IRB 101: Human Subjects Protection Program

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Compliance Administrator
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 TEN TIPS
So Why Bother...

- Bound by law 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
- It is the IRB Mission
- 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.
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)?

**YES HSR!**
- Survey of high school aged teenagers in NJ on their use of Facebook. Results to be generalizable to all teenagers and published in NJ Education magazine

**NOT HSR!**
- High school teacher asking their students to do conduct a survey about Facebook and report back to the class only.
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)?

**NOT HSR!**
- MSU journalist interviewing students about their political opinions to post on MSU website as a media article

**YES HSR!**
- Audiotaping and recording community members on their political grievances in a foreign country for publishing in dissertation
Not sure if what you are doing is human subjects research?

- Submit a Research determination form
  - Available at: http://www.montclair.edu/ORSP/irb/investigator/forms.html
  - To reviewboard@mail.montclair.edu
  - Call or email the IRB for further clarification
- IRB Chair or designated member will get back to you within 5 business days to determine if you need to submit a full IRB application
OVERALL STEPS in Process

**Researcher**
1. Researcher develops protocol and research plan
2. Researcher completes online Human Subjects training course
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 2-6 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
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 procedure and form (45 CFR 46.116)
  - accurately reflect the study
  - written in simple lay language
  - appropriate to the participant pool (language)
- Other documents (flyers, ads, scripts)
THE IRB APPLICATION

Q1-Q3: PI information
Q4: Training
Q5: Funding
Q6: General Information about the Proposal
Q7: Vulnerable Populations
Q8: Description of Study Population
Q9: Methods or data involving added risk
Q10: Mitigation of identified risks
THE IRB APPLICATION CONT'D

Q11: Research Site
Q12: Recruitment Material
Q13-Q14: Data collection methods
Q15: Informed Consent Process
Q16: Procedures for adverse events
Q17: Data Retention
Q18: Summary of the procedures and methods
Q19: Signatures
Documents for IRB submission

- Application
- Consent form
  - Translated consent forms
- Site agreements
- Recruitment material (flyer, ad, brochure etc.)
- Certificate of human subjects training
- Grant proposal
- Scripts
- Data collection instrument (survey, interview questions etc.)
IRB REVIEW PROCEDURES and categories
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 publicly available existing data set

**Exempt** Review- Goal: One to Two 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: 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 greater than minimal risk to human subjects
- Triggers
  - Medically invasive, e.g., clinical trial
  - Coercion
  - Deception or incomplete disclosure
  - 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
- People with cognitive disabilities
- Pregnant women
- **Full Review** Goal: Six to Eight weeks
Extra attention to Vulnerable populations

- Children
- Pregnant Women
- Teens
- Prisoners
- Cognitively Disabled
- Ethnic groups
IRB 101:
Tip #1 Complete submission

- Obtain all signatures
  - Faculty sponsor signature required if you are a student
- Attach all your certificates
- Answer every question
  - If not applicable state “not applicable”
IRB 101:
TIP #2 clear research design

- Do not copy and paste your entire grant proposal or manuscript
- What will you do? In simple and clear terms
- Data
  - Describe your collection methods
- Clearly describe your benefits
IRB 101: TIP #3 proper Informed consent

- Understand Consent vs. assent
- Documented vs. undocumented consent
- 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 – 8th grade reading level
- Ask for help!
IRB 101: Tip #4 Recruitment

- Determine who your study population is
- If you are using your own students or staff then you must adjust your data collection to avoid undue coercion
- Using SONA
  - SONA is a course requirement for certain psych courses; 1 SONA credit = 1 hour of research time
  - Population is accessible to Psych faculty researchers and psych major grad students only
  - If you are using SONA you cannot pay your subjects
IRB 101:
**TIP #5 be consistent**

- Be careful using terms like Confidential or anonymous
- Participation time should be the same in application and in your consent form
**IRB 101:**

**TIP #6 Data security/PRIVACY**

- What identifiers are you keeping?
  - Limit identifiers
  - Plan for confidentiality
- Are you reporting data in aggregate?
- Have you asked your participants if they can be recorded or videotaped?
- Data retention
  - Policy is for 4 years after project completion
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
IRB 101: TIP #8
dealing with risk and disclosure

- Counseling and Psychological Services (CAPS)
- Other counseling services
- Content specific resources
- Referrals
- Consider a waiver of documenting consent; only if it is the single identifying link to your sensitive data
IRB 101: TIP #8
dealing with risk and disclosure - examples

- The risks are no greater than those in ordinary 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.
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
IRB 101: TIP #8
dealing with risk and disclosure - examples

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
Understand faculty sponsorship

- Faculty sponsor is affirming research design by signing your application
- Your Faculty Sponsor should provide training and oversight in conducting research
- A faculty sponsor should be a permanent faculty member (adjunct faculty and faculty from other universities cannot serve as your sponsor)
IRB 101: TIP #10
Ask for Help

- Open office hours available on web
- Call our offices
- Visit our FAQs
Human Subjects Training and Responsible Conduct of Research Web-based course

CITI

https://www.citiprogram.org

http://www.montclair.edu/ORSP/RCT/index.html
# Application Forms & Templates

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<th>Applications</th>
<th>Templates</th>
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| **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**  
**Amendment Application to Add/Change/Remove personnel only**  
*Right click and save the pdf document to utilize the fillable option* |
| **Assent Form** |
| **Project Completion Form** |
| **Debriefing Form** |
| **Research Determination Form** |
| **Sample of Implied Consent Letter for Surveys** |
| **Adverse Events Form** |
| **Site Approval Letter** |
| **Electronic stationery that you can personalize for your own department** |
IRB contact information

- Compliance Administrator: Hila Berger
  - bergerh@mail.montclair.edu
  - Ext. 7781
- IRB Program Assistant: Amy Krenzer
  - reviewboard@mail.montclair.edu
  - Ext. 7583
- IRB Chair: Dr. Debra Zellner
  - Ext. 4327
- IRB Office: College Hall 248
Additional references

- To adjust readability on consent form:
  - [http://www.montclair.edu/ORSP/irb/investigator/forms.html](http://www.montclair.edu/ORSP/irb/investigator/forms.html)
    - Select “Improving Consent Readability” document

- Templates for consent form/debriefing:
  - [http://www.montclair.edu/ORSP/irb/investigator/forms.html](http://www.montclair.edu/ORSP/irb/investigator/forms.html)

- Federal Guidelines:
  - [http://www.hhs.gov/ohrp/](http://www.hhs.gov/ohrp/)
Thank you!