IRB Standard Operating Procedures		
SOP#: 20 **Revision#:**	**Title: Closing an IRB Protocol**	**Effective Date:** **December 14, 2021**
Approved By:	**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 - information which has the potential to be expanded from the isolated circumstances in which it is acquired to any broader context.

Human subject - a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information.

Identifiable private information - private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Identifiable data - any data collected from a study participant that can be linked to their identifiable private information.

De-identified data - any data collected from a study participant for which their identifiable private information has been permanently unlinked.

IRB - an institutional review board established in accord with and for the purposes expressed in the federal regulations for the protection of human research subjects.

Minimal risk - the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Research - systematic investigation, including research development, testing and evaluation, designed to develop or contribute to 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 period (regardless of whether data collection and analysis of identifiable data were completed prior to the end of the study's approved time period);
- data collection is complete, all study-related interventions are complete (such as stimuli in experimental designs), and (for anyone approved by the study protocol to access identifiable data, including but not limited to the research team and grant funders) use of and access to identifiable data has ended (even if the IRB-approved time period for the study has not yet ended); and/or
- the principal investigator will no longer be affiliated with NEIU, and prior to departing the university they do not intend to transfer the IRB protocol to someone else affiliated with NEIU.

HOW AN INVESTIGATOR SHOULD CLOSE A STUDY

Before closing a study, if additional analysis is intended, the principal investigator should create and save a de-identified data set (i.e., remove all identifiable private information from the data set, and destroy any codes linking participants to their study data).

When study closure is required (as outlined in the above "When to Close a Study" section), the principal investigator should fill out and submit one final Annual Report to terminate the project. For principal investigators who are students, the study's faculty sponsor should guide the student through the study closure process.

WHEN THE IRB MAY CLOSE A STUDY WITHOUT INVESTIGATOR PERMISSION

The IRB may close a study without the principal investigator's permission (in which event the IRB will notify the PI of the study closure) if at least one of the following occurs:

- the principal investigator is no longer affiliated with NEIU, and they did not transfer the protocol to someone affiliated with NEIU prior to departing the university;
- the protocol has lapsed (e.g., the study's approved time period has elapsed, and the principal investigator has neither requested an extension of the study's time period nor closed the study);
- an application for a continuing review has been submitted, but the principal investigator has not sufficiently responded to or addressed the IRB's requests for revisions within the allotted response time period; and/or
- the IRB determines that the protocol should be terminated (due to reasons such as those related to misrepresentation in the submitted IRB application, lack of adherence to approved guidelines in the approved protocol, or concerns over the ethical protection of human subjects).

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.

Regulations
45 CFR 46.102

Author Reference
Indiana University's "Study Closure"
UCLA's "Closure of Human Subjects Research Studies"
University of Washington's "Close Your IRB Application"

Contact Information
Please direct questions or concerns about this policy to:

Contact	Phone	E-Mail
IRB Office	773-442-4675	irb@neiu.edu
Dean of the College of Graduate Studies and Research	773-442-6012	gradstudies@neiu.edu

Disclaimer
The University reserves the right to modify or amend sections of this IRB SOP at any time at its sole discretion. This IRB SOP remains in effect until such time as the Responsible Officer calls for review. Requests for exception to any portion of this policy, but not to the policy statement, must be presented in writing to the Responsible Officer.