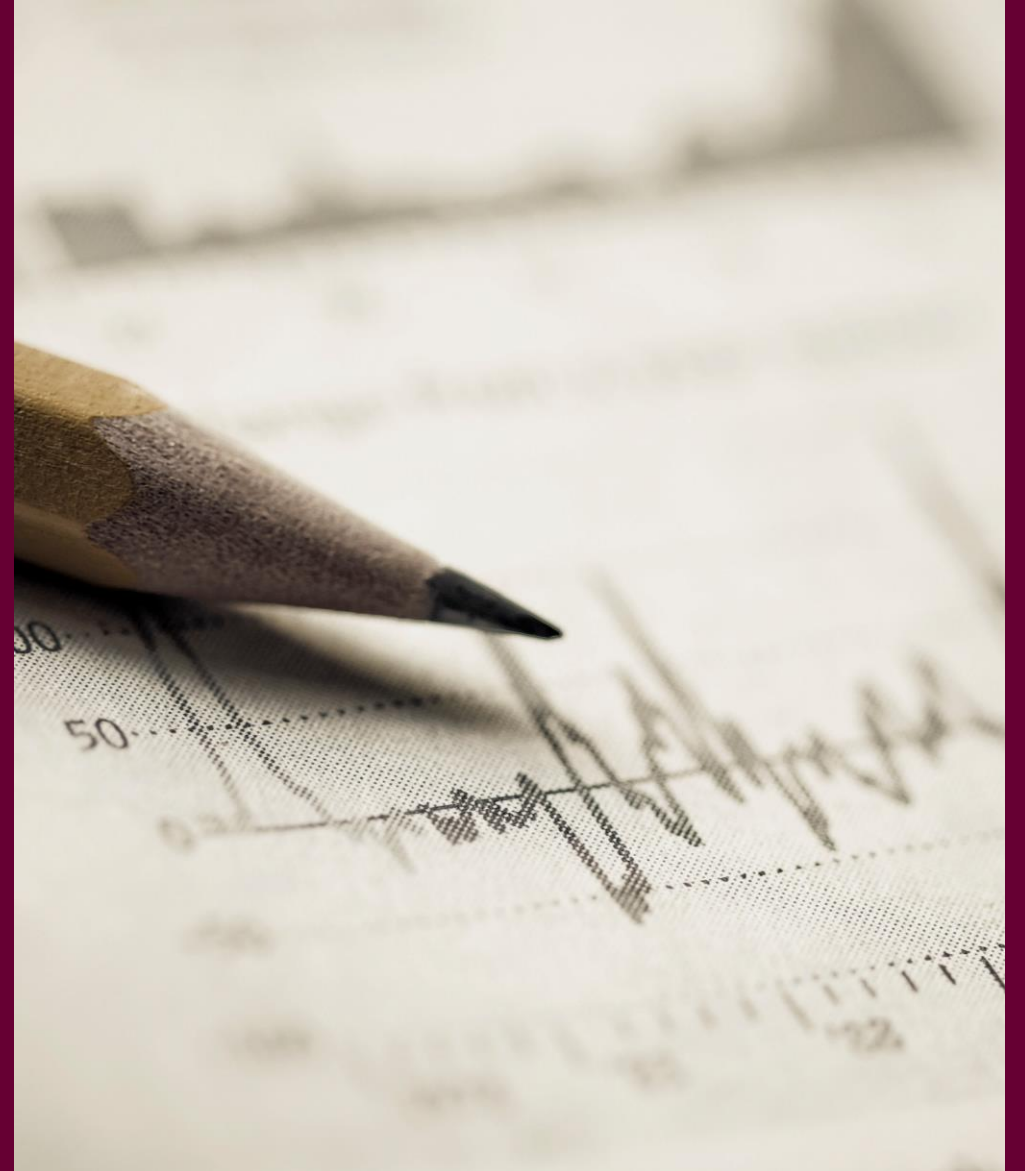


UNDERSTANDING THE IRB: APPLICATION PROCESS AND REQUIREMENTS FOR GRADUATE STUDENT RESEARCH

AGENDA

- Purpose and mission of the IRB
- What constitutes human subjects research
- When IRB review is required
- Categories of IRB review
- The application process step-by-step
- Common challenges and solutions



WHAT IS AN IRB?

- Institutional Review Board
- Federally mandated committee (45 CFR 46)
- Reviews and approves research involving human subjects
- Mission: Protect the rights, safety, and welfare of research participants
- Ensures ethical conduct of research

RESPONSIBILITY OF AN IRB

- Review and Approval - new projects
- Modifications for Approval - active approved projects
- Disapproval of human subjects research projects if they do not meet the federal regulations

In applying for approval of your project, written protocols are provided to the IRB via the electronic application system **IRB Manager**.

HISTORICAL CONTEXT

Key Events in Research Ethics:

- Nuremberg Code (1947)
- Tuskegee Syphilis Study (1932-1972)
- Belmont Report (1979)
- Common Rule (1991, revised 2018)

The U.S. Department of Health and Human Services (HHS), specifically through the Office for Human Research Protections (OHRP), oversees and enforces the Common Rule (45 CFR 46)

THE THREE ETHICAL PRINCIPLES (BELMONT REPORT)

1. Respect for Persons

- Autonomy and informed consent
- Protection of vulnerable populations

2. Beneficence

- Minimize risks, maximize benefits
- Do no harm

3. Justice

- Fair distribution of research burdens and benefits
- Equitable selection of participants

WHAT IS HUMAN SUBJECTS RESEARCH?

1. Research: a systematic investigation, designed to develop or contribute to *generalizable knowledge*

2. Human Subject: Living individual about whom an investigator obtains:

- Data through intervention or interaction, OR
- Identifiable private information

**Both criteria must be met for IRB review*

DOES YOUR PROJECT NEED IRB REVIEW?

YES: IRB Review Required

- Surveys or interviews for thesis/dissertation research
- Experiments with human participants
- Analysis of identifiable private data
- Classroom research intended for publication

DOES YOUR PROJECT NEED IRB REVIEW?

NO: IRB Review NOT Required

- Quality improvement projects (may need IRB confirmation)
- Classroom activities for educational purposes only
- Analysis of publicly available, de-identified data
- Literature reviews

**When in doubt, contact the IRB!*

IRB Reviews.

CATEGORIES OF IRB REVIEW

Three Review Levels:

- **1. Exempt** - Minimal risk research in specific categories
- **2. Expedited** - Minimal risk research using approved procedures
- **3. Full Board** - Greater than minimal risk; requires committee review

**Category determines timeline and requirements*

EXEMPT RESEARCH

Common Exempt Categories for Graduate Students:

- Educational tests, surveys, interviews (with conditions)
- Benign behavioral interventions with adults
- Secondary research with de-identified data
- Public benefit or service program evaluation

Review Time: 2 weeks (+/-)

EXPEDITED REVIEW

Common Expedited Categories:

- Survey, interview, focus group research (non-exempt)
- Minimal risk studies of individual or group behavior
- Collection of data from voice, video, and digital recordings
- Research on existing data/documents/records

Review Time: 3-4 weeks

FULL BOARD REVIEW

When Required:

- Research involving more than minimal risk
- Research with vulnerable populations (prisoners, pregnant women)
- Medical/clinical interventions
- Sensitive topics with identifiable data

Review Time: 4-6 weeks + (monthly committee meetings)

Before you apply.

ESSENTIAL PREPARATION

Required Steps:

- Complete CITI Training (Human Subjects Research - Social & Behavioral Research track)
- Develop your research plan - know your methods
- Discuss with advisor - ensure alignment
- Gather all materials - instruments, consent forms, recruitment materials

CITI TRAINING REQUIREMENT

- Completion required BEFORE submission
- Social & Behavioral Research modules (for most grad students)
- Valid for 3 years
- The certificate must be uploaded with application
- Free access through CMU portal

<https://about.citiprogram.org/>

CITI Training



Initial training takes about 3-4 hours to complete.

The IRB application.

KEY ELEMENTS OF THE IRB APPLICATION

All applications require:

- Research plan/protocol summary
- Participant population description
- Recruitment methods
- Data collection procedures
- Risk assessment and mitigation

KEY ELEMENTS OF THE IRB APPLICATION

All applications require:

- Confidentiality/privacy protections
- Informed consent process and documents

DESCRIBING YOUR PARTICIPANTS

Include:

- Number of participants (and justification)
- Age range and demographics
- Inclusion/exclusion criteria
- Special populations (if any)
- Why this population is appropriate

***Vulnerable Populations:** Children, prisoners, pregnant women, and cognitively impaired - require additional protections*

RECRUITMENT PROCEDURES

Describe:

- How you'll identify potential participants
- Initial contact method (email, flyer, announcement)
- What you'll say in recruitment materials
- Relationship between researcher and participants
- Compensation (if offered)

***Must Attach: All FINAL recruitment materials
(emails, scripts, flyers, etc.)***

INFORMED CONSENT

Consent Must Include:

- Study purpose and procedures
- Duration of participation
- Reasonably foreseeable risks
- Benefits (if any)
- Confidentiality protections
- Voluntary nature and right to withdraw
- Contact information for questions

INFORMED CONSENT

Exempt Research (only):

- Study Overview
- Voluntary nature and right to withdraw
- Contact information for questions
- Expressed Consent
 - *Check box*
 - *Completion of the Survey*

Consent Form



Adult Consent Form Template Language

Identifying the risks.

LEVELS OF RISK

- The level of risk of a study determines the actions of the IRB. Most studies are low risk, such as those a participant would encounter in daily life. These studies are often Exempt, but may be Expedited.
- Studies that have an increased risk (more than daily life) are either expedited or full board review, based on the type of study and risks associated.

MINIMIZING RISK

- Use anonymous or de-identified data when possible
- Secure data storage (password-protected, encrypted)
- Limit access to identifiable information
- Aggregate data in reporting
- Provide referral resources for sensitive topics
- Plan for handling distressed participants

PARTICIPANT SAFETY

- This refers to the manner in which you are protecting the anonymity of the individuals.
- “*Anonymous*” data means that identifiers were never collected or part of the data (i.e., an anonymous survey).
- “*De-identified*” data are data that had identifiers, but the identifiers were removed at some point in the research process.

DATA CONFIDENTIALITY

Data Management and Storage

- Computers, technology, and storage (i.e., locked cabinet, encrypted drive, CMU OneDrive, Qualtrics)
- Who has access to identifiable data
- How long data will be retained (minimum 3 years)
- Data destruction plan
- If data will be shared or used for future research

Data Stewardship



Please review CMU's Data Stewardship Policy.

IT Review & Support



Request an IT Review through the CMU Helpdesk Ticket System

SPECIAL CONSIDERATIONS

Common for Graduate Student Research

- Surveys and questionnaires (attach instruments)
- Interviews (attach interview guide/questions)
- Audio/video recording (describe and get permission)
- Online data collection (privacy considerations)
- International research (additional requirements)

Submitting an IRB application.

THE APPLICATION PROCESS

Step-by-Step:

- Complete CITI training
- Complete application form
- Upload all supporting documents
- Faculty advisor review and approval
- Sign and Submit to IRB (advisor)
- IRB administrative review (completeness check)
- IRB substantive review
- Receive determination

IRB



Manager

CMU account access is required

What do you want to focus on?

IACUC

IBC



IRB



Show Everything



You have 0 reviews pending.

My Reviews (0 Open)

Type	Assigned	Due	Review	Item
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Projects (14 Active)

- You are associated with **14 active** Projects and **37 total** Projects.
- You are the PI for **14 active** and **34 total** Projects.
- You are the Co-Investigator for **2 active** and **2 total** Projects.
- You are the Faculty Advisor for **6 active** and **12 total** Projects.
- You are the IRBNet-FULL for **0 active** and **8 total** Projects.
- Committee CMU IRB has **694 active** and **4101 total** Projects.
- Committee CMU IRB #2 has **28 active** and **1492 total** Projects.
- Committee NHSR Reviewers has **0 active** and **0 total** Projects.

xForms (11 Active)

Actions

[Reviewer](#)

[Reviewer Open Events](#)

[Completed Reviews Agendas & Minutes Search Projects](#)

[xForms](#)

[Start xForm](#)

[Show Sponsor Ids](#)

Recent Items

[2026-162-Mt. P](#)

[2025-831-Mt. P](#)

[2026-173-Mt. P](#)

WHICH APPLICATION?

- Does my Project Need IRB Review?

If you think that your project does not need IRB, but need a determination for Graduate Studies, or are unsure












- Exempt

For the majority of projects that are minimal risk

- Expedited/Full

If your project is greater than minimal risk, has protected populations, or is uniquely complex

Select xForm to start

Action	Form (Click to start)	Description
	IRB\CHM\CHM Pediatric Exempt IRB Application to Conduct Research Involving Human Subjects	Pediatric Research Exempt Application
	IRB\CHM\CHM Pediatric IRB Active Study Transfers Application - Clinical Investigation Oversight at CMU	Active Study Transfer Application (CHM Application to Transfer Clinical Investigation Oversight to CMU)
	IRB\CHM\CHM Pediatric IRB Application for Reliance on External IRB	Only use for research where CMU will cede oversight to an external IRB.
	IRB\CHM\CHM Pediatric IRB Application to Conduct Research Involving Human Subjects	Use this form for research to be conducted at Children's Hospital of Michigan that is more than minimal risk or that does not fall into an exempt category that involves human subjects.
 	IRB\IRB Does My Project Need IRB Review?	Use this form if you are unsure whether your project requires IRB review.
	IRB\MP\Mount Pleasant Campus IRB Application for Reliance on External IRB	Only use for research where CMU will cede oversight to an external IRB.
 	IRB\MP\Mount Pleasant Campus IRB Application to Conduct Exempt Research Involving Human Subjects	Exempt Application
 	IRB\MP\Mount Pleasant Campus IRB Application to Conduct Research Involving Human Subjects	Use for proposed research eligible for expedited review or that must be reviewed at a convened meeting.

THE APPLICATION PROCESS

Considerations:

- Faculty advisors are the Principal Investigator (PI) on all CMU student research projects.
- The advisor signs and submits the application once completed.
- If the administrator or reviewers have questions, they will send the investigators “stipulations”

SUPPORTING DOCUMENTS

Typically Required:

- CITI certificate
- Consent form(s)
- Recruitment materials
- Survey instruments or interview guides
- Permission letters (if accessing organizations)
- DUA - Data Use Agreements (if using existing data)

POSSIBLE IRB DETERMINATIONS

Exempt Applications:

Stipulations – Application requires additional information or corrections

NHSR – Not Human Subjects Research

Not Research- Typical for QI projects

Exempt Determination – May proceed with your research as presented

POSSIBLE IRB DETERMINATIONS

Expedited and Full Reviews:

Approved - You may begin research

Approved with modifications - Minor changes required

Tabled - More information needed; substantial revisions

Disapproved - Rarely happens; significant concerns

STIPULATIONS & REVISIONS

Stipulations should be responded to in two ways:

1. Correct or address any areas within the application (make the changes directly)
2. Include a Word or PDF **Response Memo** of all responses and changes per the stipulations.

STIPULATIONS & REVISIONS

Common Reasons for Revisions

- Unclear or incomplete descriptions
- Consent form missing required elements
- Insufficient detail
- Recruitment methods not clearly described
- Data security plan is inadequate
- Missing attachments or documentation

After IRB determination.

YOUR RESPONSIBILITIES

You MUST:

- Follow approved protocol exactly
- Use only approved consent forms and materials
- Report any protocol changes (amendment request)
- Report unanticipated problems or adverse events
- Complete continuing review (if study >1 year)
- Submit closure report when complete

MODIFICATIONS DURING RESEARCH

- Participant population or recruitment
- Data collection procedures or instruments
- Consent process or form
- Study personnel
- Risk level

Submit amendment requests through IRB Manager

RED FLAGS: WHAT NOT TO DO

- ✘ Collect data before receiving IRB approval
- ✘ Change procedures without approval
- ✘ Use outdated or unapproved consent forms
- ✘ Coerce participation (grades, employment)
- ✘ Fail to report problems to IRB
- ✘ Promise absolute confidentiality (mandatory reporting exceptions)

TIPS FOR SUCCESS

- ✓ Start early - build in time for revisions
- ✓ Use plain language - write for non-experts
- ✓ Be consistent across all documents
- ✓ Include ALL required attachments
- ✓ Follow consent form template
- ✓ Describe risks honestly and mitigation thoroughly
- ✓ Proofread before submission
- ✓ Respond promptly to IRB requests

Resources.

KEY DOCUMENTS AND SUPPORT

1. [Mt. Pleasant IRB](#)
2. [IRB Documents and Resources](#)
3. [IRB Policies, SOPs and Supplemental Documents](#)
4. [CITI Links and Information](#)
5. [IRB Manager Login](#)
6. [Adult Consent Form](#)
7. [CMU Data Stewardship Policy](#)
8. [CMU IT Research Review](#)

CMU MT. PLEASANT IRB OFFICE

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