

I. Overview

A study closure report is required for all human research studies. Among other reasons for closing out a study, the closure report updates the IRB on the conduct and outcomes of the study, any new risks, safety issues or problems that may have arisen since the last study renewal, and informs the IRB of the final disposition of research records and data.

Closure reports should be submitted to the IRB within 30 days of study close-out by completing a *Study Closure Report* form. The form can be found on the VDSS IRB web page (<http://www.dss.virginia.gov/about/irb.cgi>) in the Forms Section.

Important Notes: Do not file a study closure report if any of the following six conditions apply. Such studies must remain active and continue to receive ongoing IRB review and approval:

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 is ongoing.
3. **Participant follow-up** at the VDSS IRB-approved site is ongoing.
4. **Biological specimens** containing personally identifiable information are being maintained in a repository that has been approved as part of this study or upon which analysis or research is ongoing. If, however, specimens were transferred to a separate repository that has ongoing IRB approval, the study may be closed.
5. **Data analysis or manuscript preparation** that involves the use or access to personally identifiable information is ongoing.
6. 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

In order to close a VDSS IRB approved study, the Principal Investigator (PI) needs to submit a *Study Closure Report*. The PI need not wait for the end of the IRB study approval period to submit a study closure to the VDSS IRB.

III. Principal Investigator Responsibilities

1. Submit a closure report application to the IRB within 30 days of completion or termination of all research activity, even if the current approval period has expired.
2. Store the research records for the required length of time in accordance with federal and state regulations and any additional requirements stipulated by research sponsors.
3. Subsequent use of data from closed research, whether by the original investigator or other investigators, may constitute human subjects research requiring IRB approval or Certification of Exemption from IRB review.

4. Continue to follow data security measures and assure confidentiality of records and data.
5. Report to the IRB any information learned after study closure that could affect subject safety or medical care, including but not limited to serious adverse events or unanticipated problems reported by the sponsor or others responsible for study monitoring.
6. If terminating employment or other association with VDSS, the PI is obligated to either:
 - a. Transfer the study to another VDSS investigator who must then be approved by the VDSS IRB as the new PI, or
 - b. Close the study and submit a study closure to the IRB. If closing the study, the PI is responsible for making arrangements with the department/division to assure data and records are stored properly and remain confidential.

IV. IRB Responsibilities and Procedures

1. The IRB will review all study closure notifications, and if needed, request additional information from the investigator.
2. The IRB may close projects without investigator approval in the following circumstances:
 - a. If it is determined that the investigator is no longer affiliated with VDSS.
 - b. If the IRB approval has been terminated. This would only occur after IRB review and communication with the investigator. Termination of IRB approval is reportable to: the VDSS Commissioner, the appropriate federal department¹ and is noted in the VDSS annual IRB report to the Governor and General Assembly².
 - c. In any of the situations described above, the IRB Administrator will notify the PI of the study closure.
 - d. The IRB considers the following to be abandoned and may perform an administrative closure without investigator approval. The IRB will notify the PI of the administrative closure:
 - i. Studies/protocols that have been expired for at least six months and for which no continuing review application has been submitted.
 - ii. Protocols that have been expired for at least six months and for which a continuing review application was submitted, but the investigator has not responded to the IRB's requests for revisions and/or clarifications within a reasonable timeframe, usually 30 days, and an extension has not been requested.

¹ 45 CFR 46.113

² 22VAC40-890A