavior;
(ii) using, studying, or analyzing for research purposes identifiable private information or identifiable biospecimens provided by a non-UH institution; and
(iii) using, studying, or analyzing for research purposes identifiable private information or identifiable biospecimens already in the possession of the non-UH investigator.

Examples of Scenarios That UH Is Likely Not Engaged

1. **Informing About the Research.** UH employees
(a) inform prospective participants about the availability of the research;

[2] One way to distinguish "obtain" and "release" is to check whether the UH employees possess the information when the non-UH investigators request it. If the UH employees do not have the information yet at the time of the request, the act will be "obtain"; if the UH employees possess the information at the time of the request, the act will be "release."

(b) provide prospective participants with information about the research, which may include a copy of the relevant informed consent document and other IRB approved materials, but do not obtain consent for the research at issue or act as representatives of the non-UH investigators;
(c) provide prospective participants with information about how to contact the non-UH investigators for information or enrollment; or
(d) seek or obtain the prospective participants' permission for the non-UH investigators to contact them.

For example: UH is not engaged if a clinician

- provides patients with literature about research at a non-UH institution, such as including a copy of the informed consent document, or
- obtains permission from the patients to provide the patients' names and telephone numbers to the non-UH investigators.

2. **Granting Permission to Facilities.** UH permits the non-UH investigators to use its facilities for intervention or interaction with participants of the research.

Examples: UH permits non-UH investigators to use a UH facility

- to conduct or distribute a research survey;
- to recruit research subjects; or
- to draw a blood sample for research purposes.

Note: the non-UH investigator must seek approval from the department that is in charge of the UH facility before accessing the facility.

3. **One-Time or Short-Term Interventions.** UH was not initially selected as a research site, but UH employees administer the interventions being tested or evaluated under the protocol <u>at a one-time or short-term basis</u> (e.g., a UH oncologist administers chemotherapy to a subject for the research at issue as part of a clinical trial because the subject unexpectedly goes out of town, or is unexpectedly hospitalized), provided that all of the following conditions are also met:
   (a) The non-UH investigator determines that it would be in the best interest of the participant to receive the interventions being tested or evaluated under the protocol;
   (b) UH employees do not enroll participants or obtain informed consent of any subjects for the research at issue;
   (c) The non-UH investigator retains responsibilities for
      (i) overseeing protocol-related activities;
      (ii) ensuring that the interventions are administered in accordance with the IRB-approved protocol; and
      (iii) ensuring protocol-related data to be reported to the non-UH investigator, including safety-monitoring data and adverse events; and
   (d) The IRB at the non-UH investigator's institution is informed that interventions being tested or evaluated under the protocol have been administered at an institution not selected as a research site.

4. **Releasing Identifiable Private Information.** UH employees release to non-UH investigators identifiable private information pertaining to the subjects for the research at issue. E.g, UH releases identifiable student test scores.

Note: if the identifiable private information to be released were collected for another research covered by 45 C.F.R. part 46, UH will release such information <u>only if</u>

(i) the release would not violate the informed consent of the other research, or
(ii) the release would be consistent with the IRB's determinations of waiver if informed consent was waived by the IRB for the other research.

5. **Not Identifiable Private Information.** UH employees
(a) obtain coded private information from a non-UH institution involved in the research that retains a link to individually identifying information, such as name or social security number; and
(b) are unable to readily ascertain the identity of the participants to whom the coded information pertains because, for example,
- UH employees and the holder of the key enter into an agreement prohibiting the release of the key to the UH employees under any circumstances;
- the non-UH institution has IRB-approved written policies and operating procedures applicable to the research at issue that prohibit the release of the key to the UH employees under any circumstances; or
- there are other legal requirements prohibiting the release of the key to the UH employees.

For purposes of this document, "coded" means that
(a) identifying information, such as name or social security number, that would enable the investigator to readily ascertain the identity of the individual to whom the private information pertains has been replaced with a code such as a number, letter, symbol, or combination thereof; and
(b) there is a key to decipher the code, which enables the linkage of the identifying information to the private information.

Notes on 4 and 5:
(a) The non-UH investigator must seek approval from the UH Data Governance before accessing the information.

(b) The non-UH investigator must seek review from the UH IRB before a UH biorepository releases biospecimens to the non-UH investigator.

6. **Accessing Identifiable Private Information While Visiting.** UH employees access or use individually identifiable private information only while visiting the non-UH investigator's institution, provided that the non-UH investigators' research activities are overseen by the IRB of non-UH investigator's institution.

7. **Commercial Services.** UH employees perform commercial or other services for investigators provided that all of the following conditions are also met:
(a) The services performed do not merit professional recognition or publication privileges;
(b) The services performed are typically performed by UH for non-research purposes; and
(c) UH employees do not administer any study intervention being tested or evaluated under the protocol.

The following are examples, assuming that the services described would not merit professional recognition or publication privileges:
- An appropriately qualified laboratory whose employees perform routine serum chemistry analyses of blood samples for investigators as a commercial service;
- A transcription company whose employees transcribe research interviews as a commercial service.

8. **Medical Services.** UH is not selected as a research site, but UH employees provide clinical trial-related medical services as part of routine clinical monitoring or follow-up of participants for the research, provided all of the following conditions are also met:
   (a) UH employees do not administer the interventions being tested or evaluated under the protocol;
   (b) The clinical trial-related medical services are typically provided by UH for clinical purposes;
   (c) UH employees do not enroll subjects or obtain informed consent of any subject for the research at issue; and
   (d) When appropriate, the non-UH investigators retain responsibilities for
      (i) overseeing protocol-related activities; and
      (ii) ensuring protocol-related data to be reported to the non-UH investigators, including safety-monitoring data and adverse events.

   Note: UH is engaged if UH was not initially selected as a research site, but UH employees administer the interventions being tested or evaluated in the research, such as administering one of two chemotherapy regimens as part of an oncology clinical trial that evaluates the safety and effectiveness of the two regimens.

9. **Not for the Purpose of Research.**
   (a) UH employees access or review identifiable private information for purposes of auditing.

   (b) UH employees receive identifiable private information for purposes of satisfying U.S. Food and Drug Administration reporting requirements.

10. **Describing Research.** UH employees author a paper, journal article, or presentation describing a human subjects research project.

Procedures

1. **Consulting About Engagement.** A non-UH investigator should consult the HSP office whether a study conducted by the investigator should be reviewed by the UH IRB.

2. **Determining Engagement.** The HSP staff will determine whether UH is engaged in the study, following the guideline and flowchart in this document.

3. **After Determination.**

   3.1 **If Engaged.** If the HSP determines that UH is engaged in the study, the non-UH investigator must find a UH investigator who is willing to be a co-investigator of the study. See the SOP 120 on collaborative research for detail on how to seek review by the UH IRB.

   3.2 **If Not Engaged.** If HSP determines that the UH is not engaged in the study, it will provide an written acknowledgement stating that UH is not engaged in the study and review by the UH IRB is not needed.
      3.2.1 But the non-UH investigator must seek approval from the department that is in charge of the requested resources.

Questions

If an investigator has questions regarding engagement, the investigator may consult the HSP at uhirb@hawaii.edu or 808-956-5007.

Materials

- GUIDE 615: UH Engagement Chart

References

- The Organization has and follows written policies and procedures for determining when activities are overseen by the Human Research Protection Program (AAHRPP Element I.1.A.).