



Human Studies Program
Office of Research Compliance
Vice Chancellor for Research and Graduate Education

Submitting your SLS Research to the UH IRB: Helpful Tips to Getting it Right the First Time

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Where do I start...



Do I need IRB approval before conducting my research project?

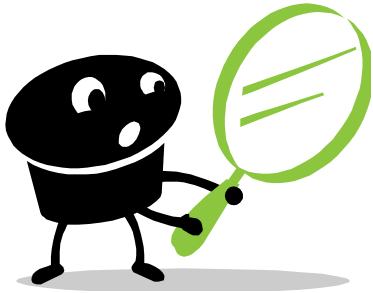
Criteria:

Is It Research?

Is It Human Subjects Research?



Human Studies Program



What is research?

Is it a systematic investigation?

Quantitative Research	Qualitative Research
Objectives Hypothesis Pre- / Post-test Variables Data collected	Research question(s) Theory generating Survey questions / Interviews Identifying patterns



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

- ▶ Project to evaluate a particular program that teaches cultural sensitivity to teachers in a middle school that includes a diverse student population.

Not research, 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.

Not research, as long as the findings from that evaluation stays within the university



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 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



Is this human subjects research?



Does your project involve only the analysis of publicly available data?

- If Yes, no need to apply
- Even if your project does not need an IRB approval, you will need a letter from HSP verifying that your project does not meet the definition of “Human Subjects Research” (per Office of Graduate Education requirement)
- **To get this letter, you will need to still submit your project to the Human Studies Program for verification.**



Exempt vs. 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**



Exempt Categories:

#1 Research conducted in established or commonly accepted education setting, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Ex.: New curricula taught in the classroom by teacher-researcher



Exempt Categories:

#2 Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

- Information obtained is recorded in such a manner that subjects can be identified AND
- any disclosure of the subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Ex.:

Comparing test scores of two classes, one that completed a traditional curricula and the other a new curricula to see if the new curricula improved retention of a new language.

Surveying or interviewing students about the number of languages they understand or speak currently, what consider as their primary language, what language they speak at home with parents/ friends.



Exempt Categories:

#3 Research involving the use of educational tests

(cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, that is not exempt under category #2 if:

- the subjects are **elected or appointed public officials or candidates** for public office;
OR
- federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.



Exempt Categories:

#4 Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Ex.: Use of de-identified data from a previous research that has been closed and stripped of all identifiers.



Exempt Categories:

Categories #5 and #6 pertain to public benefit or service programs and taste and food quality testing, respectively.



UH IRB Model Consent Forms

<https://manoa.hawaii.edu/researchcompliance/resources>

- ▶ 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



Video and Photos

▶ Pre:

- Need permission in consent
- Separate language
- In what setting? If public, then no need to consent.
- What is the purpose?

▶ During:

- How will they be kept?
- Will they be reviewed prior to publication or analysis?

▶ Post:

- When will they be destroyed?
- Will they be used for future studies? Educational materials?
May need additional consent.



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 a study information 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



What are assents?

- ▶ Age appropriate reading level
 - 13-17 (written)
 - 7-12 (written)
 - Under 7 (oral)
- ▶ Like oral consent, need to have a “consent script”
- ▶ Need to use with parental consent
 - If parents consent, does the child need to participate?



Consent for English-speaking participants who cannot read

- ▶ Short Form with written summary/ script
 - Short form states that required consent form elements have been presented orally
 - Participant signs short form
 - Witness signs both short form and copy of written summary
 - Person obtaining consent signs copy of written summary
 - Copy given to participant

Second language: short form and presentation should be in same language as participant; witness should be fluent in both English and second language



Culturally-relevant approaches to obtaining consent

- ▶ U.S. vs. Mediterranean/ Spanish/ Arabic
 - Dialogue
 - Brief
- ▶ Who is obtaining consent?
 - Status of consenter
- ▶ Community consent vs. individual consent
 - Community leader as proxy for individuals belonging to that community
 - Family (spouse) vs. individual
- ▶ Differing definition of adult vs. child
 - Rites of passage, lifestages (Samoan, Tongan)



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



Deception Studies

IRB frowns upon the use of any deception on participants in a research project

BUT

Some studies may require such a design

- ▶ For studies that involve DECEPTION must include a debriefing process that includes a debriefing form.

- ▶ Debriefing form:
 - Explains true purpose of study
 - Discusses what part of the research was the deception
 - Why deception was necessary
 - Request permission whether participant consents to the participation of the research after knowing the true purpose of the project



Debriefing Process

- ▶ Time:
 - Consider length of time participant is deceived to when he/she is debriefed
- ▶ Design:
 - How are participants debriefed? As a group, or one-on-one? In a private setting or as a presentation?
- ▶ Maintaining confidentiality of the true purpose of the study:
 - If individuals are participating at different times, what research methods assure that earlier participants will not leak out the true intent to participants who are just entering into the research?



What is PII?

- ▶ **Personally Identifiable Information (PII):** If a research plans to collect PII, there needs to be a justification for this.
 - Name
 - Date of birth
 - Telephone number
 - Home address
 - Email address
 - Social Security Number
 - Fingerprint
 - Driver's License Number
 - Login Name
 - Handwriting
- ▶ **Beware!**
 - General information such as gender, salary, zip code of residency can be used in combination to identify an individual.
 - Audio and video recordings of individuals can also be used as identifiers.



Name use in research publications

- ▶ Why?
 - Give credit or memorialize individual or community
- ▶ Possible implications for revealing names
 - May not be a foreseeable risk at the time or place
 - How it may be shared and taken out of context
 - PI's responsibility to balance pro vs. con
- ▶ Solution
 - Semi-Pseudonym (HeLa cells), but beware



How do you store PII?

- ▶ Coding: Use a master list and store consents away from master list and data.
- ▶ Encryptions
- ▶ Use locks, passwords
- ▶ Transporting data: keep PII separate from data
- ▶ Shred PII data with documentation and witness
- ▶ Share data in a private space



Completing the Application

- ▶ Submit a complete application (<https://manoa.hawaii.edu/researchcompliance/submit-new-protocol>) that includes your **CITI training, consents, recruitment materials** and **survey questions/ interview questions**.
- ▶ Make sure both student PI and Faculty Advisor (FA) signs the application and include their CITI training certificates to the application packet
- ▶ Answer the application questions thoroughly and effectively.
 - Even though we don't want your grant application or your thesis, we are not experts in your field



Resources

The new Human Studies Program website:

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

Is my project not human subjects research, exempt or non-exempt?

<http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html>

The old Human Studies Program website:

<http://www.hawaii.edu/irb/>

▶ FAQs



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