



Demystifying the IRB

Amy Nichols-Belo, QEP Faculty Fellow 2019-2020

Associate Professor, Global Health Studies and Anthropology

Mercer University College of Liberal Arts and Sciences

Segments and Subtopics

1. What is the IRB and why should I care?
 - Human subjects concerns
 - What kinds of projects need IRB approval
 - What is “research”?
 - Types of review
 - But my discipline doesn’t “do” the IRB
2. IRB for the Teacher-Scholar (Case Studies)
 - But it’s just a class project ...
 - It’s for the community Is that research?
 - Pedagogical innovation and SOTL
 - I didn’t think this was research, but maybe it is?
3. Navigating the Mercer IRB process (Tutorial)
 - Citi Training
 - Process
 - Forms
 - Guiding students





1. What is the IRB and why should I care?

Humans subjects concerns

- Mercer defines a human subject as “any living individual about whom an investigator (whether professional or student) conducting research obtains information or biospecimens through *intervention* or *interaction* with the individual, and uses, studies, or analyzes the information or biospecimens; or obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.”
- Special concerns for pregnant women, human fetuses and neonates, children, cognitively impaired persons, prisoners, students and employees, and economically or educationally disadvantaged individuals.



What kinds of projects need IRB approval?

- Will you or your students be talking to or surveying other humans?
- Are you or your students planning on sharing this work?
- Mercer IRB: You need IRB review if the project ... “is research *and*...directly involves human subjects or their private or identifiable information from biological samples, the review of medical records, or deception of research”
- According to [Code of Federal Regulation, 45 CFR 46.102](#) (d), “Research is a *systematic investigation*, including research development, testing, and evaluation, designed to develop or *contribute to generalizable knowledge*.”



Types of review

1. Full Board Clinical Trials
2. Expedited – Minimal Risk
3. Exempt –
 1. Research not involving human subjects
 2. Some scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship)
 3. Public health surveillance activities
 4. Collection and analysis of information, biospecimens, or records for criminal justice or criminal investigative purposes
 5. Certain activities in support of intelligence, homeland, security, defense, or other national security missions. [§____.102(l)]



But my discipline
doesn't "do" the
IRB

It's not your discipline, it's the project. When in
doubt, obtain review

