IRB Training
Human Subjects Protection Program and Cayuse IRB

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Objectives

- What is the Institutional Review Board (IRB) responsible for? And why?
- What is Human subjects research?
- What do we look for when reviewing a protocol?
  - Document requirements for submission
  - Approval designations: Full, Expedited, Exempt
- Using Cayuse electronic system
So Why Bother...

- Primary objective is to protect human participants
- Bound by law (45 CFR Part 46) under our FWA Federal Wide assurance
- Thus, we report to U.S. Department of Health & Human Services; Office of Human Research Protection (OHRP)
- OHRP will take corrective actions for non-compliance
  - Including stopping all research projects related or unrelated to the study in question
IRB Mission

- to support faculty, staff, students to complete their research in compliance with federal and state laws and MSU policy. As such, the IRB is charged to review, approve initiation of, and conduct periodic reviews of research projects that involve human participants.
IRB BOARD

- 12 Faculty/Staff and 1 community member
Definition of human subjects research

- **Human subject** means a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

- **Research** is defined as a systematic investigation that is hypothesis driven with the intent to develop knowledge that can be generalized.
Human Subjects research (HSR)?

- Student conducting an interview of a school counselor for a research paper in class only
  - NOT HSR! – Classroom experience
  - Student may still want to consider a consent form and privacy issues

- Student conducting interviews that are answering a research question. Interview includes pre-determined questions on counselor’s personal opinions and this project will continue interviews with more subjects. The student thinks they might want to share this at the next student symposium.
  - YES HSR!
Human Subjects research (HSR)?

- An MSU Center is conducting surveys after their workshops. Workshops are a free service offered to clients. Purpose is solely to improve future programming.

  NOT HSR! – Quality Improvement/Assurance Center may still want to consider a consent form and privacy issues.

- MSU Children’s Center conducting surveys after workshops and would like to present program as a model to other Centers on how to provide a particular service to parents.

  YES Program Evaluation can be HSR too!
IRB REVIEW PROCEDURES and categories
General themes involved in the IRB review (45 CFR 46.111)

- how participants are recruited to be in the study
- how the privacy of participants will be protected
- the physical, psychological, and sociological risks to participants
- any discomfort and stress to participants
- benefits outweigh the risks
- consent process (45 CFR 46.116)
  - accurately reflect the study
  - Consent form written in simple lay language
  - appropriate to the participant pool (language)
Three categories (45 CFR 46.109)

- Exempt
- Expedited
- Full Board – MORE than minimal risk
Criteria for Exempt

- Research activities that
  - (1) present **no more than minimal risk** to human subjects and
  - (2) involve only procedures listed in one or more of the government categories (1-6)
- Example: data analysis with existing data set
- Example: regular classroom activity where results are now intended for research

**Exempt Review** - Goal: Two to three weeks
Criteria for Expedited Research activities that

(1) present no more than minimal risk to human subjects and
(2) involve only procedures listed in one or more of the government categories (1-9)

At MSU

Expedited: Collection of data through non-invasive procedures (e.g., weight)

Most research on individual or group characteristics or behavior (including motivation, identity, social behavior, cultural beliefs) and research using survey, interview, focus group, program evaluation

Expedited Review - Goal: Three to five weeks
Criteria for Full Board

- Research activities that present greater than minimal risk to human subjects
- Triggers
  - Population involves persons with cognitive disabilities
  - Any disclosure of illegal activities, sexual attitudes, genetics, religious beliefs, mental health that could place participants at risk of criminal or civil liability, be damaging to the participants' financial standing, employability, insurability, reputation, or be stigmatizing
    - Depression and mental health disorders
    - Violent crimes
    - Opinion about employer
  - Coercion; Deception or incomplete disclosure
  - Pregnant women
  - Medically invasive, e.g., clinical trial
- **Full Review** - Goal: Four to six weeks (can be longer depending on IRB meeting schedule and PI response time)
Proper Informed consent

- Template available online only to be used as outline
  - Remove any instructions including the audio and video request on consent form if you are not audio or video recording
  - Keep the tense the same throughout
    - Either “you” or “participant”
    - Do not use previous or outdated consent forms for your study
- The consent should clearly and succinctly tell people what your study is about; including any screening procedures
- Readability level
  - Adults – 6th-8th grade reading level for general public
  - Informed consent translations if population is predominantly non-English speakers
- Ask for help!
Dealing with risk and disclosure

- TOPICS: mental health, violent attacks
  - Counseling and Psychological Services (CAPS)
  - Other counseling services

- Referrals
  - Health Care Provider
  - Therapist
Clarify Recruitment

- Templates available on MSU website
  - MSU logo should be on all your recruitment material
  - Identify yourself on the flyer/recruitment “I am an MSU student in the Center for Audiology”

- Screening in recruitment
  - Justify inclusion or exclusion criteria in screening
  - Describe all screening procedures in application
  - Only minimal screening can be done at initial interaction
    - E.g. male under age 40
  - All other screening must be part of your consent process
    - E.g. mental health screening
Instrument Design for Surveys

- Online
  - MSU IRB does not require use of one survey tool
  - Survey tools open to Faculty and Students
    - MSU limesurvey [https://oit-app2.montclair.edu/msusurvey/admin/admin.php](https://oit-app2.montclair.edu/msusurvey/admin/admin.php)
      - Data stored in-house; similar features to survey monkey
      - Qualtrics
  - Other survey tools:
    - The Survey Monkey, SoGoSurvey, SurveyGizmo, Google Forms
  - Paper survey layout and design is up to the researcher
Be consistent

- Confidential vs. anonymous
  - Only anonymous if researcher and others cannot identify the participant (i.e. online survey)
- Participation time should be the same in application and in your consent form
- Use of data in the future
  - If you ask for permission to use data in future studies then include this on the consent
- Compensation
  - Compensation noted in the application should be noted in the consent form
OVERALL STEPS

**Researcher**

1. Researcher develops protocol and research plan
2. Researcher completes online Human Subjects training course (CITI)
3. Researcher starts and completes IRB submission on Cayuse
4. Analyst Pre-review
5. Committee / Committee member review and category assignment (timeline anywhere from 3-7 weeks)
6. Decision received electronically through Montclair.edu email

**Student Researcher**

1a) Student reviews research protocol with faculty sponsor
2a) Student & Faculty Sponsor completes online Human Subjects training course
2b) Student requests Cayuse IRB account
3a) Student opens New Study in Cayuse and adds “SS” to title of study.
3b) designates Faculty Sponsor as PI for study, and themselves as Primary Contact on IRB submission. IRB application form before submitting.
The process overview

**Researcher**
- Researcher develops protocol and research plan
- Researcher completes online Human Subjects training course (CITI)
- Researcher completes initial Cayuse IRB submission
- Form and attachments submitted through Cayuse IRB
- Committee / Committee member review and category assignment (timeline anywhere from 3-7 weeks)
- Decision in writing

**Additional steps for Student Researchers**
- Student reviews research protocol with faculty sponsor
- Student & Faculty Sponsor complete online Human Subjects training course
- Student has Faculty Sponsor review and certify IRB submission

**The process overview**
Checklist:
Documents for IRB submission

- CITI training
- Request an Cayuse IRB account (students or new employees only)
- Following IRB TEMPLATES:
  - Consent form
  - Translated consent forms if applicable
  - Assent form with Parent/Guardian Consent if research is with minors
  - Site agreements
    - for any and all off-campus research sites
  - Recruitment material (flyer, ads, emails, brochures etc.)
- Scripts (e.g. in person pleas)
- Data collection instrument (survey, interview questions etc.)
Understanding faculty sponsorship

- FS is affirming research design and implementation by serving as Principle Investigator
- FS should provide training and oversight of student in conducting research
- A faculty sponsor should be a permanent faculty member (adjunct faculty and faculty from other universities cannot serve as your sponsor)
- This may be your first time doing research, faculty sponsors must not only support your application but the entire implementation of your research activity.
- Assist your FS in accessing CAYUSE to either “Certify” or “Return to Investigators” your submission!
What’s on the IRB webpages? montclair.edu/irb

- Templates
  - All consent documents including online consent
  - Recruitment Materials
  - Site Approval Letters
- Sample Applications
- Authorization Agreements
- Links to:
  - CITI Training
  - Requesting a Cayuse IRB account
  - Registering for a workshop
Welcome to our new eIRB system, Cayuse IRB

Click the Cayuse logo to log in or click here!
Evisions Research Suite

3.2

Research Administration Modules
- Cayuse SP (Sponsored Projects)
- Cayuse 424
- Cayuse IRB (Human Studies Compliance)

System Administration Applications
- Backbone
- Research Contacts
- Workflow

Application Help
- Research Suite Support Center
- Browser Support & Configuration

Research Administration Modules

- Cayuse SP (Sponsored Projects)
- Cayuse 424
- Cayuse IRB (Human Studies Compliance)
Notifications will appear here. Click bell to view

Shows all your studies
Shows the statuses of your submissions

Other ways to access the same things

In-Draft: 2
Awaiting Approval: 0
Pre-Review: 0
Under Review: 9

Shows you your approved studies
Shows soon-to-expire studies
Shows expired studies
Click the “open Help” option in the Help tab to launch Cayuse’s web support page.
Click new study to begin

Dashboard

My Role: Researcher

Dashboard

My Studies

- IRB-FY15-16-38    sample modification
- IRB-FY15-16-36    sample app with revisions
- IRB-FY15-16-37    another sample app with revisions
- IRB-FY15-16-35    Sample initial application

My Tasks

- IRB-FY15-16-25    View Submission

Submissions by Type

<table>
<thead>
<tr>
<th>Type</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial</td>
<td>7</td>
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<tr>
<td>Withdrawal</td>
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<td>Closure</td>
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<tr>
<td>Legacy</td>
<td>0</td>
</tr>
</tbody>
</table>

Tasks

- In-Draft: 0
- Awaiting Approval: 1
- Pre-Review: 0
- Under Review: 6

Help
Type the name of your study here. If you are submitting a student-led research study, enter “SS:” followed by your study name.

...and then click the check...
Click “new submission” and select “Initial”
Cayuse IRB will assume you are the PI when you create the study. However, if you are a student researcher, you will need to assign your faculty sponsor as the PI. You can do this in the submission itself. For now, assign yourself as the PC, or “primary contact.” The PC will be the IRB’s first point of contact in all communications about the submission. When you click this, you will be brought to the actual submission and can begin.

You can also select “Edit” to begin the submission too.
You will be presented with this pop-up in which you will search for the designated person and click their name to select. Then click “Save”
Sidebar lists all the subsections of the submission. The green bar is a status bar. When the section is complete, the green check mark will show.

These arrows are used to tab through the submission.

Click the save button at any time. You can leave Cayuse IRB and complete your submission at a later time.
You will likely have to attach several things to your submission. You’ll click the “Attach” button and follow the instructions of the pop-up. You can now attach a link OR a document.
When you are finished with your submission, click “complete submission”.

*If you are not the PI, you will have to select the “Send to PI for certification” option for the PI to sign off on the submission.
Now we are back to the general “Study page.” On the study page you can see the status of your submission.

Even though we clicked “complete submission” in the earlier page, we aren’t done with our submission. As we can see, it is still in the “awaiting approval” stage. It needs to be “certified,” or signed, by the PI.

If the research team needs to make changes, click “return.” If it is ready to be submitted, click “certify.”
The submission has been sent to the IRB Staff and is now in pre-review!
Responding to request for changes:

SS A Study on College Students’…

**Linking Data**

Will the research team use a linking code with the data?

- Yes
  
  Please explain your system for using linking codes. Also describe how you will maintain confidentiality of the codes.

Students will be given a three-digit code. The code will be used so the students names will not be identified by others. The code key will be kept in a secured location away from the Instructors of the course.

**Collapse Comments**

Amy Krenzer  last Thursday at 9:56 AM  
Visibility: Unrestricted

Why do you need a code? What will you be linking the interview to?

Reply

Project Director  last Friday at 3:34 PM  
Visibility: Unrestricted

Your question is answered.

Not Resolved
See Study #906 in Cayuse for example.
My Application was approved: what now?

- Use the consent form(s) and other documents for your study participants, print directly from Cayuse (everyone gets a CF copy).
- Report any adverse events to the IRB within 72 hours (Cayuse).
- Submit a Modification (amendment) if you plan to change your research protocol.
- Add research team members a Modification submission to add/change personnel.
- Don’t let your approval expire! Your study expires on the expiration date in Cayuse, if you have not submitted a Renewal, you will have to start with a New Study submission!
- Once your study is complete and you are done with data analysis submit a Project Closure.
Ask for Help

- Email us your questions, reviewboard@Montclair.edu
- Make an appointment, we can review your draft application materials before you submit them.
- Visit our FAQs
Contact information

- **Senior IRB Coordinator:** Amy Krenzer
  - [reviewboard@mail.montclair.edu](mailto:reviewboard@mail.montclair.edu)
  - Ext. 7583

- **Compliance Coordinator IRB & IACUC:** Mylka Biascochea
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- **IRB Chair:** Dr. Katrina Bulkley
  - Ext. 5189

- **IRB Office:** NURS - 333
Questions