Navigating Through the UH IRB Application Process

A Key to a Successful Approval of Your Research

Hosted by the Faculty Mentoring Program and Preparing Future Faculty
March 5, 2015

Denise Lin-DeShetler, M.P.H., M.A.
Director
Most scientists regarded the new streamlined peer-review process as ‘quite an improvement.’
Where do I start...

Do I need IRB approval before conducting my research project?

Criteria:

Is It Research?

Is It Human Subjects Research?
What is research?

Is it a systematic investigation?

<table>
<thead>
<tr>
<th>Quantitative Research</th>
<th>Qualitative Research</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objectives</td>
<td>Research question(s)</td>
</tr>
<tr>
<td>Hypothesis</td>
<td>Theory generating</td>
</tr>
<tr>
<td>Pre-/Post-test</td>
<td>Survey questions/ Interviews</td>
</tr>
<tr>
<td>Variables</td>
<td>Identifying patterns</td>
</tr>
<tr>
<td>Data collected</td>
<td></td>
</tr>
</tbody>
</table>

Human Studies Program
What is research?

- For generalizable knowledge?
  - 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!
Is it Research?
Case examples

- Project to evaluate a particular program that teaches cultural sensitivity to teachers in a middle school that includes a diverse student population.
  No, as long as the purpose of the QI is to improve ONLY that program

- Student who wants to present results of his project on food preferences of farmers from a particular region at a national conference.
  Yes, definitely

- Project that evaluates a new curriculum conducted within a class at UH that will be presented only within the department to investigate whether the curriculum should be integrated into future classes within that department.
  No, as long as the findings from that evaluation stays within the university

Human Studies Program
Does your project involve only the analysis of publicly available data?
  ◦ If Yes, no need to get IRB approval

However, FAs: Even if your project does not need an exempt or IRB approval, your graduate student will still need a letter from HSP verifying that your project does not meet the definition of “Human Subjects Research” (per Graduate Division requirement)
  • To get this letter, your student will need to submit his/her project to the Human Studies Program for verification using an exempt application.
Does my research involve obtaining information about living individuals?

Will the information be obtained through intervention or interaction with these individuals?

Will the research involve access to private information from which individuals can be identified directly or indirectly through a link or code?

• If No for all of the above, not human subjects research.
• If yes to 1 & 2 or 1 & 3, you need to apply for IRB approval
I need IRB approval. What now?

What forms do I use?

What do I need to include in the application?

How do I submit?

When can I expect an approval?
I need IRB approval. What now?

What forms do I use?
• Two different application forms for Exempt vs. Non-exempt

What do I need to include in the application?

How do I submit?

When can I expect an approval?
Exempt vs. Non-exempt

- **Vulnerable populations**
  - Minors
  - Prisoners
  - Pregnant women
  - Mentally-impaired

- **Personal Identifiable Information (PII)**
  - Risks: physical, emotional, financial, reputational, employment, etc.

- **Invasive Procedures**
  - Obtaining blood
  - Interventionsal that could potentially bring about permanent effect (i.e., drugs, devices, informational/educational that may require counseling support)

- **Deception**
IRB Committees

3 IRB committees within the HSP (https://manoa.hawaii.edu/researchcompliance/institutional-review-board-irb-0):

1. Biomedical Sciences IRB
2. Social and Behavioral Sciences IRB
3. Cooperative IRB

Assignment to the appropriate committee for review depends on the subject matter of the non-exempt study.

Be aware that if your non-exempt study needs to be reviewed by full board, there are deadlines for submitting application.
I need IRB approval. What now?

What forms do I use?

What do I need to include in the application?

How do I submit?

When can I expect an approval?
What does a good application look like?

- Signed application (also by advisor, if applicable)
- Consent form (model on the website)
  - Parental consent and assent
  - Informational form
- All participant materials in the language of the participant (if applicable)
- CITI certificate of completion
  - Advisors should also complete their CITI training too!
- Anything the participant will see or hear
  - Survey
  - Interview questions
  - Recruitment flyer and/or recruitment script (model on the website)
- All questions on the application form are answered
  - Description of Project – exempt
  - Objectives, methods, risks, etc. – non-exempt
UH IRB Model Consent Forms

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

- Follow model consent form formatting including section headers
- Use an active voice
- The language and reading level should be 6th grade.
- Include section before the signature line for subjects to choose whether or not they want to be audio-taped, if applicable
Other types of “consent”

A research project may be allowed to use a study information form instead of a consent form if a combination of these 4 conditions are met:

1. Research involves no more than minimal risk to the subjects;
2. Waiver or alteration of informed consent will not adversely affect the rights and welfare of the subjects;
3. Reach could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Study Information Forms Have All Elements Of A Consent Form – Just No Need For A Signature. Participants Keep A Copy Of The Study Information Form
Examples of when informational form over informed consent is preferred

- Anonymous online survey (ex.: survey monkey) where there are no identifiers collected and no subsequent contact with participants.

- Research involving survey with large number of participants collecting data on brand preference on shoes.

- Interviewing victims of domestic violence about their experience with domestic violence.
Oral Consents

- Oral Consent Script
  - Must include all elements of a traditional informed consent
    - Purpose, activities, time commitment
    - Risks and benefits
    - Privacy and confidentiality
    - Voluntary

Qualification for use of oral consents:
- Minimal risk and involves no procedures for which written consent is normally required outside of the research context; OR
- Only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality
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
Required Education Training

- Collaborative Institutional Training Initiative (CITI)  
  https://www.citiprogram.org/

  ◦ Must submit certificate of successful completion with application in order for application to be reviewed.

  ◦ CITI training is good for 3 years
    • Refresher course available for renewing

  ◦ For step-by-step instructions on registering and completing UH required CITI training:  
    https://manoa.hawaii.edu/researchcompliance/get-training-0
CITI Guidance document on our website

- Must have University of Hawai‘i listed as the institution

- For **exempt** research, must complete the Human Subjects Research basic course (question 3) and Information Privacy and Security course (question 5) for “**Exempt biomedical researchers and key personnel.**”
  - If only using existing medical data for research, choose “**exempt researchers and key personnel – biomedical data and specimens only.**”

- For **non-exempt** social & behavioral research (e.g., sociology, psychology, SLS, education), must complete the Human Subjects Research basic course (question 3) and Information Privacy and Security course (question 5) for “**Non-exempt social & behavioral sciences researchers and key personnel.**”

- For **non-exempt** biomedical research (e.g., medicine, psychiatry, nursing, public health), must complete the Human Subjects Research basic course (question 3) and Information Privacy and Security course (question 5) for “**Non-exempt biomedical researchers and key personnel.**”
Supplemental Courses

- If your research involves recruitment of belonging to a “vulnerable population” (or special setting), complete appropriate course or courses under Question 4 of CITI:
  - Children (Biomed Focus)
  - Prisoners (Biomed Focus)
  - Pregnant Women, Fetuses, and Neonates
  - Children (Social & Behavioral Focus)
  - Prisoners (Social & Behavioral Focus)
  - Working with Elementary & Secondary Schools

Coming From Another Research Institution

- If you completed CITI training from another institution, you may be able to transfer some modules over to the UH CITI training.
  - You would still have to add UH as a participating institution when you go into your personal CITI account
I need IRB approval. What now?

What forms do I use?

What do I need to include in the application?

How do I submit?

When can I expect an approval?
SUBMISSION

Electronically submit to uhirb@hawaii.edu
For non-exempts only, ALSO submit 2 hard copies to:

Human Studies Program
1960 East-West Road, Biomed Bldg B-104
Honolulu, HI  96822

TURNAROUND
(~approximate)

<table>
<thead>
<tr>
<th>Type</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exempts</td>
<td>2-3 weeks</td>
</tr>
<tr>
<td>Expedited</td>
<td>3-4 weeks</td>
</tr>
<tr>
<td>Full-Board</td>
<td>1-2 months</td>
</tr>
</tbody>
</table>

Human Studies Program
SUBMISSION

Busy Seasons
High volumes of applications during:
March – April
October – November

Be aware that turnaround time may take longer
during these busy seasons

COMING SOON!

eProtocol: electronic submission system
No more hard copy submissions
Frequently made mistakes to avoid

- Missing one or the other of the following when conducting research on minors:
  - Assent form
  - Parental consent form

- Confusion between “anonymity” vs. “confidentiality” (individual vs. data)

- Missing recruitment flyer or script

- Not including term “research” in the recruitment flyer

- Not providing separate responses to the six questions to the Description of Project in the exempt application
Human Studies Program Website

https://manoa.hawaii.edu/researchcompliance/human-studies

QUICKLINKS:

- “Learning Commons – HSP”: information on required and elective training for human subjects research
- “Submit a New Protocol”: Application forms for new protocols; guidance on review categories; instructions on how to submit
- “Modify a Protocol”: Application form to request modifications on active protocol
- “Renew a Protocol”: Application form to apply for continuing review of active protocol
- “Report a Protocol Violation or Unanticipated Problem”: forms to report a protocol violation or unanticipated problem
Human Studies Program Website

https://manoa.hawaii.edu/researchcompliance/human-studies

QUICKLINKS:

- “Institutional Review Board (IRB)”: calendar of submission deadlines, meeting dates; defines what kind of protocols each UH IRB reviews; coming soon – cooperative agreements
- “Templates”: includes consent form templates, model recruitment flyers
- “Policies & Guidance”: general policies and procedures, SOPs, general guidance on developing various items required for human subjects research
- “Industry-Sponsored Research”: IRB fee schedule for industry-sponsored research; regulatory document tools for research management; investigator brochure
Human Studies Program Website

https://manoa.hawaii.edu/researchcompliance/human-studies

QUICKLINKS:

- “FAQs”
- “Check Application Status”: allows PI to search HSP database for real-time status of active studies
- “Information for Research Participants”: resources for research volunteers regarding their rights as participants and what they need to know before and during participation.
- “Other Resources”: links to federal, state and institutional regulations and policies and procedures pertaining to research involving human participants.
Other Useful Links

- **OHRP Decision Chart:**

- **Full board application deadline calendar:**
  - [https://manoa.hawaii.edu/researchcompliance/institutional-review-board-irb-0](https://manoa.hawaii.edu/researchcompliance/institutional-review-board-irb-0)

- **Important announcements and policy/ procedure changes (Under “What’s New”):**
  - [https://manoa.hawaii.edu/researchcompliance/](https://manoa.hawaii.edu/researchcompliance/)
Tips

- **Complete the CITI training early**, and have your advisor do it early too. You only have to do it every three years, and will apply to all subsequent and concurrent research projects.
  - If you anticipate doing research that have higher risk, do the more comprehensive training module.

- Use, use, use the *consent form templates*. They were created by the HSP and IRB for your convenience.

- Apply early!
  - Be aware that other students will be submitting around the same time too, so turnaround time increases with volume (October-November, March-April).

- Make sure you **let your advisor review** before signing off your application. They are the subject matter experts to your discipline.

- For students conducting research using Hawai’i public school resources, **consult HIDOE** – may need to apply for separate approval.
Above all else... Don’t panic!

When in doubt, ask for help.
Thank you!

Contact Us:

UH Human Studies Program
University of Hawaii at Manoa
1960 East-West Road
Biomedical Building B-104

Telephone: 808.956.5007
E-mail: uhirb@hawaii.edu
Website: https://manoa.hawaii.edu/researchcompliance/human-studies