IRB 101:
HUMAN SUBJECTS PROTECTION PROGRAM

Wednesday, September 30, 2015

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Research Compliance Officer

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IRB Coordinator

Objectives

- What is the 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
- IRB 101 TOP TIPS

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

IT IS ETHICAL!

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.

2015 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

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 surveys others 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.

- A - yes HSR
- B - no HSR
- C – I don't know

Human Subjects research (HSR)?

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

A - yes HSR

B - no HSR

C – I don't know

Human Subjects research (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 parents.

A - yes HSR

B - no HSR

C – I don't know

- YES Program Evaluation can be HSR too!

Human Subjects research (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 education status, but does not contain name or contact information.

- A – yes HSR
- B – n[illegible]SR
- C – I don't know

Not sure if what you are doing is human subjects research?

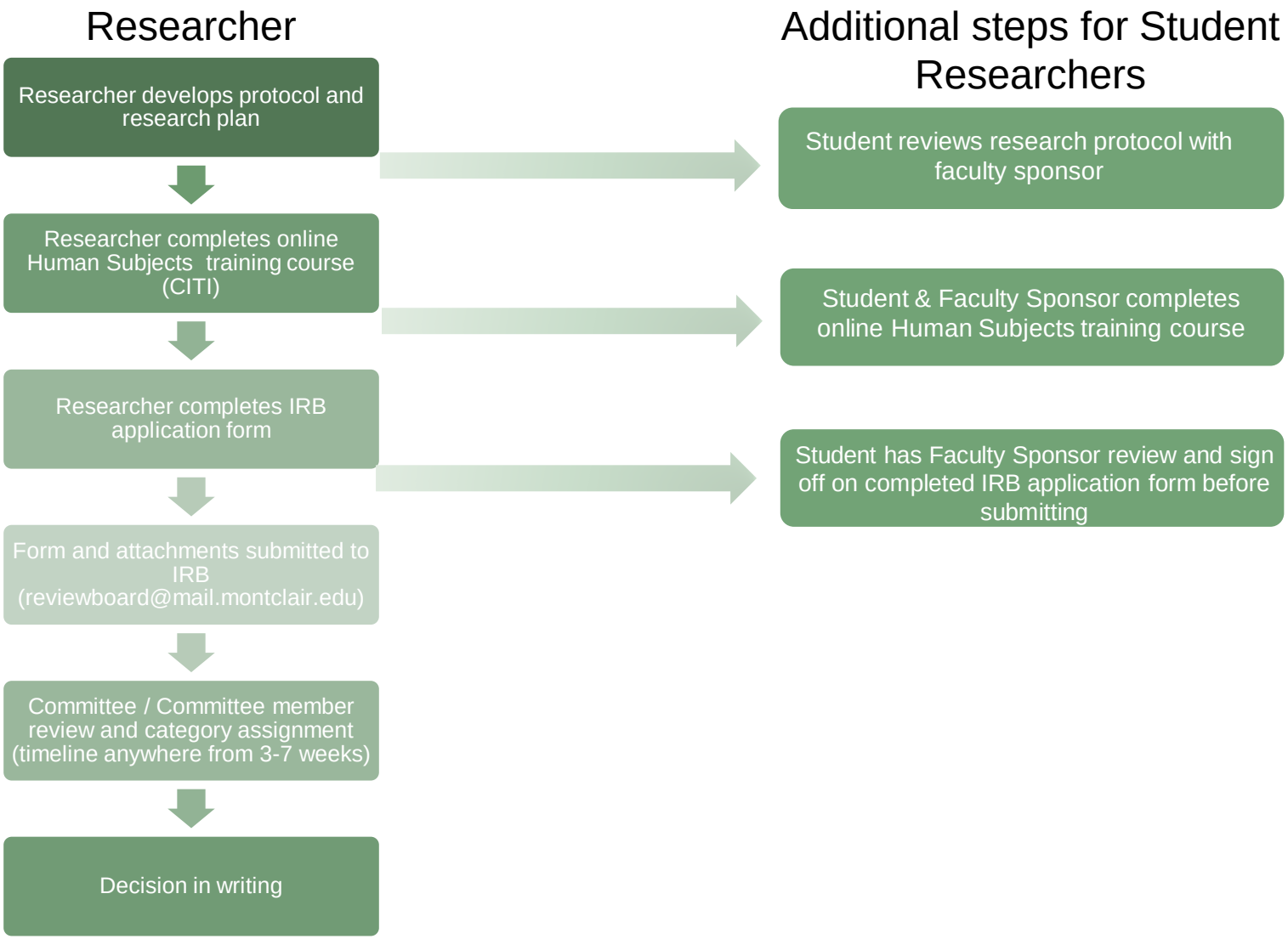
- Submit a Research determination form (RDF)
  - Available at: http://www.montclair.edu/provost/institutional-review-board/forms/
  - To reviewboard@mail.montclair.edu
  - Call or email the IRB for further clarification
- IRB Chair or designated member will get back to you within 7 business days to determine if you need to submit an IRB application

IRB SUBMISSION PROCESS, REVIEW PROCEDURES AND CATEGORIES

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.
- Est. time 2-4 hours (not one sitting)
- Valid for 3 years
- citiprogram.org

Overall Steps in Process



How many open/active IRB applications does the IRB have (new and continuing)?

A ~200-249

B ~250-299

C ~300-349

D ~350-400

Application Forms & Templates

IRB Home
About the IRB
Membership
Application Process and Researcher Information
Review Schedule
Applications, Forms, and Templates
IRB sample applications
IRB Templates
Research Trainings and Certificates
Participants
Research Ethics
FAQs
Manuals, Guidebooks, and Regulations
Contact Our Office

Montclair State » Office of the Provost » Institutional Review Board » Applications, Forms, and Templates

Applications, Forms, and Templates

SAMPLE APPLICATIONS AVAILABLE – Click here!

Please use the versions of forms posted here. Older forms, from past years, may not include important changes. **Using old forms will result in a delay in the review process and may require you to re-do the entire form. If you are having any trouble opening forms – check this reference for help.** If the reference document does not help solve your problem, email reviewboard@mail.montclair.edu and request a specific document to be emailed to you as an attachment.

Do not complete forms in an open browser window, they will not save correctly, see note below.

Applications and Forms

IRB Application
Continuing Review Application
Amendment Application
Amendment Form to Add/Remove/Change Personnel
Amendment Form to Add/Remove Research Sites
Project Completion Form
Research Determination Form
Adverse Events Form
External Investigator Policy
For Non-MSU Employees or Students

Please update to the most recent Adobe Reader & do not fill out in the browser

Application Forms & Templates

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IRB Templates

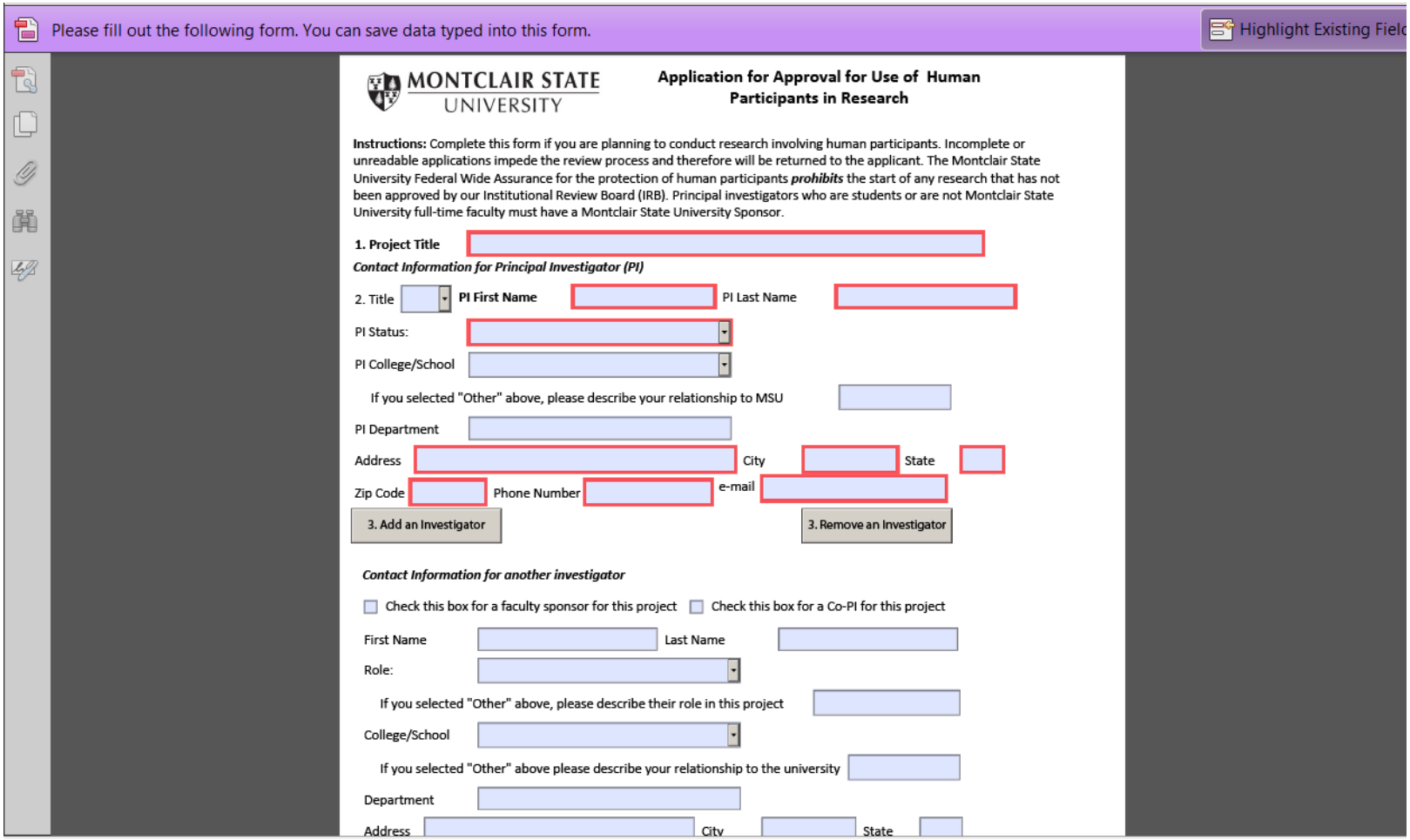
Templates

Consents/Assents:

- Online Template for Consent
- Consent Form for Adults
  (In person, signed consent)
- Parent/Guardian Consent Form
  (Also submit Assent Form)
- Assent Form
  (Also submit Parent/Guardian Consent Form)
- Improving Consent Readability Level
- Debriefing Form

Site Approval Letter Template
Research Team Roster
Flyer Template
Recruitment Materials Template

THE IRB APPLICATION



Please fill out the following form. You can save data typed into this form.

Highlight Existing Field

MONTCLAIR STATE UNIVERSITY

Application for Approval for Use of Human Participants in Research

Instructions: Complete this form if you are planning to conduct research involving human participants. Incomplete or unreadable applications impede the review process and therefore will be returned to the applicant. The Montclair State University Federal Wide Assurance for the protection of human participants ***prohibits*** the start of any research that has not been approved by our Institutional Review Board (IRB). Principal investigators who are students or are not Montclair State University full-time faculty must have a Montclair State University Sponsor.

1. Project Title

Contact Information for Principal Investigator (PI)

2. Title **PI First Name** PI Last Name

PI Status:

PI College/School

If you selected "Other" above, please describe your relationship to MSU

PI Department

Address City State

Zip Code Phone Number e-mail

3. Add an Investigator 3. Remove an Investigator

Contact Information for another investigator

Check this box for a faculty sponsor for this project Check this box for a Co-PI for this project

First Name Last Name

Role:

If you selected "Other" above, please describe their role in this project

College/School

If you selected "Other" above please describe your relationship to the university

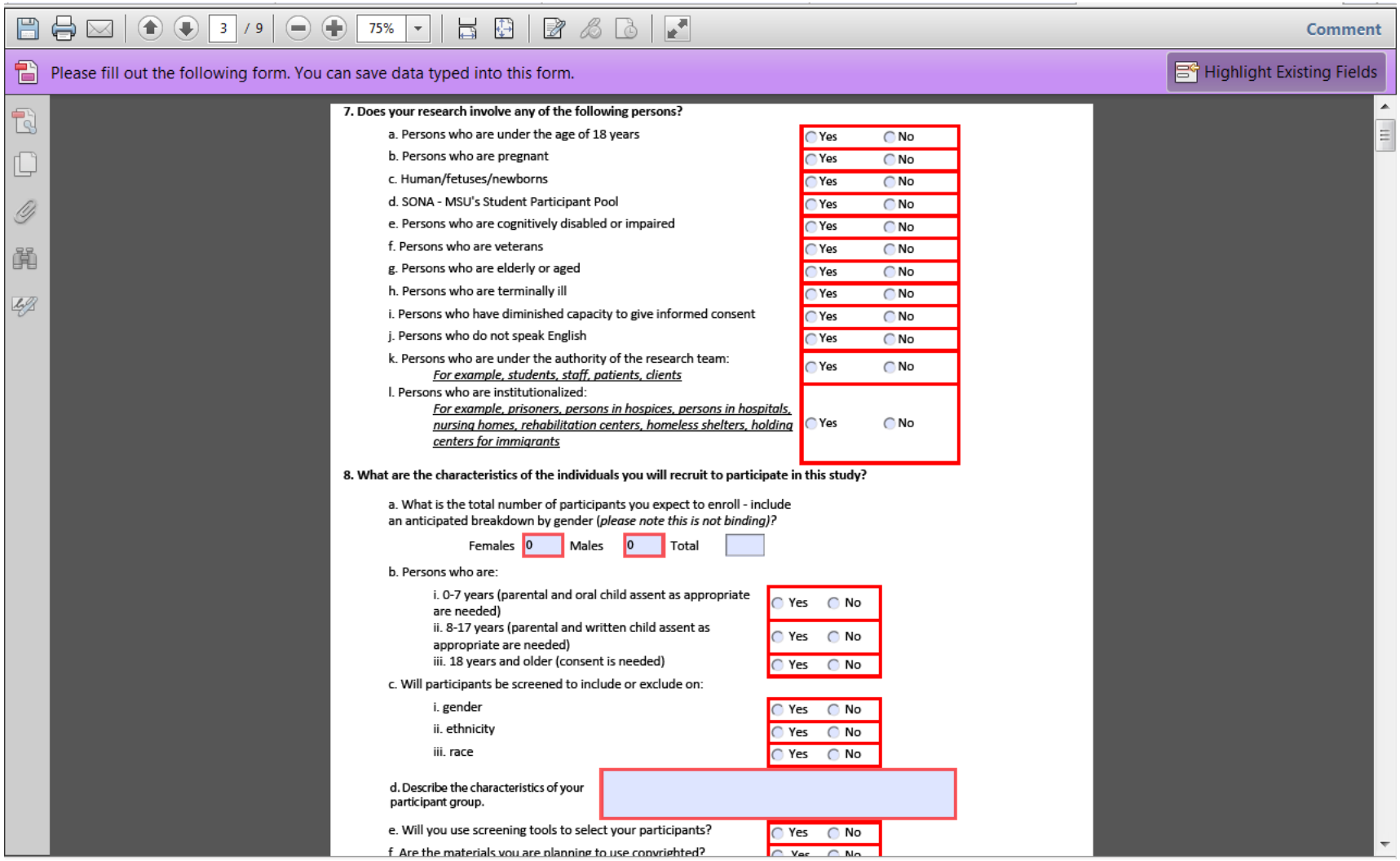
Department

Address City State

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)

THE IRB APPLICATION



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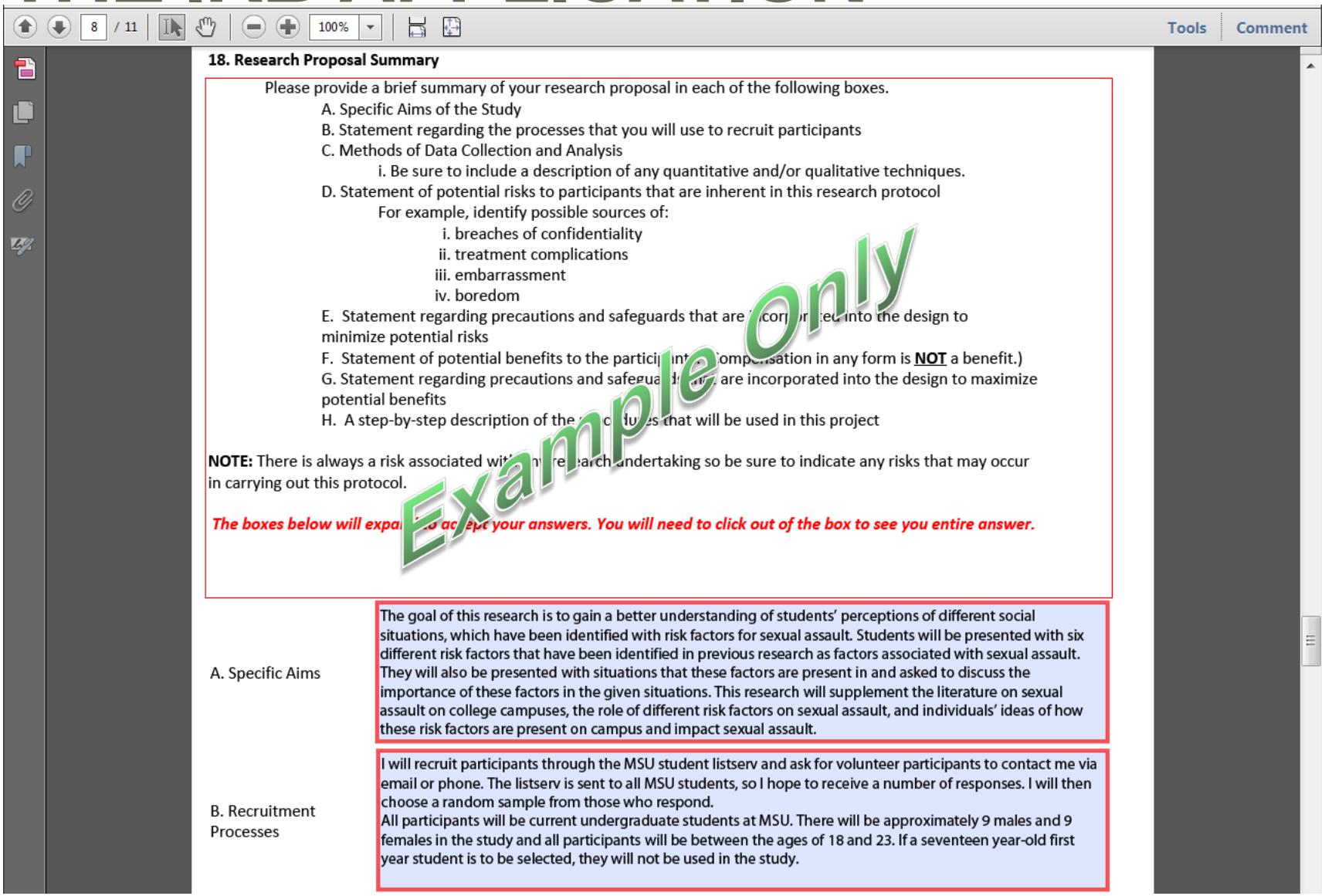
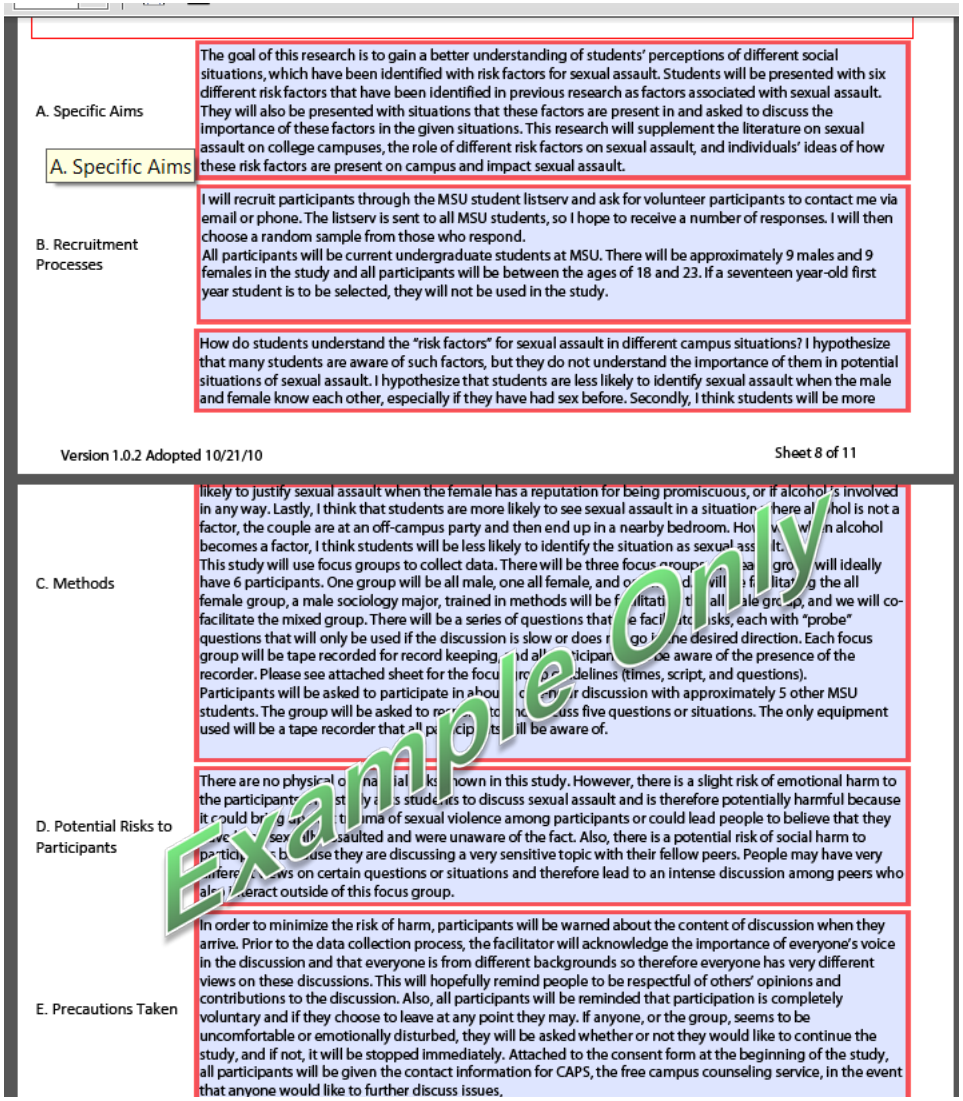


THE IRB APPLICATION



A. Specific Aims	The goal of this research is to gain a better understanding of students' perceptions of different social situations, which have been identified with risk factors for sexual assault. Students will be presented with six different risk factors that have been identified in previous research as factors associated with sexual assault. They will also be presented with situations that these factors are present in and asked to discuss the importance of these factors in the given situations. This research will supplement the literature on sexual assault on college campuses, the role of different risk factors on sexual assault, and individuals' ideas of how these risk factors are present on campus and impact sexual assault.
B. Recruitment Processes	I will recruit participants through the MSU student listserv and ask for volunteer participants to contact me via email or phone. The listserv is sent to all MSU students, so I hope to receive a number of responses. I will then choose a random sample from those who respond. All participants will be current undergraduate students at MSU. There will be approximately 9 males and 9 females in the study and all participants will be between the ages of 18 and 23. If a seventeen year-old first year student is to be selected, they will not be used in the study.
	How do students understand the "risk factors" for sexual assault in different campus situations? I hypothesize that many students are aware of such factors, but they do not understand the importance of them in potential situations of sexual assault. I hypothesize that students are less likely to identify sexual assault when the male and female know each other, especially if they have had sex before. Secondly, I think students will be more

Version 1.0.2 Adopted 10/21/10 Sheet 8 of 11

C. Methods	likely to justify sexual assault when the female has a reputation for being promiscuous, or if alcohol is involved in any way. Lastly, I think that students are more likely to see sexual assault in a situation where alcohol is not a factor, the couple are at an off-campus party and then end up in a nearby bedroom. How when alcohol becomes a factor, I think students will be less likely to identify the situation as sexual assault. This study will use focus groups to collect data. There will be three focus groups, each group will ideally have 6 participants. One group will be all male, one all female, and one mixed. I will facilitating the all female group, a male sociology major, trained in methods will be facilitating the all male group, and we will co-facilitate the mixed group. There will be a series of questions that are facilitator risks, each with "probe" questions that will only be used if the discussion is slow or does not go in the desired direction. Each focus group will be tape recorded for record keeping, and all participants will be aware of the presence of the recorder. Please see attached sheet for the focus group guidelines (times, script, and questions). Participants will be asked to participate in about one hour discussion with approximately 5 other MSU students. The group will be asked to respond to and discuss five questions or situations. The only equipment used will be a tape recorder that all participants will be aware of.
D. Potential Risks to Participants	There are no physical or financial risks known in this study. However, there is a slight risk of emotional harm to the participants as they are asked as students to discuss sexual assault and is therefore potentially harmful because it could bring up the trauma of sexual violence among participants or could lead people to believe that they have been sexually assaulted and were unaware of the fact. Also, there is a potential risk of social harm to participants because they are discussing a very sensitive topic with their fellow peers. People may have very different views on certain questions or situations and therefore lead to an intense discussion among peers who already interact outside of this focus group.
E. Precautions Taken	In order to minimize the risk of harm, participants will be warned about the content of discussion when they arrive. Prior to the data collection process, the facilitator will acknowledge the importance of everyone's voice in the discussion and that everyone is from different backgrounds so therefore everyone has very different views on these discussions. This will hopefully remind people to be respectful of others' opinions and contributions to the discussion. Also, all participants will be reminded that participation is completely voluntary and if they choose to leave at any point they may. If anyone, or the group, seems to be uncomfortable or emotionally disturbed, they will be asked whether or not they would like to continue the study, and if not, it will be stopped immediately. Attached to the consent form at the beginning of the study, all participants will be given the contact information for CAPS, the free campus counseling service, in the event that anyone would like to further discuss issues.

Checklist: Documents for IRB submission

- CITI training completed
- Application completed with signatures
- Consent form
  - Translated consent forms if applicable
- Site agreements
  - for any and all off-campus research sites
- Recruitment material (flyer, ads, emails, brochures etc.)
- Scripts (e.g. in person pleas)
- Grant proposal
- Data collection instrument (survey, interview questions etc.)

How to make changes in Initial Application:

- Non-Mac Users
  - Delete the signature
  - Make changes
  - Sign and send

Save an unsigned copy!

- Mac Users – Electronically signing application locks it forever
  - Always save an **unsigned** application in latest version
  - Use **unsigned** application to make changes on – save again as latest version
  - Sign and save as another file so it can be sent into IRB

Three categories (45 CFR 46.109)

- Exempt
  - (subcategories 1-6)
- Expedited
  - (subcategories 1-9)
- Full Board
  - (subcategories 1-10)

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

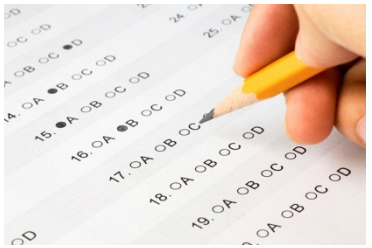
- ***Exempt*** Review- Goal: 3 to 4 weeks

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)
  - Expedited: Curriculum program evaluation involving surveys
  - 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: 4 to 6 weeks

Criteria for full board

- Research activities that present **greater than minimal risk** to human subjects
- Triggers
  - 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
  - Population involves persons with cognitive disabilities
  - Pregnant women
  - Medically invasive, e.g., clinical trial
- ***Full Review***- Goal: 6 to 8 weeks (involves review of entire committee)

When are you submitting your application?

Before December 15:

- Use current Adobe forms application found on IRB webpage
- Want to go over your application before submitting, make an appointment for an IRB pre-review.

After December 15:

- Use current Adobe forms application found on IRB webpage
- **Or** use Cayuse eIRB system
- Want to go over your application before submitting, make an appointment for an IRB pre-review.

Sometime in early 2016, we will transfer to only using Cayuse eIRB for new submissions.

- No paper applications
- Completely online submissions
- Ease of communication back and forth with IRB
- All approved documents available online 24/7

IRB Deadlines

(all applications are accepted on rolling basis; deadlines will apply for Full Board studies)

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	*Meeting Date for Full Review*
June 19, 2015	**July 15, 2015**
July 17, 2015	August 19, 2015
August 17, 2015	**September 16, 2015**
September 28, 2015	October 21, 2015
October 19, 2015	**November 18, 2015**
November 16, 2015	December 16, 2015
December 28, 2015	**January 20, 2016**

IRB 101 TOP TIPS TO IRB SUBMISSION

IRB 101:
TIP #1 Complete submission

- Obtain all signatures
- Answer every question
- Attach your grant proposal and match the title (if applicable) Also title match on Consent Documents
- Use **mail.montclair.edu** email address for submissions
  - Fill in Subject Line and Body of Email – next slide

Emailing the IRB

-------- Original Message --------
Subject:IRB Application - James Force
Date: Mon, 27 Jan 2014 19:46:31 -0500
From:[redacted]
To: Reviewboard <reviewboard@mail.montclair.edu>

Review Board,

I am submitting an application for the experiment I am running for my Master's Thesis in General Psychology. Attached are all the documents that are required as per Page 10 on the IRB Application. There should be....
-The IRB Application itself
-Consent Form 1
-Consent Form 2
-Debriefing Form
-Pilot Study Consent Form
-SONA Script
-In-Person Plea Script
-Script for the experiment itself (Script Draft JF)
-Restraint Scale
-Writing Task Prompts
The file names of all of my documents are as written above, and also have my initials (JF) at the end of them. One thing to note: the IRB Application attached to this email is completed but is missing my Faculty Sponsor's signature since that part cannot be digitally signed. I have a physical copy of the application with my Faculty

IRB 101:
TIP #2 Clear research design

- What will you do? In simple and clear terms
  - Participant observation; Surveys; or Interviews
  - Intervention
  - Deception or Incomplete disclosure
- Clearly describe your benefits
- Do not copy and paste your entire grant proposal, thesis, or manuscript

Instrument Design for Online Surveys

- MSU IRB does not require use of one survey tool
- Survey tools
  - MSU survey https://surveys.montclair.edu/survey/login.jsp?r=1
    - Only one screen; difficult to consent unless you create 2 surveys
  - MSU limesurvey https://oit-app2.montclair.edu/msusurvey/admin/admin.php
    - Data stored in-house; similar features to survey monkey
- Other survey tools:
- http://idealware.org/articles/fgt_online_surveys.php
- For consent use the template for implied consent for online surveys

IRB 101:
TIP #3 Proper 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
- 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
- Ask for help!

IRB 101:
TIP #4 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
- Eligibility?
  - If it applies – include it! i.e. “Recruiting right-handed males over the age of 25.”

Example of requested revisions from a reviewer

- **Application**
- # 13: Please revise the last sentence to read as follow "According to regulations, all data but audio files, will be kept for a minimum of 3 years after project completion, before being destroyed."
- #17i – PI has marked that they will request permission from the participants to use data in future studies. Please add that permission (see consent template) to the Consent Form.
- #18B - PI plans to interview 10 people from online. What if more than 10 request to participate? How will PI select who is included and who is excluded from participation?
- **Consent Form**
- Change time to reflect time noted on application form.
- Include benefits to your field of study.

IRB 101:
TIP #5 Data security, privacy, and storage

- 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

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 app?
- 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?

Data Security and Storage - Examples

- Data Storage
  - The data will be stored on a partitioned, password protected sub-directory on a password protected work stations, stored in a locked office on the campus of Montclair State University. 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.

IRB 101: TIP #6 Inclusion of risks to participants

- Risks 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

IRB 101: TIP #7
Dealing with risk and disclosure

- 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.

IRB 101: TIP #8
Dealing with risk and disclosure - examples

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.

Focus Group – added 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."

IRB 101: TIP #8
dealing with risk and disclosure - examples

While you are in this study, you may feel upset about something we ask you. If something that you talk about makes you feel upset, we will give you the name of someone who can help you. You may be worried that something you say will not be kept private. We use a code number for each person in the study. We never use your name. The interviewer will never give any personal information about you to anyone. The only time the interviewer would tell anyone about you, is if you or your baby were in danger. That means things like child abuse or sexual abuse. When we talk about the study, we will ONLY talk about the entire group of girls and babies in this study. No one, except your social worker or the person who gives you the services will know that you are in the study. * courtesy of Dr. Lisa Lieberman

During this interview, we will ask you some questions about your age, who you live with, whether you are married or single, if you use drugs, if you have HIV and if you have any other medical problems. We will note down your answer to these questions. Your answers could be risky outside of this research because it could get you arrested, or you could lose your job, or your reputation. But, we will make every effort to make sure that your information is kept private. We will conduct the interview in a private room at _____. We will never share your personal information with anyone outside of the research. If any of the questions make you uncomfortable, with your permission, we will refer you to your counselor or case manager who can assist you. *courtesy of Dr. Meena Mahadevan

IRB 101: TIP #8
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: what now?

- Use the stamped consent form(s) and other documents for your study participants (everyone gets a CF copy)
- Report any adverse events to the IRB within 72 hours
- Apply for an amendment approval if you plan to change your research protocol
- Add research team members using the IRB amendment application to add/change personnel
- Don’t let your approval expire!
- Once your study is complete and you are done with data analysis submit a project completion form

IRB/Compliance contact information

- IRB Coordinator: Amy Krenzer
  - reviewboard@mail.montclair.edu
  - 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: College Hall 248