University of Hawai‘i Human Studies Program

Institutional Review Board (IRB)
Definitions:

A *Human Subject* is a living human being about whom an investigator conducting research obtains:

“data through intervention or interaction with the individual, or identifiable private information”

45 CFR 46.102(f)
**Intervention**: Includes both physical procedures and manipulation of the participant or his or her environment for research purposes.

**Interaction**: Includes communication or interpersonal contact between investigator and subjects.

45 CFR 46
What is Identifiable Private Information?

Information that can be used on its own or with other information to identify, contact, or locate a single person, or to identify an individual in context.

Examples:

• Name
• Social Security Number
• Birth Date
• Student I.D. Number
• Address
An “investigator” in this context is anyone conducting research, *including students*.

**However…**

The UH Board of Regents (BOR) Policy states that only “Board appointees may serve as principal investigator for an externally funded contract or grant” ([RP 12.202](#)).

Thus, student-led research should have the faculty advisor as Principal Investigator in the protocol. Students should serve as Co-Investigators on their projects.
What is research?

Theses and Dissertations?
- Yes, by definition

Term Papers / Class projects
- No, unless the intent is to publish or present

Evaluations and Quality Assurance?
- Maybe

Funded Research?
- Definitely!
When do I **not** need to submit an application to the UH IRB?

- If you are not UH-affiliated
- If the research is only for a class grade, you will never use the data again, and after the grades are in, the data is destroyed
- When the research data is only to inform a program, institution, or other project (internal)
- The data is publicly available: online, in the library, census data
  - If you don’t need a password, membership, or special permission to access the data, it is likely publicly available
When **Do I need to submit an application to the UH IRB?**

- If you are UH-affiliated and want to conduct research with living human beings or data from living human beings
- If the research project is a requirement of your degree
- If the research project is funded
- If you want UH-affiliated people as your participants, or you want to use UH-facilities or property
- If you wish to present your results publicly: publish (journal, book, online), present, or any other public forum (conference)
What do I need to communicate with my Advisor?

1. Complete the CITI training

2. Once the eProtocol application has been filled out by the student, let the advisor know. The advisor is expected to review the application before submission.
What could happen if I don’t get approval prior to conducting my research?

Students
- Will not be able to use the data.
  - Graduation halted/delayed (The Graduate Division office checks for IRB approval before approving your graduation.)
  - Restart the research from the beginning after approval
Research involving living human beings **CANNOT** begin without prior UH IRB approval.

- Decisions cannot be overruled.

When in doubt, ask.

Apply before conducting research!
How do I submit an application?

1. Log on to the CITI website using SSO, complete the required modules

2. Fill out the eProtocol application including
   ◦ Consent form/assent form
   ◦ Recruitment materials
   ◦ Surveys/Interview questions
   ◦ Anything the participant will see/experience
   ◦ Translated documents if applicable
CITI:
Collaborative Institutional Training Initiative
https://www.citiprogram.org/
Enter the site through the SSO option.

Required Courses:
• Basic
• Information, Privacy, and Security

Evidence of having completed the training is required for all researchers and key personnel in order for the application to be processed.
eProtocol
https://uhmanoa.keyusa.net/
eProtocol

Use only Firefox, Safari or Internet Explorer
- Google Chrome is not a compatible browser

Before entering the eProtocol site, please disable your browser's pop-up blocker or allow for exceptions for https://uhmanoa.keyusa.net

Log in with your UH username and password
* Do not use the back and forward button – you will be dropped from the site. Navigate within the system.
The Consent Process

Information
Voluntary Participation
Comprehension

- Belmont Report

The information that is given to the subject shall be in language understandable to the subject. 45 CFR 46
Informed Consent is a process of information exchange that includes:

- Participant recruitment materials
- Verbal instructions
- Written materials
- Question / answer sessions
- Agreement - documented by a signature when required
UH IRB Model Consent Forms

https://www.hawaii.edu/researchcompliance/templates

• Follow model consent form formatting including section headers.

• Use an active voice.

• The language and reading level should be 6th – 8th grade.
What if my survey is online?

- Make the consent form the first page of the survey
- Replace the signature line with a statement that going to the first page of the survey implies their consent to participate
- Add a statement asking the participant to save or print the consent form for their records

*compensation can never be given for “completion” or “finishing”*
What if I want to audio or video record?

Exempt Applications
• Audio record for the purpose of transcription

Non-Exempt Applications
• Audio record for libraries (languages)
• Video record (documentaries, for the purpose of analysis, other)
• Photo taking

*Must specifically describe why, and request permission on the signature page for each item with a “yes” and a “no” check box. Must also describe what will be done with the item in the future.
IRB Committees

3 Institutional Review Board (IRB) committees within the UH HSP:
- Biomedical Sciences IRB
- Social and Behavioral Sciences IRB
- Cooperative IRB

Assignment to the appropriate committee for review depends on the subject matter.
Levels of Review

Based on Risk to the Participant

• Exempt
• Expedited
• Full

Expedited and Full are also referred to as “Non-Exempt.”
How long will it take for my approval?

Up to you – depends on the completeness of the application.

Exempt
• Continuous acceptance and review.
• Reviewed in office.
• Two to three weeks.

Expedited
• Continuous acceptance and review.
• Reviewed in office, then an IRB reviewer.
• Three to four weeks.

Full
• Due date found on the calendar on our website.
• Reviewed in office, then assigned to a primary and secondary IRB reviewer, to be discussed and voted on at the convened meeting.
• Four to eight weeks.
• For example, the due date is October 3rd for the October 21st Social and Behavioral IRB.
Oversight Agencies

Office of Human Research Protections (OHRP)
Food and Drug Administration (FDA)
  - Even though the FDA and OHRP fall under the U.S. Department of Health and Human Services (DHHS), the two agencies have separate regulations that apply to research to human participants in research.

State of Hawai‘i
University of Hawai‘i
What UH promises...

“This institution is guided by the ethical principles regarding all research involving human subjects, as set forth in the ‘Belmont Report,’ regardless of whether the research is subject to Federal regulation.....”

UH AP 5.503

This includes all faculty, staff, students, and anyone using UH resources.
Contact Us:

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