Study Closure

Purpose
1) This policy describes the general requirements for closing a study with the Chapman Institutional Review Board (IRB).

Policy
1) Studies should be closed when all study activities including analysis of private information or identifiable biospecimens, and interaction or intervention with participants, is complete.
   a) Datasets that are de-identified (i.e., do not contain any of the identifiers outlined in section 12 of the Cayuse submission) can continue to be analyzed after study closure.
2) At any time the IRB may contact the Principal Investigator (PI) to verify if research is ongoing and if the PI does not respond within 60 calendar days, the IRB may close the study.

Procedure
1) Once a study is complete, researchers should submit a closure submission in Cayuse IRB.
2) If researchers wish to re-open a study, they must complete a new submission to the IRB via Cayuse.

Record Retention
1) All data and records produced must be maintained for at least three years in accordance with institutional requirements, or in accordance with applicable funding requirements or regulations (45 CFR 46.115(b), 21 CFR 312.57, 21 CFR 812.140(d)), whichever is the longest.