IRB Survival Kit: What to Do When Your Research Involves Human Participants

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Objectives

- Timeline of Human Subject Protections Events
- 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 TEN TIPS TO SUCCESSFUL SUBMISSION AND APPROVAL

Timeline of Events

1932-1972	• US Public Health Service (PHS) Tuskegee Study (PHS Syphilis Study)
1947	• WWII Medical Experiments resulted in the Nuremberg Code
1963	• Milgram "Obedience to Authority" Study
1964	• Declaration of Helsinki adopted by World Medical Association
1974	• National Research Act of 1974
1979	• The National Commission published the *Belmont Report*
1981	• Common Rule Title 45 CFR 46

So Why DO IRBs Exist…

- 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 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 members
- 2 community members

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. A summary to be 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.

Human Subjects research (HSR)?

NOT HSR!

- Collecting data by survey from factory owners. Questions are about the machinery in the plant and the product developed.

YES HSR!

- Collection data by survey from factory owners. Questions are about the number of employees in the factory, product description, salaries, and owner's educational background.

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)?

- Student conducting an interview of health educator for a research paper in class only

NOT HSR! – Classroom experience

Student may still want to consider a consent form and privacy issues

- Faculty member conducting an interview for quoting as a source in a publication. Interview includes pre-determined questions on educator's personal opinions and there is the possibility to continue interviews with more subjects

YES HSR!

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 7-10 business days to determine if you need to submit a full IRB application

IRB REVIEW PROCEDURES
AND CATEGORIES

OVERALL STEPS IN PROCESS

Researcher	Student Researcher
1. Researcher develops protocol and research plan	1a) Student reviews research protocol with faculty sponsor
2. Researcher completes online Human Subjects training course (CITI)	2a) Student & Faculty Sponsor completes online Human Subjects training course
3. Researcher completes IRB application form	3a) Student has Faculty Sponsor review and sign off on completed IRB application form before submitting
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	

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

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 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)

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.)

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 publicly available existing data set
- ***Exempt*** Review- Goal: One to Two weeks

Criteria for Expedited

- Research activities that

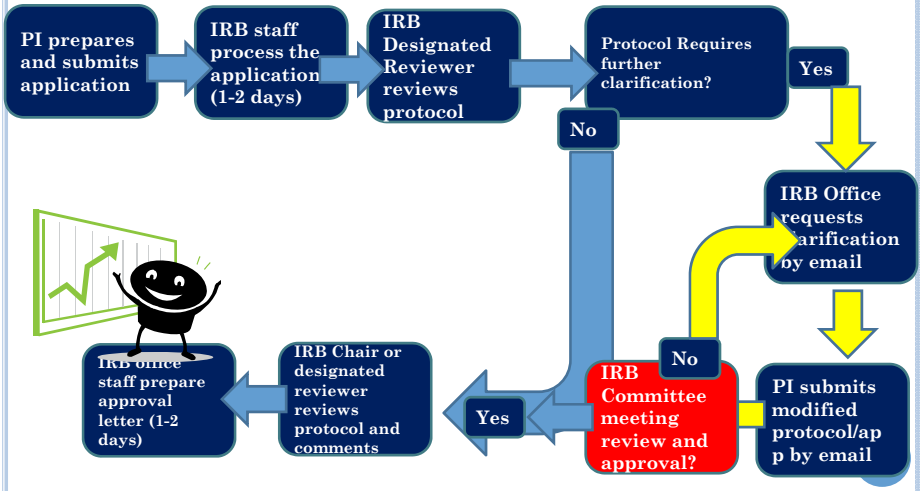
  (1) present **no more than minimal risk** to human subjects and

  (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

MSU IRB PROCESS



IRB 101 TOP TEN TIPS TO IRB SUBMISSION

IRB:
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.

IRB:
TIP #2 CLEAR RESEARCH DESIGN

- Do not copy and paste your entire thesis proposal
- 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

IRB 101:
TIP #3 PROPER INFORMED CONSENT

- Understand Consent vs. Assent
  - Assent must always be companied by Parent/Guardian 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:
TIP #4 RECRUITMENT

- Determine who your study population is
- 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 and psych graduate researchers only
  - If you are using SONA you <u>cannot</u> pay your subjects

IRB:
TIP #5 BE CONSISTENT

- Confidential vs. anonymous
  - Anonymous is only used if no one will know who participated in the research study
- Participation time should be the same in application and in your consent form

IRB :
TIP #6 DATA SECURITY/PRIVACY

- What identifiers are you keeping?
  - Limit identifiers
  - Plan for confidentiality
- Have you asked your participants if they can be recorded or videotaped?
- Data retention
  - Policy is for 4 years after project completion

IRB: 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

EXTRA ATTENTION TO VULNERABLE POPULATIONS

- Children
- Pregnant Women
- Teens
- Prisoners
  - Longer review time
  - Prisoner rep. required on committee
- Cognitively Disabled
  - Check state laws for legally authorized representatives
- Ethnic groups

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 documentation of consent if it is the only identifying link to your 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 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: 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: TIP #9

UNDERSTAND FACULTY SPONSORSHIP

- Your FS affirms research design by signing application
- FS required to train and oversee student 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: TIP #10
Ask for Help

- Open office hours available on web
- Call our offices
- Visit our FAQs

IRB Deadlines

Deadline for Submission for Full Review	*Meeting Date for Full Review (Wednesdays, unless otherwise noted)*
November 14, 2011	December 14, 2011
December 23, 2011	January 25, 2012
January 23, 2012	February 22, 2012
February 27, 2012	March 28, 2012
March 26, 2012	April 24, 2012 - Tuesday
May 7, 2012	May 30, 2012

Article Entered Into News System: ***Thursday, November 17 2011***
Article Last Edited: ***Thursday, November 17 2011***

View more articles from IRB.

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

IRB contact information

- Research Compliance Administrator: Hila Berger
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  - 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 resources

- To adjust readability on consent form:
  - 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
- Federal Guidelines:
  - http://www.hhs.gov/ohrp/