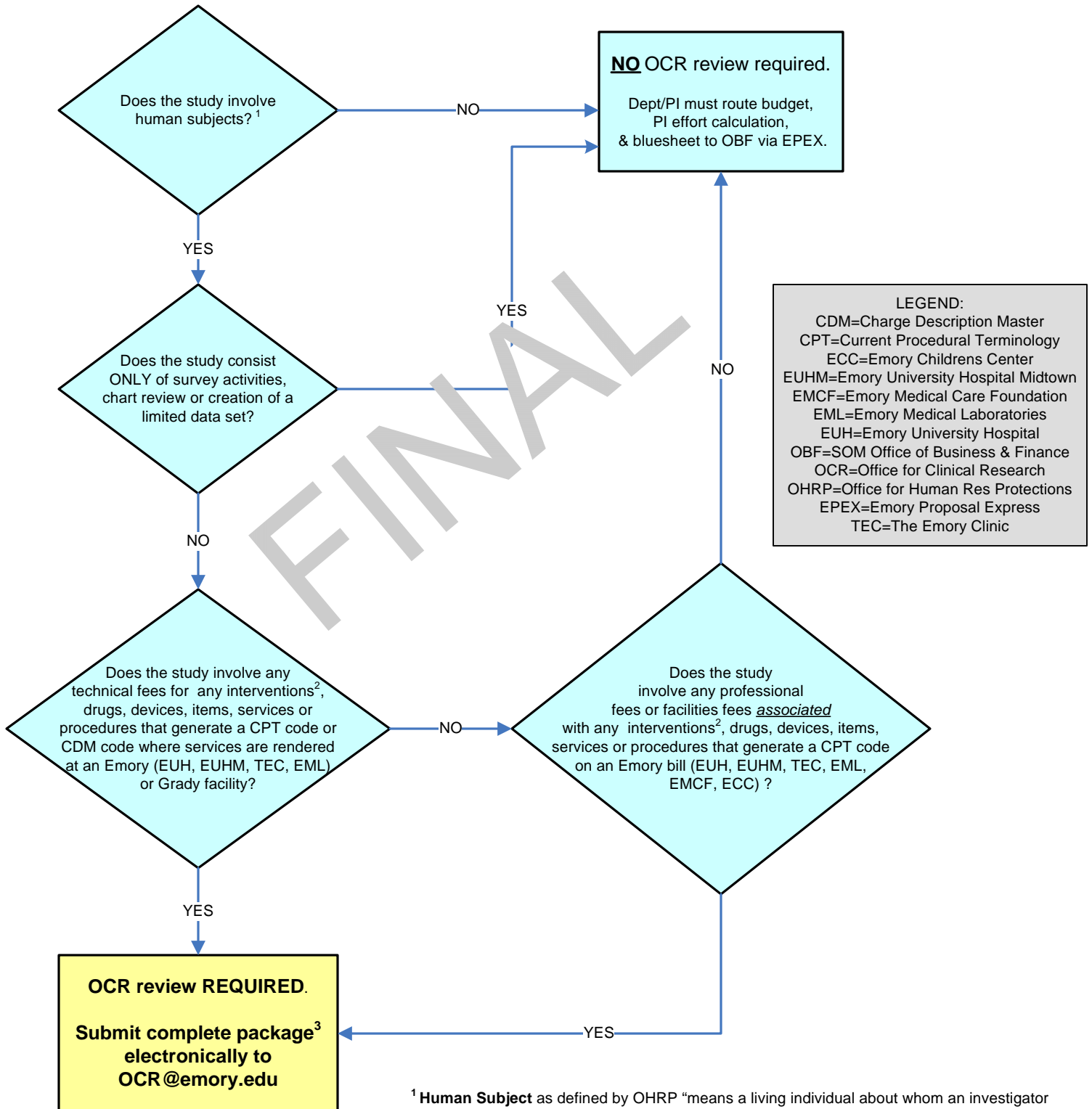


DOES YOUR STUDY REQUIRE OCR REVIEW?



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) Identifiable 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.