### DOES YOUR STUDY REQUIRE OCR REVIEW?

1. **Does the study involve human subjects?**
   - **YES**: OCR review REQUIRED. Submit complete package electronically to OCR@emory.edu
   - **NO**: Dept/PI must route budget, PI effort calculation, & bluesheet to OBF via EPEX.

2. **Does the study consist ONLY of survey activities, chart review or creation of a limited data set?**
   - **YES**: OCR review REQUIRED. Submit complete package electronically to OCR@emory.edu
   - **NO**: Dept/PI must route budget, PI effort calculation, & bluesheet to OBF via EPEX.

3. **Does the study involve any technical fees for any interventions, drugs, devices, items, services or procedures that generate a CPT code or CDM code where services are rendered at an Emory (EUH, EUHM, TEC, EML) or Grady facility?**
   - **YES**: OCR review REQUIRED. Submit complete package electronically to OCR@emory.edu
   - **NO**: Dept/PI must route budget, PI effort calculation, & bluesheet to OBF via EPEX.

4. **Does the study involve any professional fees or facilities fees associated with any interventions, drugs, devices, items, services or procedures that generate a CPT code on an Emory bill (EUH, EUHM, TEC, EML, EMCF, ECC)?**
   - **YES**: OCR review REQUIRED. Submit complete package electronically to OCR@emory.edu
   - **NO**: Dept/PI must route budget, PI effort calculation, & bluesheet to OBF via EPEX.

---

1. **Human Subject** as defined by OHRP “means 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) Indentifiable private information.”

2. **Intervention** as defined by OHRP “includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.”

3. **Complete Package** includes OCR Request for PRA and Budget Development Form, protocol, clinical trial agreement, investigator effort calculations report, draft budget, informed consent—sponsor and Emory drafts, most recent FDA communications, signed Blue Sheet, and EPEX submission.