

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, are 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) When the Principal Investigator (PI) leaves Chapman, any IRB studies that include the departing PI must be revised to remove the individual or closed depending on the circumstances.
 - a) Where the departing PI is listed as the lead, a new lead PI must agree to lead the study. Otherwise, the study will be closed.
 - b) If the collaboration will continue, the new lead PI should arrange with the IRB to continue the collaboration with the departing PI (e.g., initiate a reliance arrangement with the new institution).
- 3) At any time, the IRB may contact the Principal Investigator (PI) to verify if the 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.

Revision history:

- Oct 2023 - Clarifies policy for when a PI leaves Chapman.
- May 2023 - Document version date appearing more clearly in the footer.
- 14Jul2022 - Original publication date.