

Guidelines for Closing Human Subjects Research

I. Overview

All human research studies must close and submit a *Study Close-Out Report*. The report updates the IRB on study conduct, outcomes, new risks, safety issues, or problems since the last study renewal, and informs the IRB of the final disposition of research records and data.

The *Study Close-Out Report* must be submitted within 30 days of the end of the study. The *Study Close-Out Report* is on the VDSS IRB “Forms” web page (<https://www.dss.virginia.gov/research-and-planning/institutional-review-board-irb/institutional-review-board-forms/>).

Important Notes: Do not file a Close-Out Report (i.e., the study must stay active and continue to receive IRB oversight) if any of these six conditions apply:

1. Study enrollment at a VDSS-IRB approved site is ongoing.
2. Research-related interventions and/or follow-up at a VDSS-IRB approved site are ongoing.
3. Participant follow-up at the VDSS IRB-approved site is ongoing.
4. Data analysis or manuscript prep involving personally identifiable info is ongoing.
5. If there is an external study sponsor and the sponsor has not provided permission to close the study with the IRB.

II. Study Closure Report Procedures

To close a VDSS IRB-approved study, the PI must submit a *Study Close-Out Report*; they need not wait for the IRB approval period to end.

III. Principal Investigator Responsibilities

1. Submit a *Study Close-Out Report* to the IRB within 30 days of research completion or termination, even if the current approval period has expired.
2. Store research records for the required time per federal, state, and sponsor requirements.
3. Subsequent use of data from closed research, whether by the original investigator or other investigators, may require IRB approval or IRB-approved exemption for human subjects research.
4. Continue to follow data security measures and assure confidentiality of records and data.
5. Report to the IRB any post-closure information affecting subject safety or care, including serious adverse events or unanticipated problems reported by the sponsor or study monitors.
6. If terminating employment or association with VDSS, the PI must either:

- a. Transfer the study to another VDSS investigator approved by the IRB, or
- b. Close the study and submit a closure report; the PI must arrange proper storage of data and records with the department/division.

IV. IRB Responsibilities and Procedures

1. The IRB will review all closure notifications and request additional information from investigators if needed.
2. The IRB may close projects without investigator approval in the following circumstances:
 - a. The investigator is no longer affiliated with VDSS.
 - b. IRB approval is terminated after review and communication. Termination is reported to the VDSS Commissioner, the federal department¹, and noted in the annual IRB report to the Governor and General Assembly². In these cases, the IRB Administrator must notify the PI of closure.
 - c. The IRB may administratively close abandoned studies without investigator approval and attempt to notify the PI if:
 - i) The study is expired at least six months with no continuing review submitted.
 - ii) The study is expired at least six months, with a continuing review submitted, but no PI response to IRB requests for revisions and/or clarification within ~30 days and no extension requested.

¹ [45 CFR 46.113](#)

² [22VAC40-890-90A](#)