IRB, Ethics, and Educational Research

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irb@emory.edu 404-712-0720 or 1-877-503-9797
Regulations came out of many negative research practices in the US and around the world.

DHHS regulations 45 CFR 46 are applied to all research at Emory, not just biomedical or federally-funded.

Emory requires exempt studies to be submitted to IRB for initial screening.
Who is the Emory IRB?

- An institutional review board
- A committee dedicated to ensuring ethical treatment of human subjects in research
- 6 biomedical panels, 1 sociobehavioral
- Appx. 80 members: Emory faculty (including nonscientists) and unaffiliated members
Emory University IRB
Guidance for Investigators
 Proposing Research

Questions? Contact the IRB staff at (404) 712-0720 or irb@emory.edu

Full Board
All other studies must be reviewed at a convened meeting of the IRB where quorum is present

Expedited
Only if IRB determines that study poses no more than minimal risk AND all study procedures fit one or more categories in a special list published in the Federal Register
➢ E.g., surveys, questionnaires, focus groups, noninvasive biological samples

Exempt
• PI must submit study proposal via eIRB for this determination
• Informed Consent usually must be obtained; HIPAA may still apply
• Many surveys and interviews of adults, educational program evaluations
• The IRB is the only unit authorized to make this determination
• Exempt determination is valid indefinitely unless changes in project affect the analysis. PI must request clarification from IRB (submit an “amendment” in eIRB)

Not “Research” with “Human Subjects”
1. PI can make this determination without the IRB.
2. PI is encouraged to consult IRB in making this decision if unsure (email request to irb@emory.edu).
3. PI can submit study proposal via email to get an official letter.
➢ Is it “research”? Term of art defined at 45 CFR Section 46.102(d): a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
➢ Does it involve “human subjects”? Term of art defined at 45 CFR Section 46.102(f): a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information
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Research or Not?

Not Research as defined by 45 CFR 46:

- Some education activities
- Some oral history projects
- Quality improvement, assurance, assessment studies
- <5 Case reports or case series
- Some ethnographic studies
- Public health practice
- But… it always depends.

Research (45 CFR Section 46.102(d)): a systematic investigation designed to develop or contribute to generalizable knowledge.
Generalizable knowledge is information gathered to draw general conclusions beyond the study population. The researcher approaches the project with the intention of extrapolating from the chosen sample to generate knowledge about that larger reference group. By contrast, non-research projects gather information about a chosen sample to describe a local phenomenon, or draw conclusions that are intended to be used for the benefit of that local sample alone.
If the goal/intent is to assess the success of an educational strategy in relation to an established standard, *how well it works at Emory or Oxford*, it is not “Research” for IRB purposes.
One can publish works that meet and do not meet the IRB-specific definition of “research.” Publishing is simply sharing information with an external audience. The Emory IRB can give you a letter with its determination, which can be provided to publishers and journals to satisfy IRB clearance requirements. If not research, the publication should not attempt to generalize conclusions.
Example

“Collaboration with theater troupe to stage a series of human molecular-structure experiences outdoors”

May be research: if…

the evaluation activities were designed to expand the knowledge base of a scholarly field (i.e. the field of education).

(Would usually be exempt research)

May not be research:

if the new technique were being evaluated with a primary goal of improving the education of Emory students
Example

“Evaluation of the use of an established learning technique (PBL) in an Emory science course”

Is it research?

Since the technique is already an established one, would likely not need IRB review unless it were being used in a novel way with an intent to add to scholarly field
What if it is “Research?”

Consent? Opt out? Minors? Coercion? These are issues the IRB will ask about and can help you address.

What if the intervention is not research, but some extra data collection is research? Consent? Peer pressure? Make sure that each person is given a non-coercive opportunity to consent or decline. IRB can waive consent in some instances.
Exempt Research

- Some aspects must be cleared, so submission in eIRB required
  - Informed consent, CITI training, reasonableness, site permissions if applicable
  - PI cannot make determination – has to be submitted
- Exempt determinations can be made by qualified IRB staff and members
- This determination cannot be made retroactively.
Steps to start a new study

- Obtain an eIRB account
- Take the CITI program course
- Prepare a Lay Summary, Protocol and other documents (see next slide)
- Submit in eIRB and obtain approval by Faculty Advisor Department head
Go to our website and click on Researchers and Forms and Tools:

http://www.irb.emory.edu/researchers/formstools/formstools.cfm

Guidelines for Lay Summary and Protocol.
If needed, also guidelines for ICF.
Other guidelines and information.
For Further Submission Guidance, Assistance...

- **IRB website**
  - [http://www.emory.edu/IRB/](http://www.emory.edu/IRB/)
- **IRB Policies & Procedures**
- **Contacts**
- **Friday Office Hours** 11AM-1PM,
  1599 Building, 5th Floor

- **Call or email the IRB Office**

  404-712-0720 or 1-877-503-9797
  irb@emory.edu
Additional Links

- **OHRP website** (use to look up International IRB sites, federal regulations, and guidance information)
  - Quality Improvement vs Research FAQ: [http://answers.hhs.gov/ohrp/categories/1569](http://answers.hhs.gov/ohrp/categories/1569)

- **ORC website** (Emory Office of Research Compliance)
  [http://www.orc.emory.edu/](http://www.orc.emory.edu/)

- **American Educational Research Association page on research ethics:**