IRB **Highway** to
Research Study Approval

IRB Workshop

Understand why IRBs exist

IRB **Highway** to Research Study Approval

IRB Workshop

GOAL!

Our 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 in-lieu of, and conduct periodic reviews of research projects that involve human participants.

Understand why IRBs exist

- Primary objective is to protect human participants
- Bound by law (45 CFR Part 46) under our FWA Federal Wide assurance
- IRB 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

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Get to know the Committee

2016 IRB Committee and Staff
12 Faculty/1 community members
Amy Krenzer, CIP, IRB Coordinator
Mylka Biascochea, IRB Program Assistant
Susan Pereny, IRB Graduate Student Worker

IRB Members

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What does the IRB Review?

Human Subjects Research (HSR)

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.

Is it HSR?

- Student surveys other students in their class on their use of LinkedIn for a class project. Will use results to interpret the groups tendencies on social media and to advise the group in class only on how to improve their use of social media in business.

Is it HSR?

- Faculty surveys and interviews students about their experience with her online teaching vs. classroom teaching for self-improvement purposes.

Is it HSR?

- 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 partners.

Is it HSR?

- Professor uses public online data set to investigate what traits may affect happiness among different demographics. Data set includes participants' demographic information such as age, gender, marital status, and eduation status, but does not contain name or contact information.

YES

NO

NO

NO

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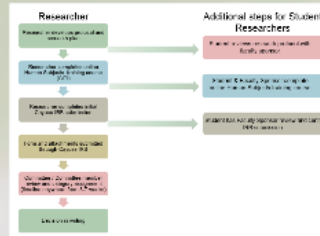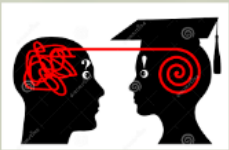
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Get to know the Submission Process

Identify your faculty sponsor

The process overview

Researcher	Additional steps for Student Researchers

CITI training

- MSU requires that all faculty, staff, students, and visitors who conduct research that involves human participants must complete a training program on the protection of human participants.
- Valid for 3 years
- citiprogram.org

Log in to Cayuse

Cayuse IRB

Welcome to our new eIRB system, Cayuse IRB

cayuse IRB

Cayuse Application Sections

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

Making Changes in Cayuse

Cayuse Resources

- Cayuse IRB FAQ
- Evisions help accessible through Cayuse
- Sample Cayuse IRB application
- Cayuse IRB for Beginners & video tutorials
- all available on IRB website:
- www.montclair.edu/irb/cayuse

Identify your faculty sponsor
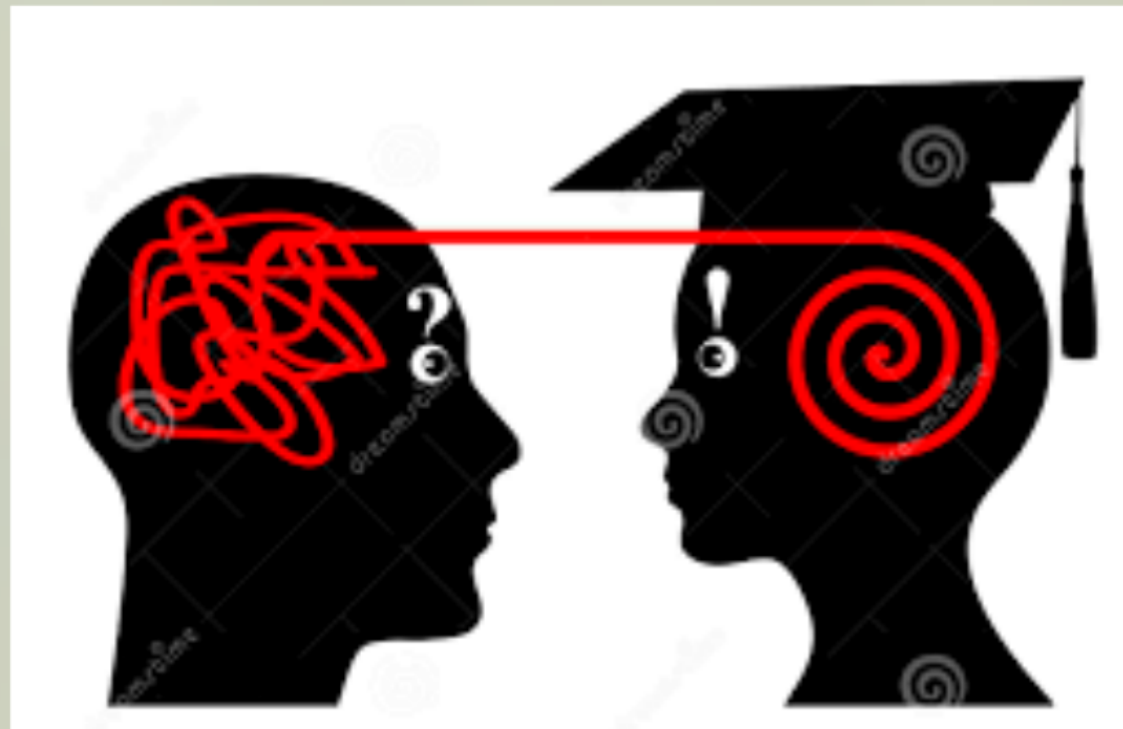
Researcher

- 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

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UNIVERSITY

| About Montclair | Academics | Admissions | Arts & Culture | Athletics | Campus Life | Giving |

IRB Home

About the IRB

Membership

Application Process and
Researcher Information

Review Schedule

Cayuse IRB

More about Cayuse IRB
Cayuse IRB Submission Process
Student Submissions
Cayuse IRB Training
Cayuse IRB FAQs

Applications, Forms, and
Templates

Research Trainings and
Certificates

Participants

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

Cayuse IRB

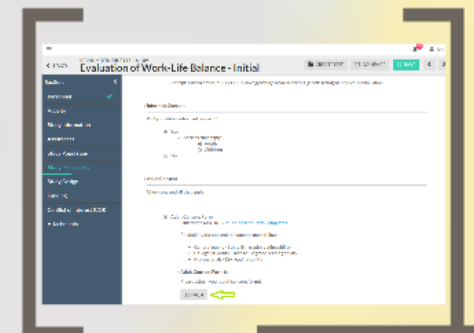### Welcome to our new eIRB system, Cayuse IRB

cayuse IRB

Request an
IRB account

Upcoming
training
sessions

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‹ STUDY | # Evaluation of Work-Life Balance - Initial

CREATE PDF | COMPARE | 💾 SAVE | ‹ | ›

Sections ‹

Personnel ✔

Activity

Study Information

Assurances

Study Population

Study Procedures

Study Design

Funding

Conflict of Interest (COI)

Attachments

Examples: blood draws, MRIs, EEGs, audiology testing, medical devices, genetic testing or physical manipulation.

* Informed Consent

Will you obtain informed consent?

◉ Yes
  * Check all that apply.
    ☑ Adults
    ☐ Children
○ No

* 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 ⇦

Making Changes in Cayuse

Study Dates

Please enter the anticipated study dates. 🏷️ *These can be estimates and are not binding.*

* Start Date

Please provide the date for when the study will begin.

12/30/2015	📅

💬 **Expand Comments**

* End Date

Please provide the date for when the study will end.

12/02/2015	📅

💬 1 **Collapse Comments**

Amy Irbanalyst last Tuesday at 12:35 PM
This end date has passed. Please revise to the correct anticipated end date.
Reply

B *I* U S ☰ ☰ 📎 🖼️

[text input field]

📝 REPLY   ✖ CANCEL

Not Addressed ▼

Cayuse Resources

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Understand IRB Determinations

Exempt

Example: data analysis with existing data set
Example: regular classroom activity where results are now intended for research

Goal: 3 to 4 weeks

Expedited

Example: Collection of data through non-invasive means (e.g., weight)
Example: Curriculum program evaluation involving surveys

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

Goal: 4 to 6 weeks

Full Board

Includes:
• 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, repuation, or be stigmatizing
• Coercion
• Deception or incomplete disclosure
• Persons with cognitive disabilities
• Pregnant women
• Medically invasive (e.g., clinical trial)

Goal: 6 to 8 weeks

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    Goal: 6 to 8 weeks

Full Board Deadlines

Montclair State » Office of the Provost » Institutional Review Board » Review Schedule

Review Schedule

Meeting Schedule for 2015-2016

IRB applications are reviewed on a rolling basis as received. Only studies that include more than minimal risk to participants will fall into a **full review category**. The schedule below applies to studies that require full review by the entire Institutional Review Board at their monthly meeting.

Deadline for Submission for Full Review

- **December 28, 2015**
- January 18, 2016
- **February 22, 2016**
- March 14, 2016
- **April 18, 2016**
- May 16, 2016

Meeting Date for Full Review

- **January 20, 2016**
- February 17, 2016
- **March 23, 2016**
- April 13, 2016
- **May 18, 2016**
- June 15, 2016

Is your content ready for submission?

Students! review all your content with your Faculty Sponsor

Informed Consent

- Understand Consent vs. Assent
  - Assent form with Parent/Guardian Consent if research is with minors
- Template available online only to be used as outline
- Should clearly and succinctly tell people what your study is about, including any screening procedures
- Readability level
  - Adults- 6th to 8th grade reading level for general public
- Ask for help!

Recruitment

- Determine who your study population is
- Justify inclusion or exclusion criteria in screening
- If you are using your own students or staff then you must adjust your data collection to avoid undue coercion (see IRB FAQs)
- Using SONA (Psychology department only)
  - 1 SONA credit=30 minutes of research time
  - Cannot also pay subjects

Data Storage and Security

- What identifiers are you keeping?
  - Limit identifiers (DOB vs. age range)
  - Plan for confidentiality
- Disclose any limits to privacy or confidentiality if you are collecting online or electronically
- Data retention
  - Policy is for 3 years after project completion

Risks and Benefits

Risk examples are:
- Emotional distress
- Loss of social status among peers or other students
- Psychological distress
- Invasion of privacy
- Loss of employment
- Embarrassment

Risks may vary with vulnerable populations
- Children, pregnant women, teens, prisoners, cognitively disabled, minorities/ethnic groups

Attachments

- Consent forms
- Surveys/Questionnaires
- Recruitment text & Flyers
- Interview/focus group protocols
- Screening instruments
- Site approval letters
- & more

Can be submitted as file or link

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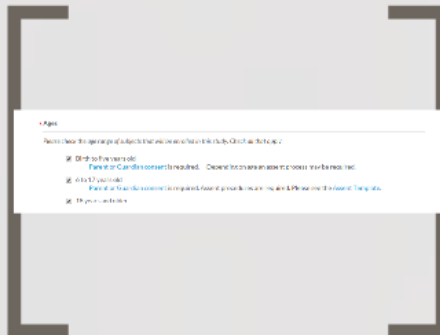
* Ages

Please check the age range of subjects that will be enrolled in this study. Check all that apply.

- ☑ Birth to five years old
    Parent or Guardian consent is required.   Depending on age an assent process may be required.

- ☑ 6 to 17 years old
    Parent or Guardian consent is required. Assent procedures are required. Please see the Assent Template.

- ☑ 18 years and older

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Questions to Ask Yourself about Data

- Am I collecting or retaining any identifiable data beyond what is absolutely necessary for the study?
- Have I planned for how I will destroy identifiable data and described in application?
- Have I used a code and planned for how I will keep the key to identifiers separate?
- Do I routinely review and update my data security?
- If my data is particularly high risk have I consulted security experts?
- Will I be traveling with my data, and have I planned for a safe backup?

Examples

Data Storage
- The data will be stored on a partitioned, password protected sub-directory on a password protected work station, stored in a locked office on the campus of MSU. Any working files, output generated from these data, and drafts of related presentations/articles will also be kept in the same manner as described above.

Internet Data Collection
- Data will be collected using the Internet; no guarantees can be made regarding the interception of data sent via the Internet by any third party (i.e. your employer). Confidentiality will be maintained to the degree permitted by the technology used.

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Dealing with Risk

Questions that include mental health status or violent attacks should refer to:
- Counseling and Psychological Services (CAPS)
- Other counseling services

Questions that include health and well-being should refer to:
- Health care provider
- Therapist

International Research - plan ahead!
- International standards and regulations are considered as part of the MSU IRB review. This will increase the review time.
- Ethics review at the international site may or may not be required.

Explaining Risk

"The risks are no greater than those you might encounter in everyday college life. If you feel uncomfortable or wish to stop the interview at any time, please let me know and we will stop the interview."

"There is a slight possibility that you may feel like you just shared something you didn't want to share within the group session. We will encourage everyone to tell a member of the research team if he or she feels at all uncomfortable at any point during this study."

Additional focus group language: "As researchers we will do everything in our power to keep your identity and comments confidential, but we cannot guarantee that others will also do so. Please do not share anything in the focus group session that you do not want known to others."

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Research Procedures

Does your research involve any of the following. Please check all that apply.

- ☐ Induction of mental or emotional distress
- ☐ Induction of physical stress
- ☐ Materials/issues commonly regarded as socially unacceptable
- ☐ Information regarding sexual attitudes, preferences, or practices
- ☐ Information regarding the use of alcohol, drugs, or other addictive products
- ☐ Information pertaining to illegal conduct
- ☐ Information in a student's educational record [this does not include self reported grades or student status]
- ☐ Information pertaining to a person's psychological health or well-being
- ☐ Information recorded in a patient's medical record
- ☐ Procedures that may be regarded as an invasion of privacy
- ☐ Information that if released, could reasonably damage an individual's financial standing, employability, or reputation within the community
- ☐ Administration of drugs
- ☑ Other risks to participants
    - * **Other risks**

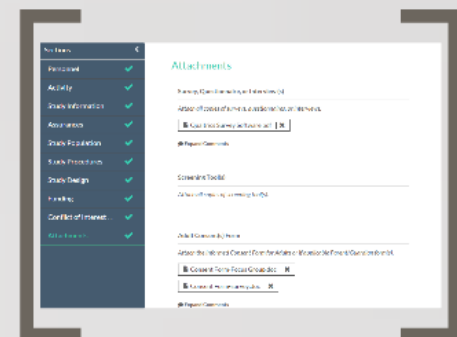   - **You must provide the justification for any other risks &**
        - **You must describe the precautions that will be used to minimize risk.**

    [   ]

Attachments

- Consent forms
- Surveys/Questionnaires
- Recruitment text & Flyers
- Interview/focus group protocols
- Screening instruments
- Site approval letters
- & more

Can be submitted as file or link

Sections

Personnel	✔
Activity	✔
Study Information	✔
Assurances	✔
Study Population	✔
Study Procedures	✔
Study Design	✔
Funding	✔
Conflict of Interest ...	✔
Attachments	✔

Attachments

Survey, Questionnaire, or Interview (s)

Attach all copies of surveys, questionnaires, or interviews.

📄 Qualtrics Survey Software.pdf | ✖

💬 Expand Comments

Screening Tool(s)

Attach all copies of screening tool(s).

Adult Consent(s) Form

Attach the Informed Consent Form for Adults or if applicable Parent/Guardian form(s).

📄 Consent Form-Focus Group.doc | ✖

📄 Consent Form-survey.doc | ✖

💬 Expand Comments

More Tips

Understand Faculty Sponsorship

- FS affirms research design and implementation by certifying submission
- FS should provide training and oversight of student conducting research
- Should be permanent faculty member
- Must support implementation of research activity

Be Clear & Consistent

- Describe what you will do in simple and clear terms.
  - Do not copy and paste your entire grant proposal or thesis.
- Confidential vs. anonymous
  - Only anonymous if researcher and others cannot identify the participant (i.e. online survey)
- Participation time should be the same in your application and 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 form
- Compensation
  - Compensation noted in the application should also be in the consent form
- Eligibility
  - Include if applicable, i. e. "Recruiting right-handed males over the age of 25."

Ask for Help!

- Email us your questions
- Call our offices
- Drop-ins welcome M-F 8:30-4:30
- College Hall 248
- Visit our FAQs

My application was approved. Now what?

- Report any adverse events to the IRB within 72 hours
- Submit a modification proposal if you plan to change your research protocol
- Add research team members on Cayuse IRB
- Don't let your approval expire- fill out the renewal form
- Once your study is complete and you are done with data analysis submit the project completion form

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Student Led Research Project

Attend Cayuse IRB Training (not mandatory)

Start IRB process– Choose New Study

- Enter Study Title- **Preface title with "SS"** i.e. "SS Word Play in Child Development"

Click on "New Submission"

- Choose "Initial" from drop down menu

First question in Personnel section:

- Click on Student
- Designate Degree Program
- List your Faculty Sponsor as Principal Investigator
- List yourself as Primary Contact

Student as Primary Contact for Faculty/Staff Led Research Project

Start IRB Process- Choose New Study

- Enter Study Title

Click on "New Submission"

- Choose "Initial" from drop down menu

First question in Personnel section:

- Click on Faculty or Staff
- List your Faculty/Staff member as Principal Investigator
- List yourself as Primary Contact

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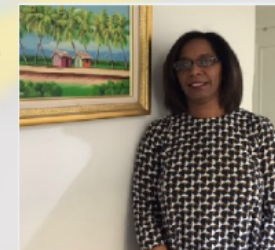
IRB Staff Can Help!

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- Ext. 7583

IRB Program Assistant: Mylka Biascochea
- biascocheam@mail.montclair.edu
- Ext. 3021

Research Compliance Officer: Hila Berger
- bergerh@mail.montclair.edu
- Ext. 7781

IRB Chair: Dr. Katrina Bulkley
- Ext. 5189

IRB Office: CO 248