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IRB Processes and Guidelines

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IRB Processes & Guidelines

College of Education Grad Summer Research Workshop

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Outline

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

http://tinyurl.com/

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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

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Why would you *want* to talk about IRB?

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

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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

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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.*

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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 decision. 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.*

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Components of IRB

- **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"

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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*

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Components of IRB

Preparing for Your Citi Program Training

- Belmont Report (1979)
  - Respect for Persons (Autonomy)
  - Beneficence (Risk/Benefit)
  - Justice (Fair Distribution of Risk/Benefit)
- "Common Rule" 45 CFR Part 46 (1991)
  http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
- Informed Consent
- Risk vs. Benefit
- HIPPA, FERPA
- Types of data collection & relevant considerations (e.g., audio, video, etc.)

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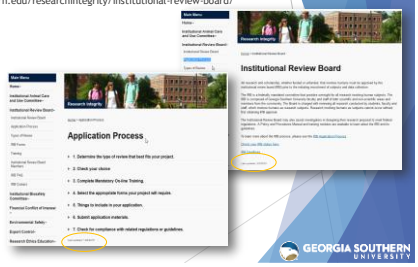
IRB Process @ Southern

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



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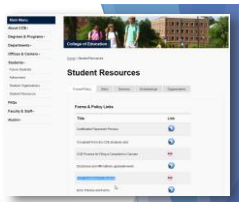
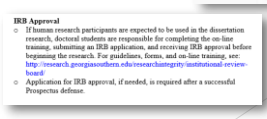
IRB Process @ Southern

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





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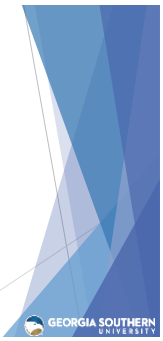
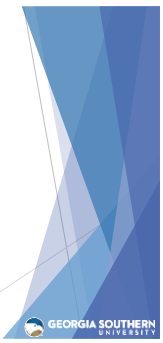
IRB Process @ Southern

- 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



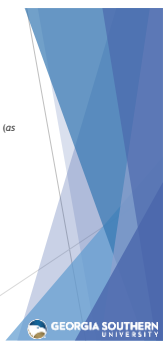
IRB Process @ Southern

- 3 important steps **BEFORE** research can begin:
  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)



IRB Process @ Southern

- 3 important steps **BEFORE** research can begin:
  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 designees 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

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IRB Process @ Southern

- Per CFR 45, 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*"

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

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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	Studies using up time/resources in abnormal ways (e.g., lots of questions)
Evaluation of classroom activities which may include pre/post tests, surveys, interviews or observations	Interviews, observations or surveys where questions go beyond scope of educational activity being studied
Affective data (i.e., attitudes towards learning)	Activities not recognized as "best practices" in the field

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IRB Process @ Southern

3. **"greater than minimal risk"**
   - Vulnerable Populations
     - *Children as vulnerable population requiring extra protections for minors (CFR 45 part46, D)*
   - Family Educational Rights & Privacy Act (FERPA)
     - *Researcher without normal reason/permission to educational records must secure parental permission prior to collecting any data. This requires additional review and parental consent (e.g., how will you secure parental permission, what about students when permission is not secured, etc.)*
   - Protection of Pupil Rights Amendment (PPRA)
     - *Parental rights regarding conducting surveys, evaluations, analyses, etc. when topics include personal information, beliefs, political views, psychological concerns, sexual behaviors/attitudes, religious practices, relationships, and behaviors which may be considered: illegal, anti-social, self-incriminating, or demeaning.*

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IRB Process @ Southern

- Per CFR 45, 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

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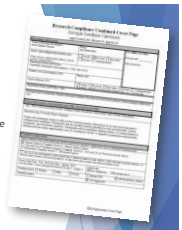
IRB Practice Activity

- **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?



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IRB Tips & Advice

From Faculty & "The Source" itself…..

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Straight From the Source

1. Address **ALL** reviewers' comments/concerns in your revised IRB. Addressing 1 or 2 comments leads to more "back and forth" and slows down the process.
2. Explain thoroughly what you plan to do (*methods*) and write for a "naïve" audience.
3. Proofread to make sure narrative is consistent throughout. Inconsistencies leads to more questions, more "back and forth", and more delays for you.
4. Understand the purpose & task of IRB protocol: peer review process to **ensure participants are protected**. Emphasize details of methods (*rather than lit review*) and balance between risk/benefits to participants.

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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.

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Helpful Tips for IRB

- Use language in informed consent documents that is appropriate for participants; avoid use of academic/research terminology. [HINT: Word tools]
- 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.

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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.

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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/

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Questions