OFFICE OF RESEARCH AND SPONSORED PROGRAMS *Division of Research Compliance*		**Institutional Review Board (IRB) Standard Operating Procedures**	
Title: Study Closure Requirements			
Effective Date:	15-Aug-2023	**Document Number:**	IRB-SOP-037.01
Approval/Date: **Chad W. Hargrave** **Vice President & Chief Research Officer** 9 May 2024 **Date**			
REVISION HISTORY			

PURPOSE

This SOP describes the general requirements for the study closure process and specifically clarifies the steps for creating a Closure Submission in Cayuse Human Ethics.

SCOPE

This SOP delineates systematic process activities and functions for compliance with the U.S. Department of Health and Human Service, Office for Human Research Protections (OHRP) and Common Rule requirements, and SHSU requirements for the management, coordination, and operation under the oversight of the IRB. It applies to all researchers, including students and research staff involved in conducting human subjects research, as well as all IRB members and IRB staff reviewing research involving human subjects.

DEFINITIONS AND ABBREVIATIONS

1. Definitions
   1.1. Cayuse Human Ethics- formerly, Cayuse IRB, this is SHSU's electronic solution for allowing PIs to submit their IRB applications.
   1.2. Closure Submission- A closure submission indicates that the research is complete and will not be continuing. Closed studies are marked as finalized and can no longer be modified. This step should be completed by the PI once all human research activities have ceased or have been completed and after all identifiable data has been de-identified and securely stored according to the approved protocol.
   1.3. Office for Human Research Protections- provides leadership in the protection of the rights, welfare, and wellbeing of human subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS). OHRP provides clarification and guidance, develops educational programs and materials, maintains regulatory oversight, and provides advice on ethical and regulatory issues in biomedical and behavioral research.

1.4. Study Details- This is the tab that researchers are taken to immediately after creating their study. Here they will see where important study information will populate once a submission has been started.

1.5. U.S. Department of Health and Human Service- The primary funding agency overseeing all human research protections regulations, including all IRB registrations and FederalWide Assurances. OHRP is housed under this federal agency.

2. Abbreviations

2.1. DHHS- Department of Health and Human Service

2.2. IRB- Institutional Review Board

2.3. OHRP- Office for Human Research Protections

2.4. PI- Principal Investigator

2.5. SHSU- Sam Houston State University

2.6. SOP(s)- Standard Operating Procedure(s)

RESPONSIBILITIES

The PI is responsible for:

1. submitting the Closure form through Cayuse Human Ethics
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 the period of time that is indicated in the approved protocol (such as signed consent forms, de-identified data, data collection measures, and study advertisements).

IMPORTANT: If the PI is a student, the Faculty Sponsor of the student's approved IRB must ensure that the PI Responsibilities have been completed. The IRB office strongly encourages graduate students to incorporate this step into their final activities as a student at SHSU. For example, graduate students would need to close out their IRB submissions after they submit their final Thesis or Dissertation packets to the Graduate Studies office.

1. 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 PI will no longer be affiliated with SHSU, and prior to departing the university they do not intend to transfer the IRB protocol to someone else affiliated with SHSU.

2. 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 SHSU, and they did not transfer the protocol to someone affiliated with SHSU 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 new study has been submitted, but the principal investigator has not sufficiently responded to or addressed the IRB's requests for revisions in a timely manner (i.e., within 2-3 weeks);
- 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 in a timely manner (i.e., within 2-3 weeks); 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).

3. 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:

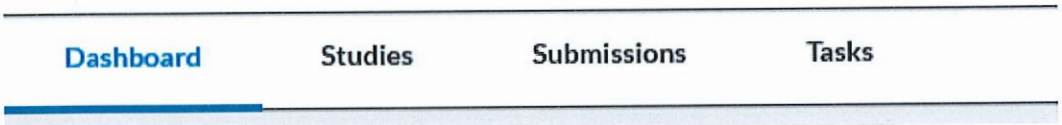
- communicating with study participants for study-related purposes other than data collection (such as answering participant questions, or recruitment for a different IRB-approved study).
- distributing remuneration to study participants.

- 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).

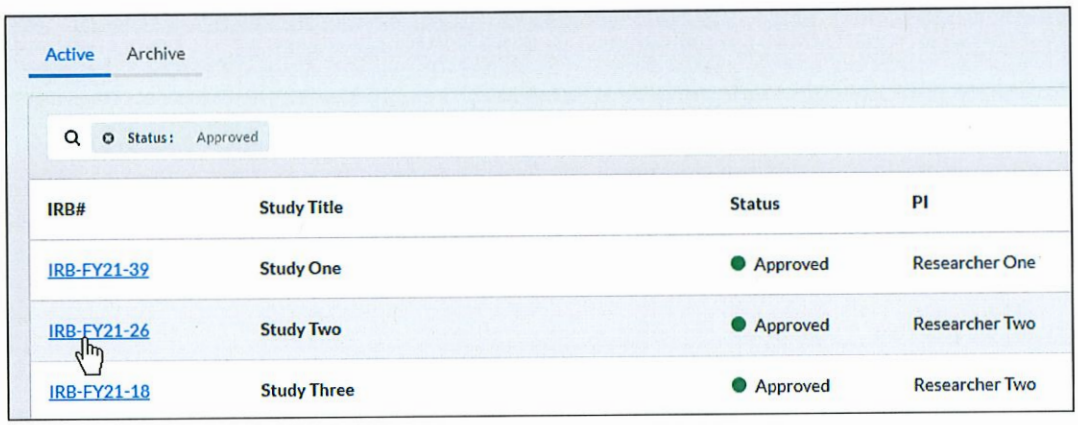
IMPORTANT: Once a study has been closed, if the investigator wants to collect additional data, they are required to submit a new study application to the IRB.

PROCEDURE

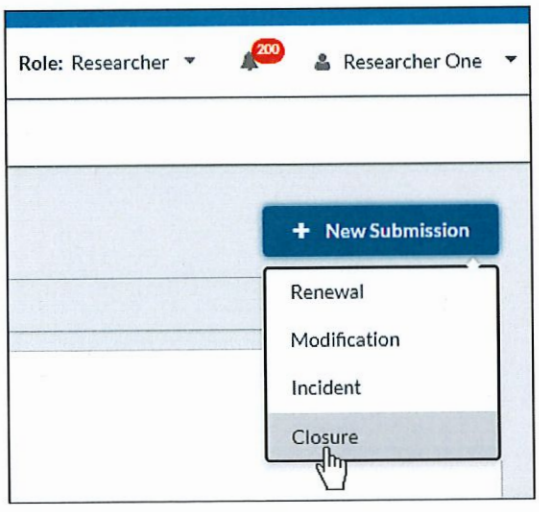
1. From your Dashboard, click **Studies**



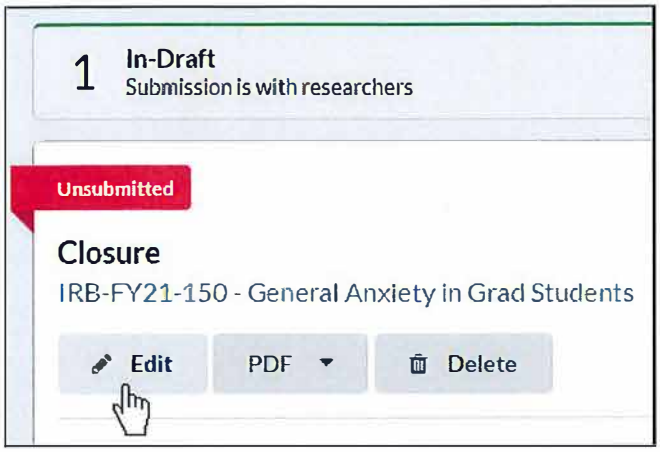
2. Find the study you would like to create a Closure for and click on the study number (Condition: the study must be approved).



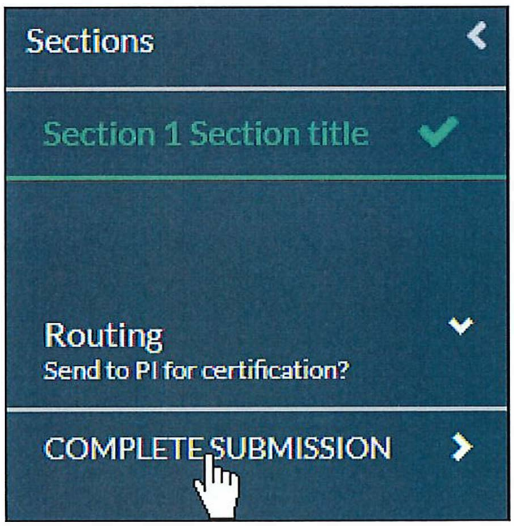
3. In the right coroner of the Study Details page, click **New Submission.** A drop-down menu will appear. Click **Closure.**



4. Click **Edit** to begin your closure submission.



5. Fill out your submission form, complete all required fields, and click **Complete Submission**.



REFERENCES

Northeastern Illinois University IRB SOPs
Cayuse Help Articles