Human Subject (Participant) Research Determination

SOP 101
Revised Date: February 11, 2019

Purpose and Scope

This document describes the criteria for a project to qualify as human subject research.

This SOP applies to all individuals and entities involved in the determination of human subject research. These include the Human Studies Program (HSP) staff and Institutional Review Board (IRB) members who review human subject research, and Investigators and their Research Staff who prepare and submit applications for review and determination.

Definitions

Determining What Constitutes as Human Research

Activities that are regulated as human subject research include those activities that meet the definitions of "research"[1] and "human subject"[2] under the DHHS regulations and/or those that meet the definitions of "clinical investigation"[3] and "human subject"[4] under the FDA regulations. The FDA regulations define "research" to be synonymous with "clinical investigation."

1. Any individual planning an activity that may fall under these regulations must:
   a. Review the DHHS definitions, first considering whether the activity is research, and if so, whether it involves human participants,

      AND

   b. Review the FDA definitions and determine if the activity is regulated by the FDA.
2. If the activity meets either the DHHS set of definitions or the FDA definitions (or both), then an application for approval of the activity must be submitted to the HSP for IRB review.
3. The following OHRP decision chart is recommended for determining if the activity qualifies as

[1] 45 CFR § 46.102(l), definition of "Research."
[2] 45 CFR § 46.102(e)(1), definition of "Human subject."
[3] 21 CFR §§ 50.3(c) and 56.102(c), definition of "Clinical investigation."
[4] 21 CFR §§ 50.3(g) and 56.102(e), definition of "Human subject."

human subject research under the DHHS definitions (see Chart 1): OHRP Human Subject Research Decision Charts

4. The following OHRP decision charts are also suggested for review as resources:
   a. For determining if the coded data represents human subjects (OHRP Guidance Document: Coded Private Information or Biological Specimens)
   b. For determining if UH is engaged in the research activity (OHRP Guidance Document: Engagement of Institutions in Research)

Procedures

Determining Whether an Activity Is Human Subjects Research

1. The HSP staff determines whether an activity is human subjects research.
2. In its determination, the HSP will follow the DHHS and FDA definitions described above.
3. The HSP staff will orally inform an Investigator whether the activity is human subjects research.
   a. If an Investigator desires a written opinion, the Investigator must submit an application for exempt status.[5]
4. UH Mānoa Office of Graduate Education requires that a graduate student consult with the HSP before submitting **Form II Advance to Candidacy**. Please check with the Graduate Education offices for requirements for all other UH campuses.
   a. The graduate student will submit an application for exempt status.
   b. If the HSP determines that the study is not human subject research, it will provide a "not human subjects research" letter.
   c. If the HSP determines that the study is human subject research and approves the exempt status of the study, it will provide an approval letter for exempt status.
   d. If the HSP determines that the study is human subject research but finds that the study does not qualify for exempt status, it will advise the student to submit an application for non-exempt (that is, expedited or convened IRB) review.
5. If a collaborative study, in which the UH IRB has an established IRB Authorization Agreement, is submitted, the HSP will provide an acknowledgement letter to the Investigator if a request is made that UH IRB cedes its authority to the collaborating institution's IRB, if dictated in the agreement.
6. **Providing Guidance on Activities Not Human Subjects Research.** The HSP provides

[5] 45 CFR § 46.104, Exempt research.

guidance on activities that are not human subject research on the HSP website or at HSP educational sessions. For more information, contact the HSP at 808-956-5007 or uhirb@hawaii.edu.

Research Subject to IRB Review

All research involving human subject, regardless of sponsorship, in which the university is considered to be "**engaged**," must be approved by the IRB. The University is engaged in research when the project qualifies as human subject research and one or more of the following apply:

1. The research is sponsored by the University;
2. The research is conducted, in whole or in part, by members of the University faculty, staff or students acting in their University capacity regardless of the location of the research;
3. The University receives a direct federal award to conduct human subject research, even when all activities involving human subjects are carried out by a subcontractor or collaborator.
4. An individual is engaged in the conduct of human subject research when interacting or intervening with a living individual for research purposes or when using identifiable private information about a living individual for research purposes.

Non-Research Activities That Are Subject to IRB Review at UH:

The following, highly specific activities qualify as human subject 'non-research activities' that **DO REQUIRE UH IRB REVIEW**. Data from these activities must not be used for research purposes; however safety information may be collected and provided to the sponsor:

- Emergency Use of an Investigational Drug, Medical Device, or Biologic, see:
  - APP 11: Emergency Use Checklist - Drug,
  - APP 12: Emergency Use Checklist - Device

Materials

UH HSP website:

- WKSH 301 Is My Project Human Subject Research?
- WKSH 302 Requirements for Exempt Approval
- TMP 410 Not Human Subjects Research Determination Letter
- GUIDE 615 UH Engagement Chart

References

- DHHS 45 CFR 46
- FDA 21 CFR 50
- FDA 21 CFR 56
- OHRP website
    - OHRP Human Subject Research Decision Charts
    - OHRP Guidance Document: Engagement of Institutions in Human Subjects Research
    - OHRP Guidance Document: Coded Private Information or Biological Specimens
- 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*).