Unraveling the Mysteries of IRB: How to Create a Successful IRB Application

Kristin Bacon, MPH, CIP, IRB Coordinator, TRHT Fellow ©
Aloha Kākou!

This presentation will cover...

• Who to contact to answer questions
• Research ethics evolution
• When is research human subjects research?
• What to do if research is human subjects research
• How to fill out the application
UH Human Studies Program

- Victoria Rivera, MPA, Director of the Office of Research Compliance and Interim Manager of the Human Studies Program - riveravg@hawaii.edu • (808) 956-8102
- Kristin Bacon MPH, CIP, IRB Coordinator, TRHT Fellow - kbacon@hawaii.edu • (808) 956-8480
- Jacob Kowalski CIP, IRB Coordinator - jkowalsk@hawaii.edu • (808) 956-7659
- Donna Kobayashi, Key Personnel - donnakob@hawaii.edu • (808) 956-5007
- Janine Nariyoshi, Key Personnel - jnakatan@hawaii.edu • (808) 956-5007
UH Human Studies Program

Website: https://www.hawaii.edu/researchcompliance/human-studies

Office Location:
2425 Campus Road, Sinclair 10 (basement of Sinclair Library) Honolulu, HI 96822

Main Office Phone: (808) 956-5007
Fax: (808) 956-9150
Email Address: uhirb@hawaii.edu
UH Human Studies Program Website Quicklinks

Website:
https://www.hawaii.edu/researchcompliance/human-studies

Examples of Quicklinks found on the website:
- Training
- Modify a Protocol
- Templates
- Frequently Asked Questions
- UH eProtocol
- Renew a Protocol
- Policies and Guidance
- Submit a New Protocol
- Closing a Protocol
UH Human Studies Program (HSP)

- Provides free IRB review for UH-affiliates
  ▪ Faculty
  ▪ Students
  ▪ Personnel
  ▪ If you have a UH email, you are a UH-affiliate
UH Human Studies Program (HSP)

- Works together with the UH research community to ensure the health, welfare, rights, and dignity of people who volunteer for UH research.

- A unit within the Office of Research Compliance (ORC) that provides guidance and administrative support to its three UH Institutional Review Boards (IRBs) and the ten UH campuses.
Why all the rules?

• Ethical Violations
  • Research community responded with rules to prevent and reduce harm.
  
• In most cases, researchers had good intentions, but people were hurt.
Examples of Ethical Violations

• Lack of consent or incomplete consent process
• Researchers misrepresented themselves
• People were participants in research without being informed
• Lack of sound scientific design to prevent or minimize risk
• Participants were treated as property of researchers
• Vulnerable populations were targeted
1940s WWII Nazi Human Experimentation (Medical Torture)

Nuremberg Trials

Nuremberg Code

- First concept of consent
- Benefits must outweigh Risks
- Do No Harm
- Researchers must be qualified
- Participants have the right to withdraw
• Havasupai Tribe (~650 members)
• 1989 Arizona State University
• With consent, Type 2 diabetes genetic research - blood samples, finger and hand prints – no correlation
• Without consent, samples used for other research - schizophrenia, inbreeding, and migration patterns, all taboo topics for tribal members
• Migration pattern research particularly troublesome to tribal members because findings contradicted the tribe’s origins teachings, posing a threat to traditional land claims
• None of the results were shared with the participants. Lawsuits were filed and a settlement was reached in 2010 in which tribal members were compensated $700,000, funds for a clinic and school, and samples were returned.
• Syphilis Experimentation at Kalaupapa
  • 1866 – 1969 Forced isolation of Hanson's disease patients. California physician acting as a health care officer injected six girls under the age of 12 with syphilis to learn about the progression of the disease.

• Native Hawaiian Genome Patent
  • 2003 – UH researchers proposed to patent the Native Hawaiian genome for economic and health related benefits to Hawaiian people. Traditional Hawaiian concept of property found this unacceptable. Blocked by the Association of Hawaiian Civic Clubs.
What is Human Subjects Research?

• Will you be collecting data from someone with a heartbeat?
• Will you interact or intervene with them to get the data?
• Will you be looking at pre-existing identifiable data?
Interact or Intervene?

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

*Examples*: Survey, Interview, Focus Group
Interact or Intervene?

**Intervention:** Includes both physical procedures and manipulation of the participant or his or her environment for research purposes.

*Examples:* Biomedical drug or device studies, classroom curriculum research, psychological tests

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 (day, month, year)
- Student I.D. Number
- Address
A “Principal Investigator” (P.I.) 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](#)). The UH determined that for all student-led research (regardless of funding), the Faculty Advisor serves as the Principal Investigator, and the Student as Co-Investigator. The student remains responsible for the design and implementation of the research.
Responsibilities of a Faculty Principal Investigator for Student - Led Research

• Effectively train and mentor student researchers in the ethical conduct of human subjects research
• Serve as the P.I. for insurance and liability reasons for student research
• Review and revise student applications before they are submitted
Responsibilities of a Student Co-Investigator for Student–Led Research

• Conduct the IRB approved research protocol.
• Conduct a Consent and / or Assent Process and Obtain Consent / Assent.
• Obtain IRB approval for any changes, additions, or deletions to the study from the IRB prior to implementation with a Modification Application.
• Store records for 3 years after closure
Responsibilities of both a Faculty Principal Investigator and Student Co-Investigator

• Promptly report all unanticipated problems or injuries to the IRB.
• Follow all procedures for the ethical conduct of human subjects research.
• Respond promptly to all participant concerns and questions.
Responsibilities of both a Faculty Principal Investigator and Student Co-Investigator

• Maintain participant privacy and confidentiality.
• Inform participants if risks or benefits of study change.
• Maintain cultural sensitivity.
• Design research methodology appropriate to the research setting.
How will the data be used?

IRB Approval is Required *Prior to* Conducting Research for…

- Dissertations
- Theses
- Funded Research
- Public dissemination of results (publishing or presenting)
Research involving living human beings **CANNOT** begin without prior UH IRB approval.

- Decisions cannot be overruled.

When in doubt, ask.

Apply *before* conducting research!
Scope of UH IRB Authority – What happens when research is conducted without approval?

- Suspend or terminate the enrollment or ongoing involvement of research participants.
- Data can be seized and destroyed.
- Research funds are not released until IRB approval is given.
Scope of UH IRB Authority – What happens when research is conducted without approval?

Student Researchers
- Graduation halted or delayed
  - The Graduate Division office checks for IRB approval before approving graduation.
  - Restart the research from the beginning, after IRB approval.
How will the data be used?

IRB Approval is NOT Required for…

- Term Papers / Class projects for a class grade
  - Once the grades are turned in, the project is finished.
- Publicly Available Data (online, library, census data)
- De-identified data
How will the data be used?

IRB Approval is NOT Required for...

- Internal Evaluations / Quality Assurance
  - When the intention is to evaluate a program and only report back to that program.

*Internal Evaluation data can become Human Subjects Research Data through IRB approval after the fact. Exempt category 4 when no identifiers are noted.
How to Submit an Application

1. Complete the required CITI training. Everyone listed on the Personnel page of the application will need to submit the required CITI training.

https://www.citiprogram.org
How to Submit an Application

2. Fill out and submit the eProtocol application.

https://uhmanoa.keyusa.net/
How to Submit an Application

1. Complete the CITI training first.
   
   https://www.citiprogram.org

2. Then fill out the eProtocol application. That way, the CITI training will be reported on the Personnel page of the eProtocol application.
   
   https://uhmanoa.keyusa.net/
How to Submit an Application - CITI

Collaborative Institutional Training Initiative

- Choose “Log in Through My Institution”
- Use your UH username and password

Required Training Under “Add a Course”
1. Question 3 Human Subjects Research
2. Question 5 Information Privacy and Security (IPS)
How to Submit an Application - CITI

To Do:
Upload 2 CITI certificates of completion for each person (#3 and #5) to the Attachments page of the eProtocol application.

* Applications missing CITI certificates of completion or statement of completion on the Personnel page will be returned.
How to Submit an Application - eProtocol

- Getting Started
  www.hawaii.edu/researchcompliance/irb-eprotocol

1. Video Tutorials
2. Investigator’s Users Manual

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

*Must have UH username and password to log on*
How to Submit an Application - eProtocol

1. Choose “Create Protocol”
   • Your eProtocol application form will be created and an eProtocol number will be generated.
   • You may continue to complete the application, or you may exit the system and return at a later time to complete it.
   • You must click the “Save” icon to save your work before exiting.
How to Submit an Application - eProtocol

What to upload: The IRB must review everything the participant will see or experience.

Examples:
- Consent form / Assent form / Parent Consent form
- Debriefing form (deception research)
- Survey / Interview / Focus Group Questions / Other Instruments
- Recruitment Materials (flyer, script, email)
- Translated documents (if participants do not speak English)
How to Submit an Application - Templates

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

* Consent form template REQUIRED starting January, 2019
  • Use the template for your consent form / assent form / parent consent form / debriefing form
  • Use an active voice
  • The language and reading level should be 6th grade
What do Student Researchers need to communicate to their Faculty Principal Investigators (P.I.)?

1. Verify CITI training is complete and current.
2. Once the eProtocol application has been filled out by the student, let the Faculty P.I. know.
3. The Faculty P.I. is expected to log in, review the application, and fill out the “Obligations” page before final submission.
Submitting a Modification Application

• Once the application has been approved, a modification application can be submitted in eProtocol.
• A Modification Application is used for any substantive change.
• Turn around time is typically shorter than the initial application.
• In eProtocol, click on application number, choose the Modification Application from the drop down menu.
When a Survey is Online…

• Make the consent form the first page of the survey.
• Use the consent form template for online surveys.
When Audio or Video Recording...

**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
When Audio or Video Recording…

- Must specifically describe why in the consent form.
- 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 recording/photo in the future.
Levels of Review
Based on Potential Risk to the Participant
- Exempt
- Expedited
- Convened / Full

Expedited and Full are also referred to as “Non-Exempt.”

* Not Human Subjects Research – not requiring IRB approval
Levels of Review - Exempt

• Does require IRB review and approval.
• Level of potential risk “same as every day life.”
• Certain categories of research may qualify for a determination that the study is *Exempt* from review by the IRB.
• Approval continues until project closure, no annual review.
Levels of Review - Exempt

*Examples:*

**Category 1** – Research in commonly accepted educational settings involving normal educational practices.

**Category 2** – Interaction - Research involving surveys, interviews, focus groups, public observation. Adult participants only.

**Category 3** – Benign behavioral interventions (Pre/Post)

**Category 4** – Secondary data analysis, no consent required. No identifiers recorded in results. Retrospective or prospective.
Levels of Review - Expedited

*Expedited* does *not* mean that the review happens more quickly than convened review.

- Level of potential risk “no more than minimal.”
- Must fall into one of the expedited review categories.
- If deemed appropriate, no annual review required.
Levels of Review – Convened / Full

• The research does not qualify for Exempt or Expedited review.

• The research involves vulnerable or potentially vulnerable populations and / or high risk research focus.
IRB Committees

3 Institutional Review Board (IRB) committees within the UH HSP:

- Biomedical Sciences IRB
- Social and Behavioral Sciences IRB
- Cooperative IRB

Applications are assigned to the appropriate committee for review depending upon the research focus and Cooperative agreement.
Levels of Review – Convened / Full

- Vulnerable populations
- Pregnant Women
- Prisoners
- Children (17 years of age and younger)
- Mentally disabled persons
- Economically or educationally disadvantaged persons
- The IRB may also require additional protections for any other group.
Not Human Subjects Research

Examples:

• Scholarly and journalistic activities
  • Oral history
  • Journalism
  • Biography
  • Literary Criticism
  • Legal Research
  • Historical Scholarship
Not Human Subjects Research

Examples:

• Public Health Surveillance Activities

• Collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.
Not Human Subjects Research

Examples:

• Public Health Surveillance Activities

• Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products).
Not Human Subjects Research

**Examples:**

• Public Health Surveillance Activities

• Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or human-made disasters).
Not Human Subjects Research

**Examples:**

- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for **criminal justice** or criminal investigative purposes.

- Authorized **operational activities** in support of intelligence, homeland security, defense, or other national security missions.
How long will it take for my approval?

Review time largely depends upon the quality of the application. Submit a well-written and complete application, and turn around time can be quicker.

Exempt

• Two to three weeks
• Continuous acceptance and review
• Reviewed in office
How long will it take for my approval?

Expedited
- Three to four weeks.
- Continuous acceptance and review.
- Reviewed in office, then sent to an IRB reviewer.
How long will it take for my approval?

Full

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

- Office of Human Research Protections (OHRP)
- Food and Drug Administration (FDA)
- State of Hawai‘i
- University of Hawai‘i
- The Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) – Provides accreditation
On June 14, 2017, UH System was accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) as a top research institution that follows rigorous standards for ethics, quality and protections while conducting human research.

The first research organization in Hawai‘i to be awarded this highly regarded status.

Demonstrates to potential collaborators and sponsors in the competitive global research arena that UH has built extensive safeguards into every level of research operations.
Get approval *before* starting a research project.

Questions? Please ask!

Mahalo Piha!
References


