IRB:

HUMAN SUBJECTS PROTECTION PROGRAM

Hila Berger, MPH, CIP Research Compliance Administrator

IRB authority and responsibility

- 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)
- It is the IRB Mission
- IT IS ETHICAL!



IRB Committee and Staff

- 12 Faculty/2 community members
- 2 staff

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.



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.

Not human subjects research*

- A student's classroom projects
- Teacher evaluations
- Literature Reviews
- Journalism
- Some market research
- Accreditation process
- Internal Quality assurance

*these are general headings and should not be considered a method for determining whether a project or activity requires IRB review.

Human Subjects research (HSR)?

NOT HSR!

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

YES HSR!

 Faculty member surveys and interviews students on their experiences using an e-reader with the curriculum to present at conferences

Human Subjects research (HSR)?

 MSU Children's Center conducting surveys after their workshops.
 Administered to parents. Purpose is 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!

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 <u>reviewboard@mail.montclair.edu</u>
 - 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 REVIEW PROCEDURES AND CATEGORIES

OVERALL STEPS in Process

Researcher

- Researcher develops protocol and research plan
- 2.Researcher completes online

 Human Subjects training course
 (CITI) at citiprogram.org
- Researcher completes IRB application form
- 4.Form and attachments submitted to IRB (reviewboard@mail.montclair.edu)
- 5.Committee / Committee member review and category assignment (timeline anywhere from 3-7 weeks)
- 6. Decision in writing

Student Researcher

→ a) Student reviews research protocol with faculty sponsor

- 2a) Student & Faculty Sponsor completes online Human Subjects training course
- →3a) Student has Faculty Sponsor review and sign off on completed IRB application form before submitting

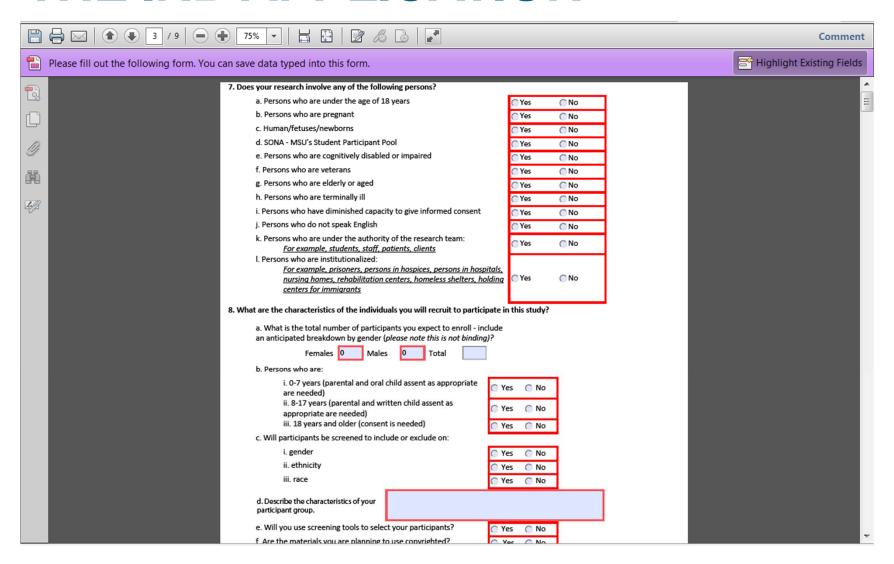
Transferring research activities to MSU

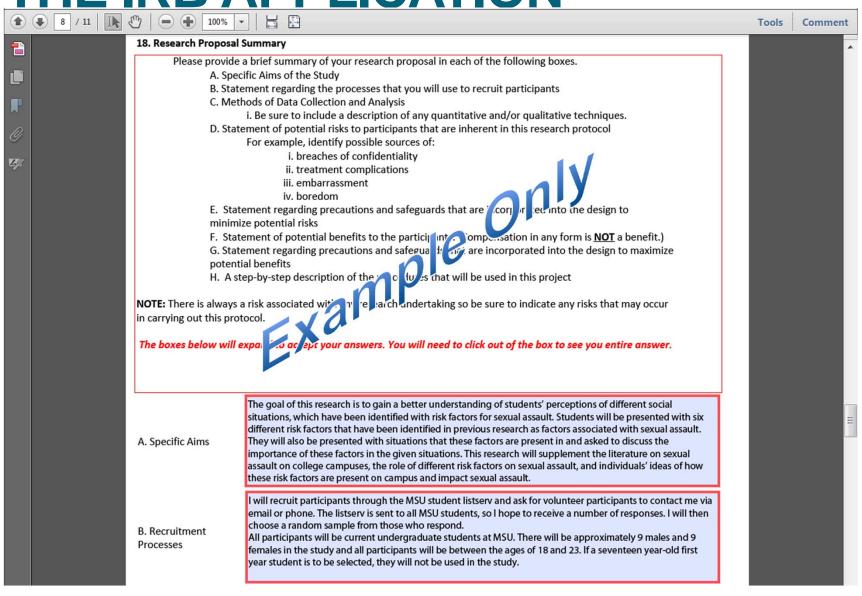
- If you have an active approval at another institution you should apply with MSU IRB
- If you are still publishing on the data and may have to revisit data you should apply with MSU IRB
- Include all previous approval letters and documentation with your full submission
- Mention your research activities conducted at your previous institution in the body of your email to reviewboard@mail.montclair.edu

Application Forms & Templates

Applications and Forms	Templates
IRB Application *Right click and save the pdf document to utilize the fillable option (Caution: Please complete two fields, save document, close, & re-open to make sure you can save this document)	Consent Form for Adults (see Improving Consent Readability Level)
Continuing Review Application	Parent/Guardian Consent Form (see Improving Consent Readability Level)
Amendment Application	Assent Form
Amendment Form to Add/Remove/Change Personnel	Debriefing Form
Amendment Form to Add Research Site(s)	Site Approval Letter
Project Completion Form	Sample of Implied Consent for Online Surveys
Research Determination Form	Electronic stationery that you can personalize for your own department
Adverse Events Form	External Investigator Policy For Non-MSU Employees or Students

	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	
9	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	
Ä	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.	
43	1. Project Title Contact Information for Principal Investigator (PI)	
	2. Title PI First Name PI Last Name	
	PI College/School	
	If you selected "Other" above, please describe your relationship to MSU	
	PI Department	
	Address City State	
	Zip Code Phone Number 8-mail 8	
	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	





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 A. Specific Aims 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 A. Specific Aims these risk factors are present on campus and impact sexual assault. I will recruit participants through the MSU student listsery and ask for volunteer participants to contact me via email or phone. The listsery 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. B. Recruitment All participants will be current undergraduate students at MSU. There will be approximately 9 males and 9 Processes 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 Sheet 8 of 11 Version 1.0.2 Adopted 10/21/10 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 : here al hol is not a factor, the couple are at an off-campus party and then end up in a nearby bedroom. Hov vt n alcohol becomes a factor, I think students will be less likely to identify the situation as sexual ass This study will use focus groups to collect data. There will be three focus groups C. Methods questions that will only be used if the discussion is slow or does n go in the desired direction. Each focus group will be tape recorded for record keeping, and a licipan and aware of the presence of the recorder. Please see attached sheet for the focus of the state of the presence of the recorder. Please see attached sheet for the focus of the state of the s Participants will be asked to participate in about o is a discussion with approximately 5 other MSU uss five questions or situations. The only equipment students. The group will be asked to recorder that all participles Il be aware of. own in this study. However, there is a slight risk of emotional harm to There are no physical or nar the participants ... y a stude as to discuss sexual assault and is therefore potentially harmful because ma of sexual violence among participants or could lead people to believe that they D. Potential Risks to aulted and were unaware of the fact. Also, there is a potential risk of social harm to **Participants** base they are discussing a very sensitive topic with their fellow peers. People may have very Nows on certain questions or situations and therefore lead to an intense discussion among peers who eract outside of this focus group. 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 E. Precautions Taken 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,

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)



Checklist: Documents for IRB submission

- Application completed with signatures
- 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.)
- Grant proposal
- Scripts (e.g. in person pleas)
- Data collection instrument (survey, interview questions etc.)



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: secondary 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)
 - 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: Four to Six weeks



Criteria for full board

- Research activities that present <u>greater than minimal</u> <u>risk</u> 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: Six to Eight weeks (involves review of entire committee)

ASK FOR HELP! IRB contact information

- IRB Coordinator: Amy Krenzer
 - reviewboard@mail.montclair.edu
 - Ext. 7583
- Research Compliance Administrator: Hila Berger
 - bergerh@mail.montclair.edu
 - Ext. 7781
- IRB Chair: Dr. Debra Zellner
 - Ext. 4327
- IRB Program Asst.: Jessica Hegyi
 - hegyij@mail.montclair.edu
 - Ext. 3021
- IRB Office: College Hall 248

PI sends submission to IRB

IRB office processing

Is the submission complete?

Sent to a reviewer

Scheduled for Full Board, Expedited or Exempt in accordance with regulations

Review Performed – either Full Board or by designated reviewer

Does the Submission Meet Criteria for Approval?

Common Problems

- Missing documents
- Documents incomplete
- Personnel not completed CITI
- No faculty sponsor signature
- Provided information is not consistent among all documents

Email sent to PI identifying problems with submission. PI asked to re-submit

Yes, Approval Processing

Approval letter and stamped documents sent to PI



No, Modifications required.

Email sent to PI with clarifications and revisions. PI must respond within 30 days

IRB 101 TOP TEN TIPS TO IRB SUBMISSION

IRB 101: TIP #1 Complete submission

- Obtain all signatures
 - Faculty sponsor signature required if you are a student
- Answer every question
 - If not applicable state "not applicable"
- Use mail.montclair.edu email address for submissions
- Using a Mac? Save an unsigned version first.
- To make changes, you must first delete your electronic signature
- Attach your grant proposal and match the title

IRB 101: TIP #2 Clear research design

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

IRB 101:

TIP #3 Proper Informed consent

- Understand Consent vs. Assent
- Alternatives to consent may be an option
- Template available online only to be used as outline
 - Remove audio and video request on consent form if you are not audio or video recording
- 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!

CONSENT Example... explaining the study

Poor

This survey is about cervical cancer and screening

- Screening what?
- Cervical cancer risk?
- Cervical cancer symptoms?

Better

This survey will ask you questions about perception of cervical cancer risk and screening behaviors of college aged female students. I hope to learn about what young women know about cervical cancer and risk factors, how they perceive risk, and how that effects whether or not they have been screened for cervical cancer.

IRB 101: TIP #4 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
 - <u>FAQs</u> online provide options
- Using SONA (Psychology department)
 - SONA is a course requirement for certain psych courses; 1 SONA credit=1 hour of research time
 - Population is accessible to Psych faculty and psych graduate researchers only
 - If you are using SONA you cannot also pay your subjects

Recruitment Example

- This study will be recruiting at MSU
 - This study will recruit 30 students and 30 staff members at MSU.
 - Students: We will be soliciting students outside the student center. Students
 agreeing to be involved will be given contact information to the study
 coordinator. The coordinator will email the consent form to interested
 participants. Only students that return the signed consent form will receive a
 link to the survey.
 - Staff: Staff will be solicited through the for sale listserv accessible to all students and staff. The email plea is attached with this application....
- am recruiting my own students
 - The faculty member will leave the room 15 minutes prior to the end of class. The GA will enter the room explain the study and hand out consent forms. Students can choose to complete the consent form and survey or leave the class with no obligation. The GA will collect the signed consent form and completed survey in separate envelopes. Results will only be available to the PI after grades are submitted.

IRB 101: TIP #5 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

IRB 101: TIP #6 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
- Have you asked your participants if they can be recorded or videotaped?
- Data retention
 - Policy is for 4 years after project completion

Data Security and Storage cont'd

Data Storage

 The data will be stored on a partitioned, password protected subdirectory 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 #7 Inclusion of risks to participants

- No study is without risk
- 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 #8 Dealing with risk and disclosure

- TOPICS mental health, violent attacks
 - Counseling and Psychological Services (CAPS)
 - Other counseling services
- Referrals
 - Health Care Provider
 - Therapist
- International Research
 - International standards and regulations are considered as part of the MSU IRB review.
 - 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 in ordinary life. If you feel uncomfortable of 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.

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 #9 Understanding faculty sponsorship

- FS is affirming research design and implementation by signing application
- FS should provide training and oversight of student in conducting research
- Signature line on consent form (required but only required to be present for certain studies)
- 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.

IRB 101: TIP #10 Working with your own students

NOTE: If one's own students are used as subjects, the investigator must explain why he or she cannot use another instructor's students, and he or she must follow one of the following procedures:

- 1. Use a third party for recruiting subjects, obtaining consent, and collecting data (including interviewing). The data must be held by the third party and not given to the instructor until the course is completed and grades are submitted.
- 2. If data you are using are the assignments of students that would normally be given during the course you may request from each student permission to use the student's work AFTER the course is completed and grades are submitted.
- 3. If the study is anonymous, the instructor may perform the study. In such a study, no signatures or identifiers or any kind are obtained. The instructor passes out an informed consent document to the class. A survey is handed out or emailed to everyone. The instructor then tells the class that if anyone would like to complete the survey, they may do so outside of class time and leave the survey in a designated location other than the classroom.

Misconceptions about the IRB and the review process

- The IRB Chair makes the decision of whether or not your project is approved.
- Each application is assigned to a different board member to review and approve. Full category studies are reviewed by the entire board.
- Amy Krenzer, IRB Coordinator, sends you her comments.
- Amy forwards to you the comments of the IRB reviewer.
- The IRB Board does not want to approve human subject research.
- We are here for the soul purpose of protecting human research subjects and approving applications to ensure the ethical conduct of research
- Board members are paid.
- Board members are volunteers; they volunteer their time and effort.
- All submissions need review at the monthly full board meeting.
- Only full category applications are reviewed by the full board. Exempt and expedited reviews are done by individual IRB reviewers.

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 <u>adverse events</u> 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 <u>approval</u> expire!
- Once your study is complete and you are done with data analysis submit a project completion form

IRB Deadlines



ASK FOR HELP! IRB contact information

- IRB Coordinator: Amy Krenzer
 - reviewboard@mail.montclair.edu
 - Ext. 7583
- Research Compliance Administrator: Hila Berger
 - bergerh@mail.montclair.edu
 - Ext. 7781
- IRB Chair: Dr. Debra Zellner
 - Ext. 4327
- IRB Program Asst.: Jessica Hegyi
 - hegyij@mail.montclair.edu
 - Ext. 3021
- IRB Office: College Hall 248

Additional resources

- Additional Workshops
- http://www.montclair.edu/provost/researchintegrity-and-compliance/training/
- To adjust readability on consent form:
- http://www.montclair.edu/provost/institutionalreview-board/forms/
 - Select "Improving Consent Readability" document
- Templates for consent form/debriefing:
- http://www.montclair.edu/provost/institutionalreview-board/forms/
- Federal Guidelines:
 - http://www.hhs.gov/ohrp/