

7.9 Closing a Research Study

The completion or early termination of the study, is a change in activity and must be reported to the IRB. Although subjects will no longer be "at risk" under the study, a final report to the IRB allows it to close its files as well as providing information that may be used by the IRB in the evaluation and approval of related studies.

Studies may be closed when the involvement of human subjects ceases (interventions, interactions, observations, and the gathering, use, study, and analysis of identifiable private information, including specimens, are all complete). Studies may be closed when the only remaining research activity involves the analysis of unidentifiable individual level data, or aggregate data sets.

For multi-site research, the study may be closed once all research activities (as above) are complete at the University of Virginia and any sites for which the IRB is the "IRB of record". If the investigator is serving as the lead investigator or the University of Virginia is the coordinating center, please note that the study must remain open as long as the coordinating center is still receiving, studying, using, or analyzing identifiable private information from other sites (even if local interventions, interactions, observations, and data gathering is complete).

Investigators may submit study closures to the IRB using a closure form . With closure submissions, the investigator must provide a summary of the research activity and any findings available at that time.

Investigators may maintain the data that they collected, including identifiable private data, if this is consistent with the IRB-approved research plan. However, investigators may not conduct any additional analysis of identified data without re-applying for IRB approval. Investigators must continue to protect the confidentiality of the data as described to the IRB and honor any other commitments that were agreed to as part of the approved research including, for example, future use of data or specimens, provision of research results to subjects, and provision of any outstanding payments or compensation.

The IRB will provide a Receipt Acknowledgment of any Closure documentation received from the study team and note the closure in the IRB files. Reporting IRB Actions

All IRB actions are communicated to the investigator, and/or designated contact person for the research study, in writing within ten (10) working days via a Approval/Assurance form prepared by the IRB staff and signed by the IRB Chair or designated IRB member. For an approval, along with written notification of approval, a copy of the approved consent/assent/permission form/s (if applicable) containing the IRB stamp with the dates of the approval and expiration will be sent to the investigator. For approvable with conditions, the notification will include a listing of the conditions that must be satisfied. For a deferral, the notification will include the modifications and/or clarifications required along with the basis for requiring those modifications. For a disapproval, termination or suspension, the notification will include the basis for making that decision and give the investigator an opportunity to respond in person or in writing.

All letters to investigators must be available in the study files maintained by the IRB.

The IRB reports its findings and actions to the organization in the form of its minutes, which are distributed by IRB staff to the University of Virginia Institutional Official.