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

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

Exempt

- PI must submit study proposal via eIRB for this determination
- Informed Consent usually must be obtained; HIPAA may still apply
- Exempt categories can be found at 45 CFR 46.104.
- 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 (use our tool to request a determination).
- 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(I): 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(e): a *living* individual *about* whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens or (2) *identifiable* private information or identifiable biospecimens.

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