IRB Processes and Guidelines

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Outline

- Framing Principles/Thoughts for IRB
- Purpose & Components of IRB
- IRB Process at Southern
- Practice Activity
- Helpful Tips for IRB
- Questions

What You Need to Know

1. IRB is about protecting people
2. IRB is not just a graduate “hoop to jump through”
3. Timing is critical & unpredictable - error on the side of caution

THE IRB WILL MEET WITH YOU NOW.
Why would you want to talk about IRB?

- Difficult
  - Complicated, tough because it SHOULD be, it MUST be.
- Empathy
  - Starting over at Southern and learning the processes
- Welfare of Students/ Clients/ Subjects
  - We're manipulating actual people, not just chemical compounds.

Framing Principles & Thoughts

- IRB = Institutional Review Board
- Conduct as Researchers
  - Obligation to Act in the Public Good
  - Unpredictable and Potentially Risky Consequences are Inevitable
  - Research Ethics as a Balance Between "Can" and "Should"
  - Applicable to all research, but critical when human/animal subjects
- Ethical Research = Ethical Practice
  - Role of Ethical Codes or "Rules" guiding when not declaring
  - Describing what it is by what it isn't.
  - Critical role of peer or expert review

Purpose of the IRB

1. Protect the Rights and Welfare of Human Subjects
   - Why? Ethical & responsible behavior, Federal funding/monies.
   - Participants from all populations, whether aware of rights or not.
2. Protect the University
   - Protection from lawsuits.
   - Maintaining the reputation & character of the institution.
   - Did I mention money? ("Common Rule", Federal Policy, 45 CFR Part 46)
3. Protect the Researcher
   - Protection from lawsuits.
   - Unintentional errors placing subjects at risk.
Purpose of the IRB

- Research conducted in ethical manner & in compliance with established standards.
- Risks considered and minimized; potential benefits outweigh risks.
- Research subjects/volunteers provided with substantial information about study and volunteer only after researcher receives legally effective informed consent.
  - Disclosure: Enough info subjects can make informed decisions. Nature, scope, goals of research. Expected duration. Benefits reasonably expected. Foreseeable risks or discomfort. Assurance all private/identifying info will be handled with confidentiality
  - Competent: Legally competent adults unless judged otherwise. Under 18 years not competent (unless legally emancipated) requiring parent/guardian.
  - Voluntary: Absence of coercion, duress, misrepresentation, or undue inducement.

Components of IRB

- “Common Rule” 45 CFR Part 46
- IRB Approval Required for Research Using Human Participants for Both Faculty and Student Researchers
- Research: “systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge”
- Human Subject: “Living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information”

Components of IRB

- IRB Board
  - Faculty reviewers from disciplines conducting human subjects research
  - Reviewers are fellow researchers and student mentors
  - Community members provide external, non-research perspective
- Board Guidelines
  - Protection: Unnecessary stress; Harmful consequences; Participation without fully informed consent
  - Respect: Respecting the autonomy of all persons
  - Beneficence: Ethical, seeking the maximum benefit and minimal risk
  - Justice: Fair distribution of benefit and risk
Components of IRB

Preparing for Your CITI Program Training

- Belmont Report
  - Respect for Persons (Autonomy)
  - Beneficence (Risk/Benefit)
  - Justice (Fair Distribution of Risk/Benefit)
- Informed Consent
- Risk vs. Benefit
- HIPAA, FERPA
- Types of data collection & relevant considerations (e.g., audio, video, etc.)

IRB Process @ Southern

http://research.georgiasouthern.edu/researchintegrity/institutional-review-board/

- 3 important steps BEFORE research can begin:
  1. Complete online CITI training,
  2. Submit completed IRB application, and
  3. Receive IRB approval.
IRB Process @ Southern

3 important steps BEFORE research can begin:
1. Complete online CITI training
   - Certification valid for 3 Years
   - Portable to other institutions
   - Registration required, but free to students, staff, faculty

2. Submit completed IRB application
   - Balancing act between character/word limits and comprehensive info
   - Do not send in with minimal info and expect an instant response
   - IRB personnel assessing RISK to BENEFIT: Do they have enough info?
   - Utilize the handouts, templates, etc. from the COE
   - Plain, simple language so anyone can understand (e.g., Word über spellcheck)

3. Receive IRB approval
   - Minimum 1 month for expedited review and 60 business days for full review (as of Spring, 2016)
   - TIMELINE: Meet with your advisor & plan backwards
   - Think about this in terms of collecting data, revisions, giving advisor and faculty members time to review, comment, more revisions, etc.
IRB Process @ Southern

One last (important) note about the IRB Process...

- IRB Categories for Research
  - Full Review (greater than “minimal” risk, ergo full board review)
  - Expedited Review (no more than “minimal” risk, ergo Chair AND designee review)
  - Exempt from Committee Review (“low” risk, ergo Chair OR designee review)

- All 3 require informed consent, adherence to ethical guidelines, etc.
- Only “benefit” is potential IRB application timeline/turnaround

IRB Process @ Southern

- Per CFR 45, part 46, 101.3 (b), “research conducted in established or commonly accepted educational settings, involving normal educational practices….” qualifies as exempt as long as the study demonstrates participants “will not be at greater than minimal risk when they participate”

1. “commonly accepted educational settings”
2. “normal educational practices”
3. “greater than minimal risk”

IRB Process @ Southern

1. “commonly accepted educational settings”
   - Any setting where one would go to have an educational experience (e.g., public and/or private school, after-school club/program, Boy/Girl Scout meeting, professional development seminar for school district personnel, etc.)

2. “normal educational practices”
   - (i) research on regular and special education instructional strategies, or”
   - “(ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.”

- “normal”
- “Not normal”

- Test development
- Privileged info: SES, Sex/Gender, etc.
- Experimentation with instructional methods
- Students using ag (time measured in determined unit e.g., hint of assumption)
- Studies using psychological procedures that may subject the human research subject to aversive or potentially harmful concentration
- Studies using psychological procedures that may subject the human research subject to aversive or potentially harmful concentration
- Activities not recognized as “best practices” in the field
IRB Process @ Southern

3. “greater than minimal risk”
   - Vulnerable Populations
     - Children as vulnerable population requiring extra protections for minors (CFR 45 part 46, D)
   - Family Educational Rights & Privacy Act (FERPA)
     - Researcher, without normal reason/permission to educational records must secure parental permission prior to collecting data. This requires additional review and parental consent, if e.g., has you access to private personal information, what about students with disabilities, etc.
   - Protection of Pupil Rights Amendment (PPRA)
     - Parental rights regarding conducting surveys, evaluations, etc., where topics involve personal information, beliefs, political views, religious practices, physical or mental health status, etc.

IRB Process @ Southern

- Per CFR 46, part 46.101.b (1), “research conducted in established or commonly accepted educational settings, involving normal educational practices…” qualifies as exempt as long as the study demonstrates participants “will not be at greater than minimal risk when they participate”

Moral of the Story:
- Always consult with your advisor
- Prepare & plan for Full Review
- If you are thinking Expedited, consult with your advisor

IRB Practice Activity

- In small groups, review the sample IRB cover page,
  1. As a reviewer charged with protecting human subjects, what might be some potential questions/concerns with this proposal?
  2. As an IRB applicant, what are some areas you would want to explain more thoroughly? How might you go about doing that?
Helpful Tips for IRB

- Mindset: View the IRB process as a journal "Revise & Resubmit".
- Provide all information requested by prompts on proposal narrative.
- Include a brief review of literature in support of study and references for any citations.
- Avoid vagueness when describing research procedures; methodological details are needed.
- Provide sufficient details regarding benefits and risks of proposed research.
- Ensure consistency between information provided in proposal narrative, informed consent document(s), and any other appendices.
- Use Informed Consent Sample and Informed Consent Checklist (forms on IRB website) to guide development of informed consent documents.

Helpful Tips for IRB

- Use language in informed consent documents that is appropriate for participants; avoid use of academic/research terminology.
- Describe plan for assisting participants if any possibility exists for negative consequences as a result of research procedures.
- Be clear on whether you are promising anonymity or confidentiality to participants.
- Make sure parents/guardians understand what is being asked of their student. Differentiate between what is required of the students as part of class vs. what is optional/voluntary.
- Have a plan for students whose parents do not grant consent or for students who do not assent to participate and state this in procedures.

Helpful Tips for IRB

- Include all requested appendices including informed consent documents, recruitment materials, data collection instruments, letter of institutional cooperation, and CITI training certificates (both student and advisor for student research).
- Proofread IRB application and have it proofread.
- TIMELINE: Provide sufficient time for research advisor or department chair to review application.
- Seek assistance from a COE IRB member prior to submission if you have questions regarding IRB requirements.
- Complete class IRB application for student projects if findings will not be disseminated outside of class.
- Direct concerns regarding IRB review to the IRB office.
Resources/Links

- Georgia Southern Office of Research Services (ORSSP)
  http://research.georgiasouthern.edu/orssp/
- Georgia Southern ORSSP IRB Information & Training
  http://research.georgiasouthern.edu/researchintegrity/
- Georgia Southern IRB Forms & Process Guide
  http://research.georgiasouthern.edu/researchintegrity/institutional-review-board-forms/
- US Dept. Health & Human Services Office for Human Research Protections
  http://www.hhs.gov/ohrp/