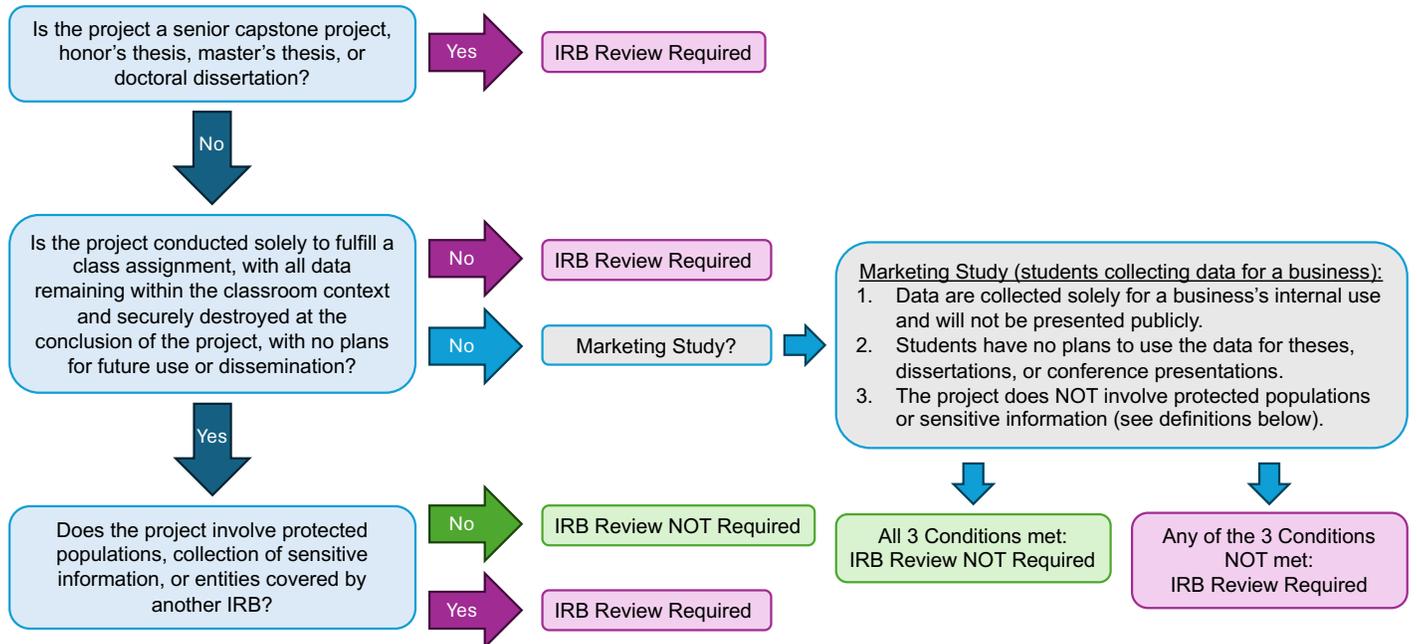


## Research with Human Subjects

Flowchart for Guidance on Whether a Class Project Requires IRB Review



## Quick Reference Table: When IRB Review is Required

**NOTE:** Refer to the [CUH IRB Charter, Appendix 1: Class Projects](#) for full guidance.

Scenario	Example	IRB Review Level
<b>Exempt</b>	Anonymous classroom survey on study habits with adult students only	<b>No IRB review required</b> if all Appendix 1 criteria are met
<b>Expedited</b>	Survey on mental health stressors among adult students (no protected populations, identifiable data collected)	<b>Expedited review</b> required
<b>Full Board</b>	Interviewing minors about nutrition habits or surveying individuals with cognitive impairments	<b>Full board review</b> required
<b>Sensitive Information</b>	Collecting data on illegal drug use, sexual behavior, or mental health history	<b>Expedited or full board</b> , depending on level of risk
<b>External Dissemination</b>	Project designed for publication, conference presentation, or future research use	<b>Expedited or full board</b> , depending on study design
<b>Protected Populations</b>	Research with minors, prisoners, or pregnant individuals	<b>Full board review</b> required

# Chaminade University of Honolulu IRB Guidance

## Protected Populations, Sensitive Information, and Class Projects

### Introduction

Chaminade University recognizes that some student class projects involve activities like research but are solely for educational purposes and not intended to produce generalizable knowledge.

Under the Common Rule (45 CFR 46.102(l)), research is defined as:

“A systematic investigation... designed to develop or contribute to generalizable knowledge.”

Projects conducted only to fulfill course requirements and not designed for publication or dissemination outside the classroom are generally not considered human subjects research and do not require IRB review.

However, classroom activities involving human participants can still pose risks to privacy, confidentiality, or well-being, requiring faculty oversight and, in some cases, IRB review.

### 1. Protected Populations

Research involving protected populations is subject to additional federal safeguards (45 CFR 46, Subparts B, C, and D). Projects with these populations require IRB review and generally cannot be classified as classroom assignments.

Examples include, but are not limited to:

- Children/Minors (under age 18)
  - *Exception:* Normal educational practices in established educational settings may qualify for exemption. Contact the IRB Office for guidance.
- Prisoners, including non-publicly available secondary data
- Pregnant Individuals
- Fetuses and Neonates
- Individuals with Impaired Decision-Making Capacity (e.g., cognitive impairment, mental disability)
- Mentally or Physically Challenged Individuals
  - **Note:** Projects involving these populations nearly always require full board review.

### 2. Sensitive Information

Even when participants are not from protected populations, research may require IRB review if it involves the collection of sensitive information, which could increase the risk of harm if disclosed.

Examples include, but are not limited to:

- Psychological well-being or mental health
- Sexual attitudes, preferences, or practices
- Alcohol or drug use
- Illegal behavior

- Financial status or employability
- Information that, if disclosed, could result in:
  - Criminal or civil liability
  - Loss of reputation
  - Stigmatization or discrimination
- Medical information typically recorded in a patient's medical record

### **3. Other Situations Requiring Special Consideration**

Some projects may fall under the jurisdiction of another IRB or require community-level review, including:

- Military installations or federal agency research
- Collaborative research with hospitals or health systems
- Projects involving Native Hawaiian, Pacific Islander, or other Indigenous communities, which may require community consultation or tribal IRB approval
- Inter-institutional collaborations, where CUH may defer review to another IRB

Faculty and students should contact the CUH IRB Chair early to determine if additional approvals are necessary.

#### **Contact Information**

For questions or guidance, please contact:

**CUH IRB Chair (Dr. Joy Tanji)**

**Email:** [irb@chaminade.edu](mailto:irb@chaminade.edu)

**Phone:** (808) 739-7428