

IRB Training

Human Subjects Protection
Program and Cayuse IRB

HILA BERGER, RESEARCH COMPLIANCE OFFICER

MYLKA BIASCOCHEA, COMPLIANCE COORDINATOR IRB/IACUC

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 un-related 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

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- ▶ 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.
- ▶ 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.

NOT HSR! – Quality Improvement/Assurance

Center may still want to consider a consent form and privacy issues

YES Program Evaluation can be HSR too!

IRB REVIEW PROCEDURES and categories

General themes involved in the IRB review

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- ▶ 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
 - ▶ Key summary
 - ▶ 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 present no more than minimal risk to human subjects
- ▶ 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

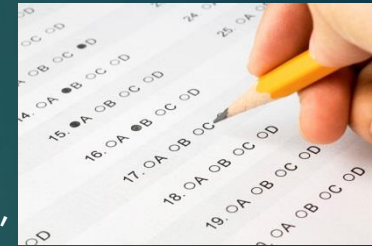
Criteria for Expedited

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- ▶ Research activities that present no more than minimal risk to human subjects

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

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- ▶ 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

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- ▶ 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

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- ▶ 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
 - ▶ Qualtrics (NEW)
 - ▶ MSU limesurvey <https://oit-app2.montclair.edu/msusurvey/admin/admin.php>
 - ▶ Data stored in-house; similar features to survey monkey
 - ▶ Other survey tools:
 - ▶ The Survey Monkey, SoGoSurvey, SurveyGizmo, Google Forms
- ▶ Paper survey layout and design is up to the researcher

Be consistent

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- ▶ 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

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

Cayuse IRB electronic system

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File Edit View History Bookmarks Tools Help

Cayuse IRB - Montclair Stat... x +

www.montclair.edu/provost/institutional-review-board/cayuse/

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Applications, Forms, and Templates
Research Trainings and Certificates
Participants

Montclair State » Office of the Provost » Institutional Review Board » Cayuse IRB

Cayuse IRB

Welcome to our new eIRB system, Cayuse IRB

cayuse IRB

Request an IRB account

Upcoming training sessions

Click the cayuse logo to login or click here!



Evisions Research Suite

evisions

Logged in as: *harrypotter*
Log out

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

+ New Study

Other ways to access the same things

Shows the statuses of your submissions

- Dashboard
- Studies
- Submissions
- Tasks
- Help

2 In-Draft	0 Awaiting Approval	0 Pre-Review	9 Under Review
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My Studies Shows all your studies

IRB-FY15-16-27	Cayuse training
IRB-FY15-16-17	Veterans and their children: How they navigate the maze of Veteran Benefits
IRB-FY15-16-18	Focus Group with MSU Student's

View All

My Tasks Shows all incomplete tasks

IRB-FY15-16-29	Complete Submission
IRB-FY2016-10	Complete Submission

View All

Submissions by Type Shows you all your submissions

Initial	10
Withdrawal	1
Modification	3
Renewal	0
Incident	1
Closure	0
Legacy	0

Approved Studies Shows you your approved studies

IRB-FY15-16-27	Cayuse training
----------------	-----------------

Studies Expiring in 30 days Shows soon-to-expire studies

Expired Studies Shows expired studies

Dashboard


Studies


Submissions


Tasks


Help

+ New Study

 **0**
In-Draft

 **1**
Awaiting Approval

 **1**
Pre-Review

 **6**
Under Review

My Studies

IRB-FY15-16- 37	A Sample Study another sample app with revisions
View All	

My Tasks

IRB-FY15-16-25	View Submission
View All	

Submissions by Type

Initial	8
Withdrawal	0
Modification	1
Renewal	0
Incident	0
Closure	0
Legacy	0

Approved Studies

Studies Expiring in 30 days

Expired Studies

- Open Help
- Release Notes
- View Dashboard Tutorial
- View Visual Search Tutorial

Click the "open Help" option in the Help tab to launch Cayuse's web support page

Dashboard


Studies


Submissions


Tasks


Help

Click new study to begin [+ New Study](#)

 **0**
In-Draft

 **1**
Awaiting Approval

 **0**
Pre-Review

 **6**
Under Review

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

[View All](#)

My Tasks

IRB-FY15-16-25	View Submission
----------------	---------------------------------

[View All](#)

Submissions by Type

Initial	7
Withdrawal	0
Modification	1
Renewal	0
Incident	0
Closure	0
Legacy	0

[Approved Studies](#)

[Studies Expiring in 30 days](#)

[Expired Studies](#)

Study Details

Submissions

A Sample Study

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



PDF

Delete

Approval Date:
N/A

Expiration Date:
N/A

Organization:
N/A

Sponsors:
N/A

Active Submissions:

Key Study Contacts

Team Member

Role

Number

Email

No Key Study Contacts.

Click “new submission” and select “Initial”

+ New Submission

Study Details

Submissions

Initial

Unsubmitted

IRB-FY15-16-41 A Sample Study

PDF

Delete

Approval Date:

N/A

Expiration Date:

N/A

Organization:

N/A

Sponsors:

N/A

Active Submissions:

N/A

Key Study Contacts

Team Member	Role	Number	Email
No Key Study Contacts.			



Unsubmitted

Initial

IRB-FY15-16-41 - A Sample Study

[Edit](#)
[PDF](#)
[Delete](#)
[Checklist](#)

You can also select “Edit” to begin the submission too

PI: Harry Potter	Current Analyst: N/A	Decision: N/A	Required Tasks: ✓ Assign PI • Assign PC • Complete Submission
Review Type: Unassigned	Review Board: N/A	Meeting Date: N/A	

[Approvals](#) [Task History](#)

Research Team

Name	Role	Result	Date
No entries.			

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

STUDY | IRB NUMBER: IRB-FY15-16-41
A Sample Study - Initial

CREATE PDF

COMPARE

SAVE

Sections

Personnel

Activity

Attachments

PRIMARY CONTACT

Search...



Name

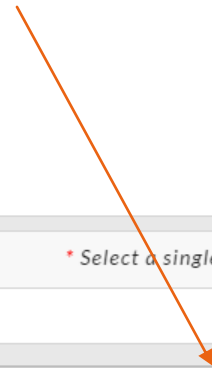
Organization

Email

Phone

Use the search box above to find records.

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"



Selected Records

* Select a single record.

No records selected. Select a record and click Save to apply.

CANCEL

SAVE

Please describe the roles of each research team member.

For example; study lead, data collector, recruiter, consenting, data analyst

My Role: Researcher

IRB NUMBER: IRB-FY15-16-41

STUDY | **A Sample Study - Initial**

CREATE PDF COMPARE SAVE

Sections

- Personnel ✓
- Activity
- Study Information
- Assurances
- Study Population
- Study Procedures
- Study Design
- Funding
- Conflict of Interest (COI)
- Attachments

Activity

* What type of activity is this submission for?

- Research Study
 - * Is this a multi-institutional study?
 - Yes
 - No
- Activities Without a Plan to Conduct Research (Case Study, Secondary Data Analysis of publicly available data-sets, or Quality Improvement project) requiring Human Subjects Research determination.

Click the save button at any time. You can leave Cayuse IRB and complete your submission at a later time.

These arrows are used to tab through the submission

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.

IRB NUMBER: IRB-FY15-16-41

A Sample Study - Initial

CREATE PDF

COMPARE

SAVE

Sections

Personnel ✓

Activity ✓

Study Information ✓

Assurances

Study Population ✓

Study Procedures

Study Design

Funding

Conflict of Interest (COI)

Attachments

* Adult Consent

Check any and all that apply.

Adult Consent Form

Link to the MSU IRB [Adult Consent Form Templates](#)

Readability for consent documents must follow:

- General public - 6th to 8th grade reading ability
- College Students - 10th to 12 grade reading ability
- Professionals - 12+ reading ability

* Adult Consent Form (s)

Please attach your adult consent form(s)

ATTACH

- Online Consent
- Requesting waiver or alteration of standard informed consent procedures
- Consent form non-English speaking participants
- Debriefing form (for use in deception studies only)
- Cognitively impaired or differently abled population consent

* Will you offer compensation to your participants?

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

IRB NUMBER: IRB-FY15-16-41

A Sample Study - Initial

CREATE PDF COMPARE SAVE

- Sections
- Personnel ✓
- Activity ✓
- Study Information ✓
- Assurances ✓
- Study Population ✓
- Study Procedures ✓
- Study Design ✓
- Funding ✓
- Conflict of Interest ... ✓
- Attachments ✓
- Routing Send to PI for certification? ▾
- COMPLETE SUBMISSION >

Translated Material(s)

Attach any translated recruitment, consent or instrument(s).

ATTACH

Grant Proposal

Please attach the sponsor notification that states the intention to award the study.

ATTACH

Outside IRB of Record

Please make sure all of the documents below have been uploaded.

Study Protocol

Attach the protocol for this study that was reviewed by the outside IRB.

ATTACH

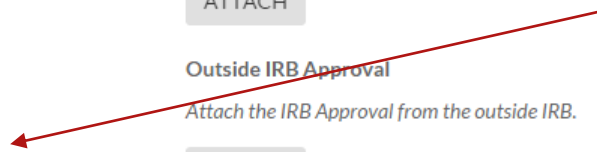
Outside IRB Approval

Attach the IRB Approval from the outside IRB.

ATTACH

*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

When you are finished with your submission, click “complete submission”



Now we are back to the general “Study page.” On the study page you can see the status of your submission

In-Draft

Needs to be certified

With IRB Staff

With IRB Reviewer(s)



Awaiting Certification

Initial

IRB-FY15-16-41 - A Sample Study

View PDF Delete Checklist

Routing:

Return Certify

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.

PI: Harry Potter	Current Analyst: N/A	Decision: N/A	Required Tasks: N/A
Review Type: Unassigned	Review Board: N/A	Meeting Date: N/A	

If the research team needs to make changes, click “return.” If it is ready to be submitted, click “certify.”

Approvals Task History

Research Team

Name	Role	Result	Date
Harry Potter	Principal Investigator	Pending Certification	

**In-Draft**

Submission is with researchers

**Awaiting Approvals**

Submission is awaiting certification or approval

3**Pre-Review**

Submission is being prepared for review

4**Under-Review**

Submission is with reviewers

Under Pre-Review

The submission has been sent to the IRB Staff and is now in pre-review!

Initial

IRB-FY15-16-41 - A Sample Study

View

PDF

Delete

Checklist

PI:

Harry Potter

Current Analyst:

N/A

Decision:

N/A

Required Tasks:

N/A

Review Type:

Unassigned

Review Board:

N/A

Meeting Date:

N/A

Approvals

Task History

Research Team

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

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Institutional Review Board ... x +

www.montclair.edu/provost/institutional-review-board/ Search

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Montclair State » Office of the Provost » Institutional Review Board

Institutional Review Board

Welcome

The Institutional Review Board (IRB) is designated by Montclair State University (MSU) to support faculty, staff, students and guests to complete their research that is compliant 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. As mandated by Federal Law and consistent with MSU policy, each investigator must have prior dated and written approval from the IRB before beginning a research project that uses human participants. This is true regardless of the funding source or if the project is funded.

Our Federalwide Assurance Identification number as filed with the Department of Health and Human Services is FWA00005270

The purpose of this website is to provide investigators and the research community at MSU with the information and materials that are needed to obtain IRB approval of research that involves human participants.

News & Events

Announcing 2016 Research Ethics Week
The 2016 Research Ethics Week will take place October 17-October 21.

IRB Graduate Student Worker Recognized in 2016 Outstanding Student Employee Awards

IRB Staff Attends Student Research Symposium

[More News & Events ...](#)

WHERE TO FIND THE MOST RESOURCES? ONLINE!

Ask for Help

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- ▶ 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

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- ▶ Senior IRB Coordinator: Amy Krenzer
 - ▶ reviewboard@montclair.edu
 - ▶ Ext. 7583
- ▶ Compliance Coordinator IRB & IACUC: Mylka Biascochea
 - ▶ biascocheam@montclair.edu
 - ▶ Ext. 3021
- ▶ Research Compliance Officer: Hila Berger
 - ▶ bergerh@montclair.edu
 - ▶ Ext. 7781
- ▶ IRB Chair: Dr. Katrina Bulkley
 - ▶ Ext. 5189
- ▶ IRB Office: NURS - 333

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Questions

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