Emory University IRB
Guidance for Investigators

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 and secondary analysis of de-identified pre-existing data or samples
- 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 (email request to irb@emory.edu).
3. PI can submit study proposal in eIRB 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

General examples: case studies (descriptive without drawing generalizing conclusions); public domain literature review; local-only QI project