IRB 101:
HUMAN SUBJECTS PROTECTION PROGRAM

Wednesday, April 23, 2014
Cohen Lounge

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Research Compliance Administrator

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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

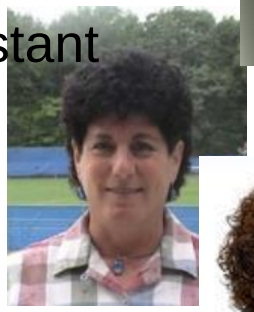
IT IS ETHICAL!

IRB Mission

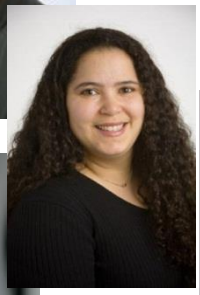
- to support faculty, staff, students to complete their research in compliance with federal and state laws and MSU policy. As such, the IRB is charged to review, approve initiation of, and conduct periodic reviews of research projects that involve human participants.

IRB Committee and Staff

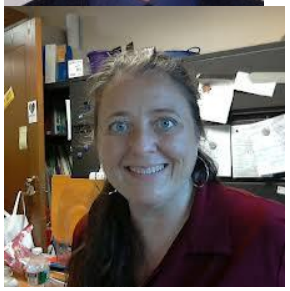
- 12 Faculty/1 community members
- Amy Krenzer, CIP, IRB coordinator
- Mylka Biascochea, IRB Program Assistant
- Raja Gounder, IRB Grad Student Assistant












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)?

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

A - yes HSR

B - n 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!

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

OVERALL STEPS in Process

Researcher

1. Researcher develops protocol and research plan
2. Researcher completes online Human Subjects training course (CITI)
3. 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

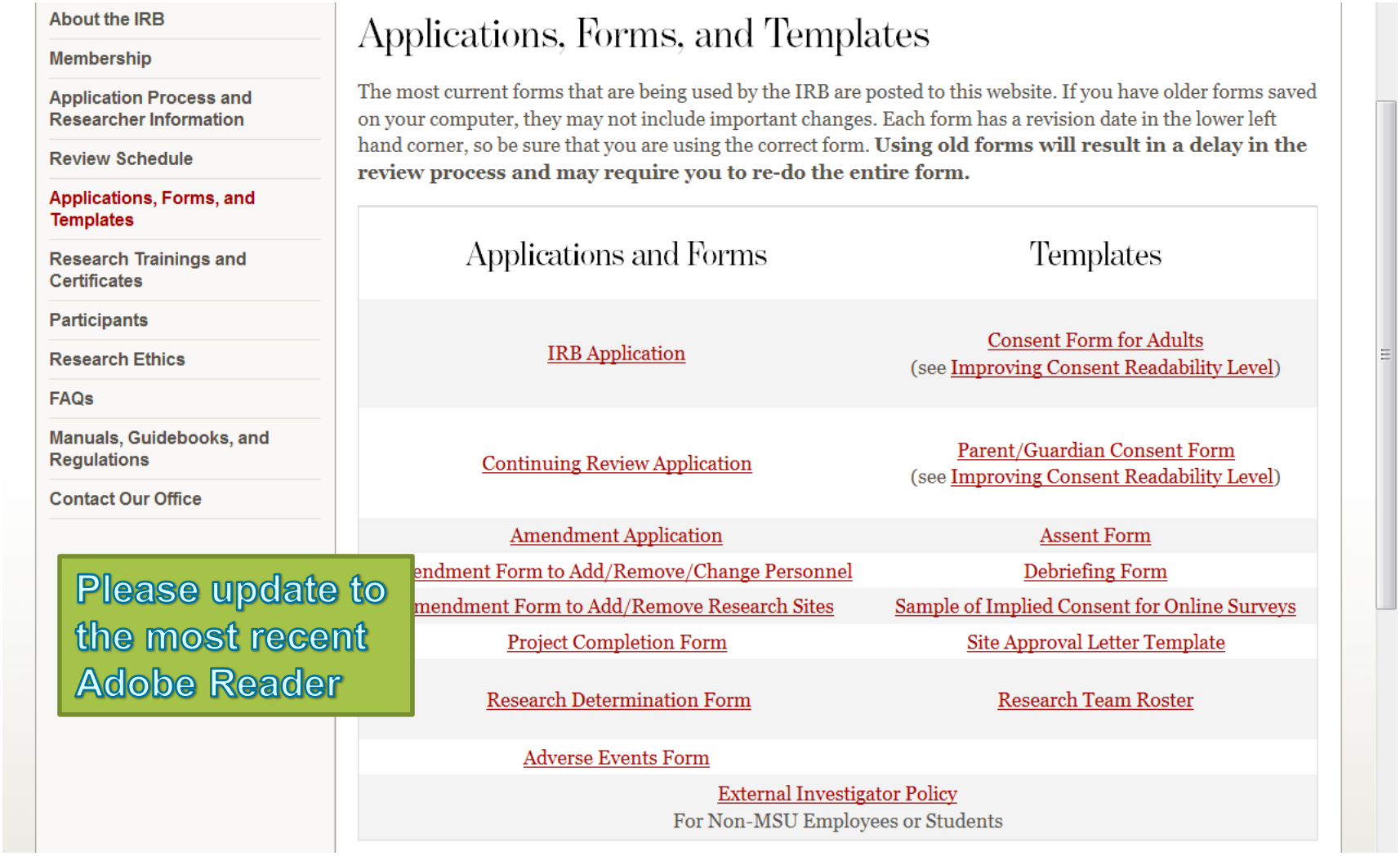
Student Researcher

1a) Student reviews research protocol with faculty sponsor

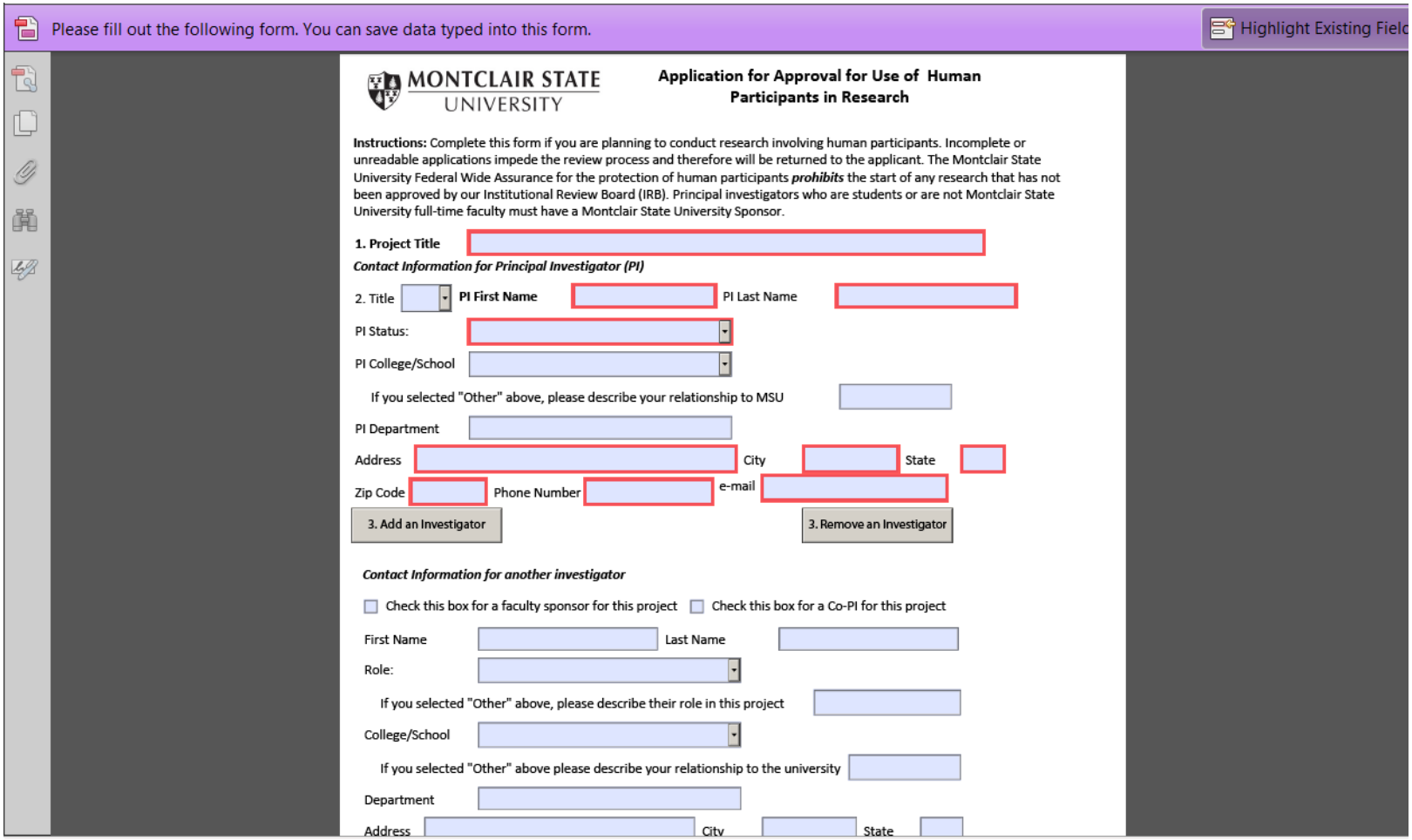
2a) Student & Faculty Sponsor completes online Human Subjects training course

3a) Student has Faculty Sponsor review and sign off on completed IRB application form before submitting

Application Forms & Templates



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

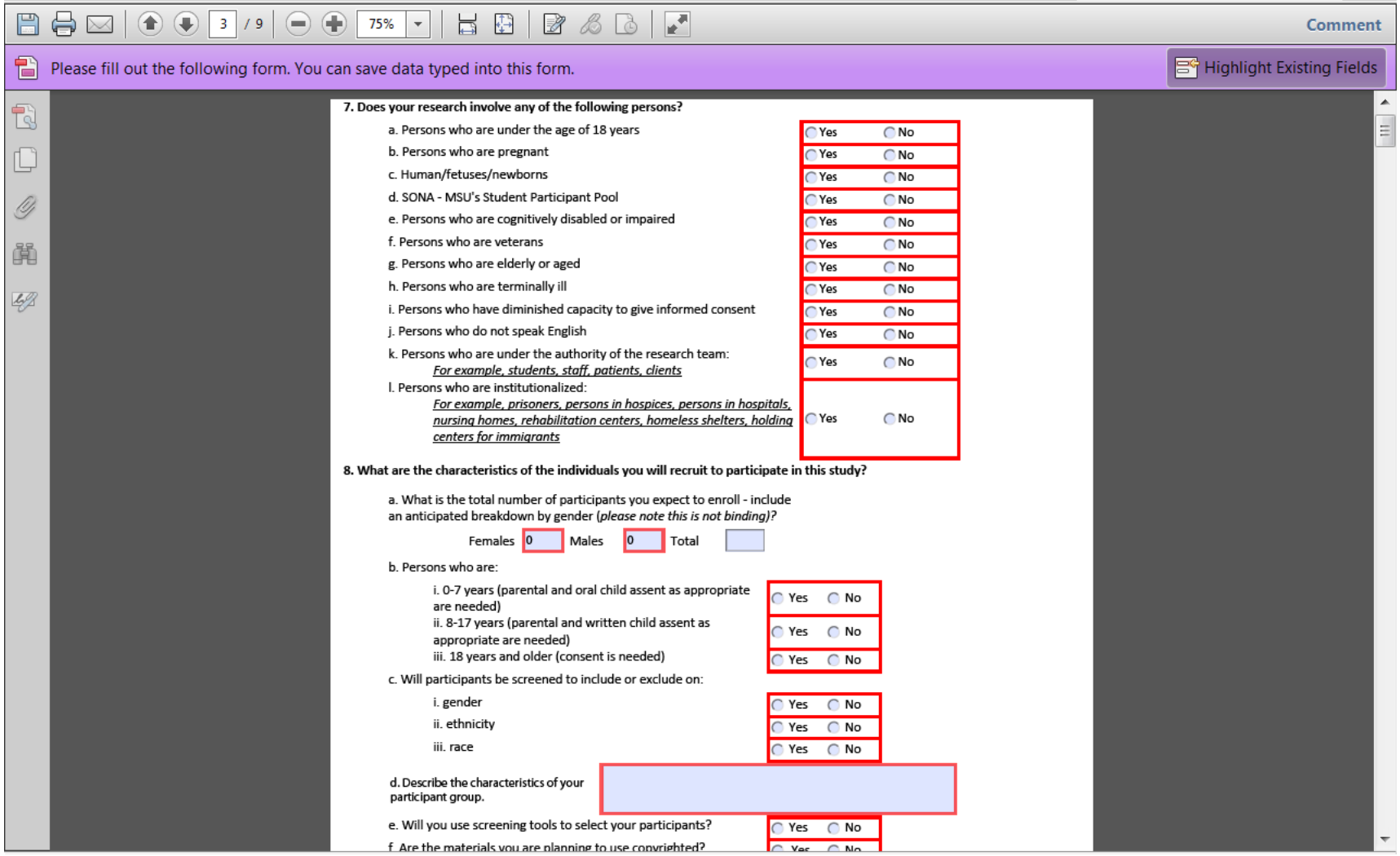
Department

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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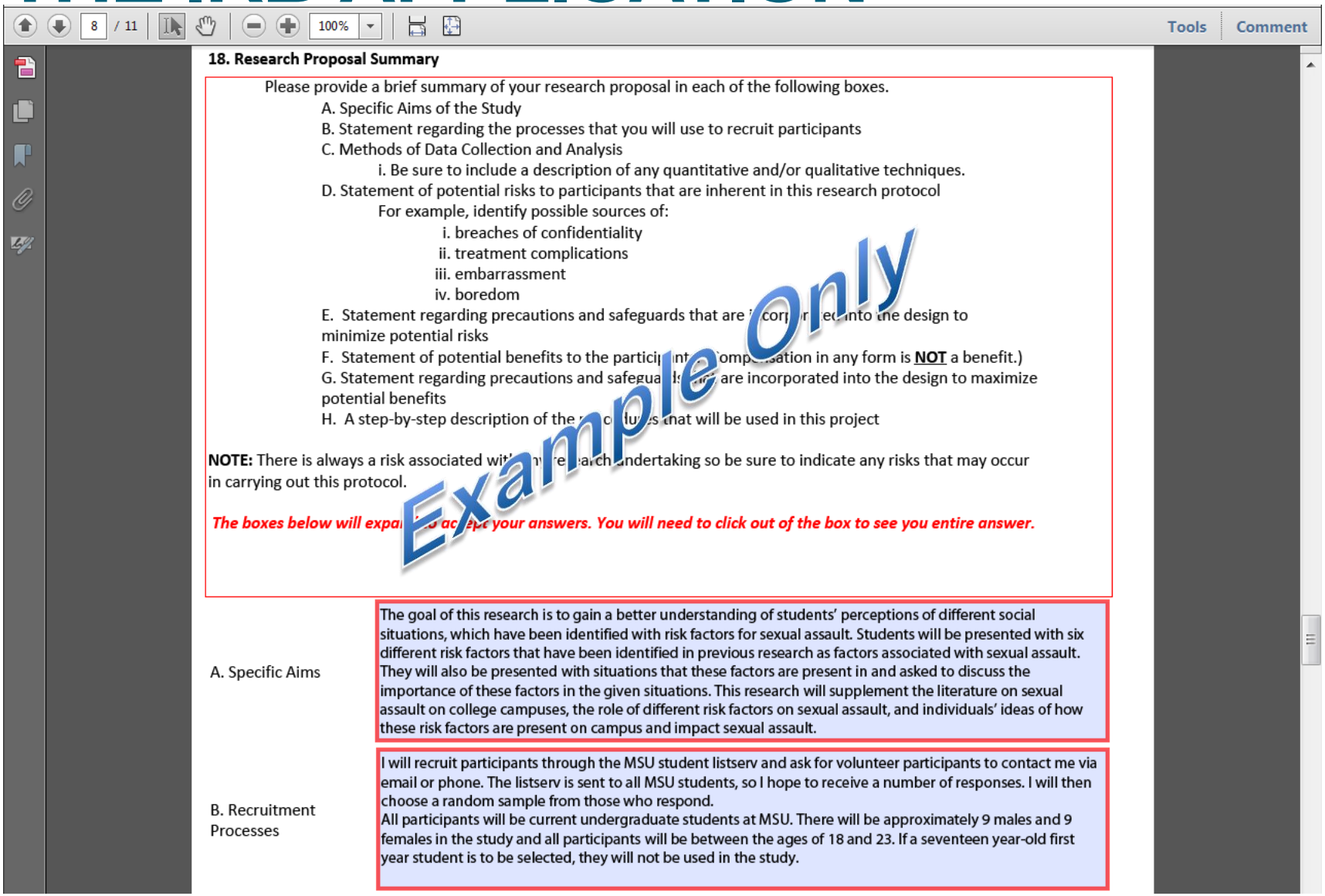

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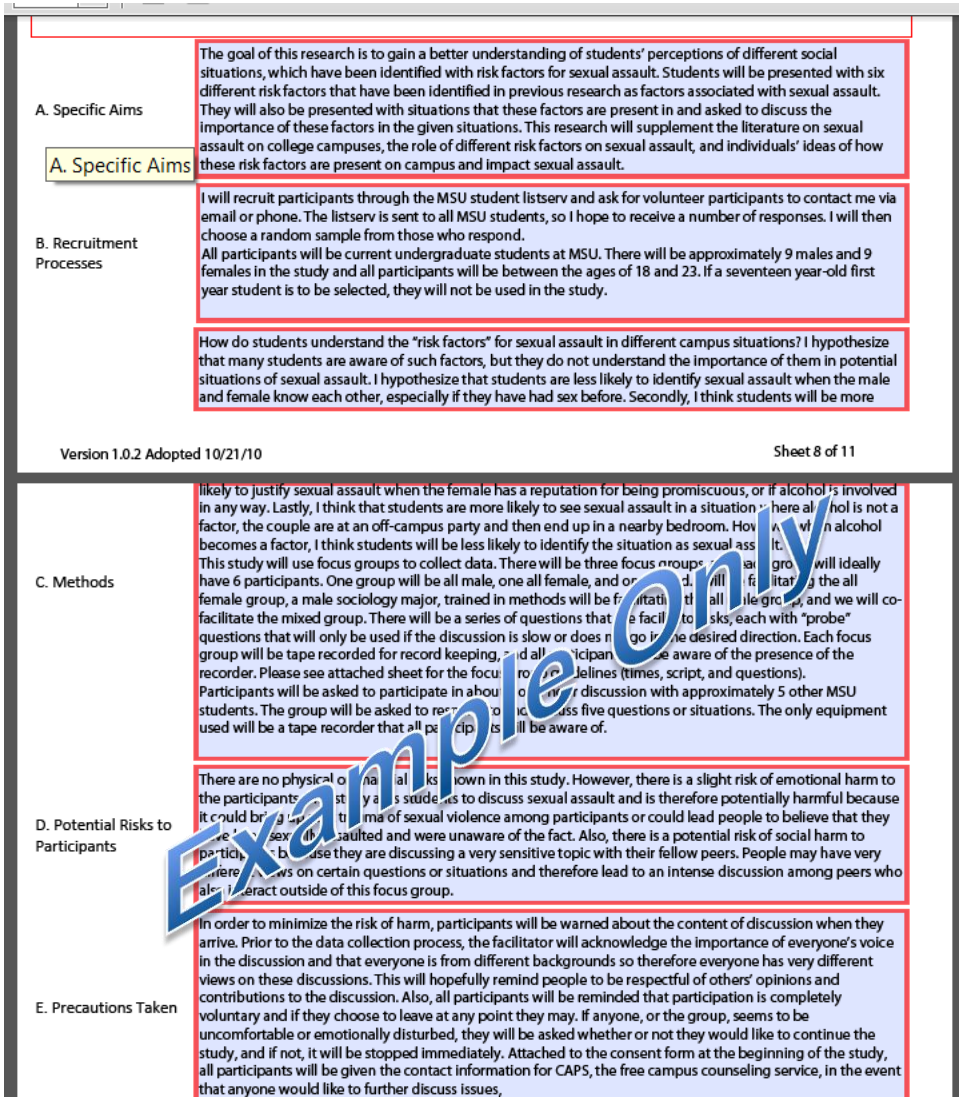

A. Specific Aims	The goal of this research is to gain a better understanding of students' perceptions of different social situations, which have been identified with risk factors for sexual assault. Students will be presented with six different risk factors that have been identified in previous research 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.
A. Specific Aims	
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

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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. However, 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 facilitate 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 facilitated to discuss, 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 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 as to discuss sexual assault and is therefore potentially harmful because it could bring up traumas of sexual violence among participants or could lead people to believe that they were 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 also 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.)

Example of requested revisions from a reviewer

- Application
- #4 - List yourself and all research team members.
- #7D - Change response to 'No' since you cannot access SONA participant pool (only for Psychology dept.)
- #16D - Left blank. Even though you may not anticipate an adverse event - you need to verify your understanding of the process for reporting an adverse event or unanticipated problem to the MSU IRB.
- #17B - MSU IRB policy as stated under #17 "All research data must be maintained for at least four years after the project is closed out or results published whichever occurs last." Please revise your answer. (ALSO correct in #18H)
- #17J-K - Please revise your process to indicate how you will make use of 3rd party recruiting and data collection in any classes in which you are the professor (also update in question #18 for all steps involved)
- Consent Form - Please submit, follow the template on our webpage
- Script and Information Sheet mentions an envelope for results, nothing is indicated in question #18H involving how finished surveys are handed in.

How to make changes in Initial Application:

- Non-Mac Users
  - Delete the signature
  - Make changes
  - Sign and send
- 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 de-identified existing data set

- Example: regular classroom activity where results are now intended for research

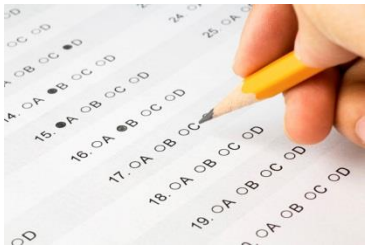
- ***Exempt*** Review- Goal: 3 to 4 weeks

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)

IRB Deadlines

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)
- 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
  - 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!

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 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 #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 4 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 a 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 Transmission

- Email is not secure
  - No built-in encryption
  - Hard to delete from email (email servicer keeps a copy)
- Alternatives
    - Internal MSU fileHAWK
    - External transfers systems that offer encryption

Data Security and Storage

- 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

- 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 #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
  - 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
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 Administrator: Hila Berger
  - bergerh@mail.montclair.edu
  - Ext. 7781
- IRB Chair: Dr. Katrina Bulkley
  - Ext. 5189
- IRB Office: College Hall 248