Navigating Through the UH IRB Application Process

A Key to a Successful Approval of Your Research

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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?

- Objectives
- Hypothesis
- Pre-/Post-test
- Variables
- Data collected
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!
Case examples
Research vs. QI?

- Quality improvement 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
Is this human subjects research?

Does your project involve only the analysis of publicly available data?
• If Yes, no need to apply

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.
Is this human subjects research?
(continued)

1. Does my research involve obtaining information about living individuals?
2. Will the information be obtained through intervention or interaction with these individuals?
3. Will the research involve access to private information from which individuals can be identified directly or indirectly through a link or code?

• If yes to 1 & 2 or 1 & 3, you need to apply to HSP
• Otherwise → not human subjects research.
I need to submit. 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 to submit. What now?

What forms do I use?
  • 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

Exempt
- Means exempt from IRB review
- No more than minimal risk
- Falls under one or more of the six exempt categories (45 CFR 46.10(b))
- No expiration date

Application Form: “Application for Approval of Research as Exempt”

Non-Exempt
- Vulnerable populations
  - Minors
  - Prisoners
  - Pregnant women
  - Mentally-impaired
- Private Identifiable Information (PII)
  - Risks: physical, emotional, financial, reputational, employment, etc.
- Invasive Procedures
  - Obtaining blood
  - Interventional that could potentially bring about permanent effect (i.e., drugs, devices, informational/educational that may require counseling support)
- Deception

Application Form: “Forms for the Biomedical and Social and Behavioral Sciences IRBs only – Application for Approval of a New Study”
IRB Committees

3 IRB committees within the HSP:
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 to submit. 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
  - Literature review, objectives, methods, risks, etc. – non-exempt
  - Recruitment methods (be mindful of undue influence)
Informed Consent

Participants must fully comprehend their involvement in the research before consenting to volunteer.
Follow model consent form formatting including section headers

- Use an active voice (e.g., “My name is....”)

- The language and reading level should be 6th to 8th grade.

- Include section before the signature line for participants to choose *whether or not* they want to be audio-taped or video-taped, if applicable

- Include section before the signature line for participants to choose *whether or not* they want to be contacted for future studies
Other types of “consent”

A research project may be allowed to use an informational 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. Research 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.

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

- 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.
But understand and remember….  

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
Online Training Requirement

Training on human subjects protection is a requirement before conducting research.
Required Education Training

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

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

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

For **exempt** research, must complete “Health Information Privacy and Security (HIPS) course, information for students or instructors” and “Human Subjects Research Basic Course. Under Question 3, select students and advisors – class projects.”

For **non-exempt** research, must complete “Human Subjects Research Basic Course, under Question 3, select Social & Behavioral Research Investigators” and Under Question 4, select “Health Information Privacy and Security (HIPS) Course – Information for Investigators

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
Required Education Training

- National Institute of Health research:
  - NIH Training is also offered for those conducting NIH-funded research

https://phrp.nihtraining.com/users/login.php

But can only apply to NIH-funded projects
I need to submit. 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 Procedures

- Exempts – electronic only via uhirb@hawaii.edu
- Non-exempts – electronic via uhirb@hawaii.edu and 2 hard copies (one with original PI signature, one copy)

Approvals expected:
- Exempt 2-3 weeks
- Expedited 3-4 weeks
- Full-board 1-2 months

Be cognizant of full-board review deadlines
Collaborative Research

Agreements with selected local institutions/ departments to reduce redundancy of IRB submissions
Special Categories of Review

UH Cooperative IRB:

- **Federally-funded biomedical research** involving UH and one or more of the following institutions:
  - Queens Medical Center
  - Hawaii Pacific Health
- UH has a separate Cooperative Application
- However, unlike the MOU process, both QMC and HPH require separate IRB applications to their own IRBs for review
  - QMC -> QMC IRB;
  - HPH -> WIRB
- Use application form: “Forms for the Cooperative IRB: Application for approval of a new study.”
Collaborative Institutions

The following state agencies have UH IRB as their IRB of record for studies conducted by UH faculty:
- HIDOE: Dept of Education
- HIDOH: Dept of Health
- HIDAG: Dept of Attorney General

Queens Medical Center
- Via MOU process, investigators may request UH IRB to cede IRB oversight to QMC IRB
- Non-exempt and exempt (QMC will only review as an expedited, for this case)
- Need QMC appointment or partnership with a QMC employee

Hawaii Pacific Health Research Institute (HPHRI)
- Research involving UH faculty and HPH resources are ceded to Western IRB (WIRB)

UH Cancer Center
- All new non-exempt oncology studies are ceded to WIRB
- Exempt studies submitted to HSP

Instructions:
Post-Approval

I got approved!
I’m done….right?
Post–Approval PI Responsibilities

- Submit continuing review application to IRB prior to expiration date (recommend 2 months prior). Exempt studies do not have an expiration date.

- Submit separate modification application when there is a need to change protocol content or administrative issues (i.e., change in PI)

- Inform IRB in a timely matter of all protocol violations (PV) and/ or unanticipated problems (UP), especially serious adverse events
  - Within 24 hours to IRB for major PV and UP

- Notification of study closure.
Modifications

- Does not include only change in protocol design
  - Change in PI
  - Change in project title
  - Change in enrollment numbers
  - Timeline of project start/ completion
  - Location of research activities, recruitment source
  - Change in research staff
Study closures

A project *should not* be closed if any of the following applies:

1. Enrollment of new study participants at the UH IRB-approved site is active;
2. Research activities (i.e., intervention and/or follow-up) at the UH IRB-approved site is ongoing;
3. Biological specimens containing personally identifiable information (PII) are being maintained in a repository that has been approved as part of this project or upon which analysis or research is active;
4. Data analysis or publication preparation that involves the use or access of the PII is ongoing;
5. Or, if they study involves an external study sponsor (i.e., pharmaceutical-sponsored clinical trial) and permission has not be given by sponsor to close the study.
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
Tips

- **Complete the CITI training early.** If you are a faculty advisor, your students will need your certificate to complete their application 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 students will be submitting around the same time too, so turnaround time increases with volume (October-November, March-April).

- If you are an advisor, make sure you **review** the student’s application before signing off. You are the subject matter expert to their discipline.

- For faculty conducting research using Hawai’i public school resources, **consult HIDOE** – may need to apply for separate approval.
Future of HSP

- Electronic submission system
  - More efficient submission and review process
  - IRB-approved stamped study documents
  - Integrated CITI training verification
  - Electronic signatures

- Education Program
  - Changes in CITI modules, esp. HIPS
  - Quality Improvement Program
Other Useful Links

- OHRP Decision Chart:

- Full board application deadline calendar:

- Important announcements and policy/procedure changes (Under “What’s New”):
  - [http://www.hawaii.edu/irb/](http://www.hawaii.edu/irb/)
Above all else...
Don’t panic!

When in doubt, ask for help.
Thank you!

Questions?

Contact Us:

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