

	Institutional Review Board	Approval Date: December 14, 2021

PURPOSE

To describe the process of closing out an IRB protocol after a study has ended.

DEFINITIONS

Generalizable knowledge -

POLICY

WHEN AN INVESTIGATOR SHOULD CLOSE A STUDY

Regardless of how a study was approved by the IRB (full review / expedited review / exempt), study closure is required for all IRB-approved studies when at least one of the following occurs:

- the study was not and will not be initiated;
- the study was discontinued prior to its completion;
- the time period approved by the IRB for the study has elapsed, and the research team did not file for an extension of the study's time period prior to the end of the approved study time

WHAT TO DO AFTER CLOSING A STUDY

After closing a study, the research team is required to do all of the following:

- cease data collection for the study;
- cease analysis of identifiable data;
- destroy all identifiable data (in accordance with the IRB-approved study protocol); and
- securely retain all study-related materials (with the exception of identifiable data) for a period of three years (such as signed consent forms, de-identified data, data collection measures, and study advertisements).

Please note that, if included in the study's IRB-approved protocol, a research team may continue to engage in the following study-related activities after a study's closure:

- communicating with study participants for study-related purposes other than data collection (such as answering participant questions, or recruitment for a different IRB-approved study);
- distributing remuneration to study participants;
- fulfillment of grant-related responsibilities excluding data collection/analysis (such as fulfillment of financial contracts for research-related equipment, services, facilities, and staff);
- analysis of de-identified data;
- dissemination of results from analysis of de-identified data (including but not limited to dissemination to grant funders, study participants, research publishers, and research conference audiences).

Once a study has been closed, if the investigator wants to collect additional data, they are required to submit a new study application to the IRB.

RESPONSIBILITIES

The Principal Investigator is responsible for:

1. submitting the close-out form
2. de-identifying data or destroying data if it contains identifiers, and
3. securely retaining all study-related materials (with the exception of identifiable data) for a period of three years (such as signed consent forms, de-identified data, data collection measures, and study advertisements).

If the PI is a student, the Faculty Advisor must ensure that the PI Responsibilities have been completed.