Clinical Research Support Office ("CRSO")
STANDARD OPERATING PROCEDURE

SOP NUMBER	**TITLE**
CFI-SOP-4004	**Protocol Closeout**
EFFECTIVE DATE	**WRITTEN BY**
10/15/2025	**CRSO Director**

APPROVAL

Jessica Heskel Digitally signed by Jessica Heskel Date: 2025.10.15 07:40:16 -04'00'

SIGNATURE **DATE**

1. POLICY STATEMENT

Following the conclusion of a clinical trial, multiple regulatory and financial processes must occur to successfully close out the study. To ensure these processes occur promptly, the Principal Investigator ("PI"), or their designee, is responsible for following institutional regulatory and financial close out practices and updating all studies in the Clinical Trials Management System ("CTMS") to a terminal status (i.e., closed, abandoned, or terminated). The Clinical Research Support Office ("CRSO") may review studies with low activity in accordance with Institutional Review Board ("IRB") policies.

2. PURPOSE

The purpose of this policy is to standardize the process for how clinical trials, that utilized CRSO pre-award services, are closed in the CTMS following study completion, ensuring that trials are closed in alignment with IRB and other financial processes, and that all accounts have been reconciled and distributed per University of Kentucky ("UK") practices.

3. SCOPE

This policy is applicable for all protocols meeting the definition of a clinical trial per National Institutes of Health ("NIH") and the UK minimum footprint, or otherwise entered in the CTMS.

4. RESPONSIBILITY

Principal Investigator, or designee

- Notifies the Regulatory Owner promptly of the ability to close out the study;

- Updates the CTMS subject statuses to a terminal state;
- Ensures updates to clinicaltrials.gov status;
- Verifies all case report forms complete and queries addressed;
- Obtains sponsor letter for closeout and confirms database lock, if required.

Regulatory Owner

- The Regulatory Owner is the assigned department based or institutional regulatory office personnel who is responsible for IRB preparations and submissions;
- Initiates the closeout paperwork for IRB and closeout task list in the CTMS;
- Validates subject statuses are in a terminal state;
- Records the IRB Closure information in the CTMS, notifies the study sponsor, and updates the Study Status in CTMS;
- Notifies the Food and Drug Administration ("FDA"), if applicable;
- Updates the archival information, as appropriate to document the storage location of study materials.

Budget Owner

- Completes the study closeout task list;
- Coordinates account closeout with Research Financial Services ("RFS") and the Office of Sponsored Projects Administration ("OSPA").

CRSO

- Monitors studies with low activity based on IRB policies;
- Coordinates account closeout with RFS and OSPA if applicable.

5. PROCEDURE

Closure of studies prior to activation

1. If a trial is entered into the CTMS and subsequently determined that it will not open due to failure to obtain required regulatory approvals, failure to reach satisfactory budget or contracting terms, or decision of PI or study sponsor not to move forward, the study status in the CTMS will be updated to "Abandoned."
   1.1. The CRSO Financial team will facilitate any start-up payments received before account creation.
   1.2. The Regulatory Owner should ensure any pending IRB submission is withdrawn or, if IRB approved, initiate the closure.
2. The CRSO will monitor studies in a "New" status with no activity in accordance with IRB practices.
   2.1. The CRSO will attempt to contact the Study Team for a progress update.

2.2. If no response is received after two attempts greater than two weeks apart, or if all listed Study Team members are no longer active employees, the study status will be updated to “Abandoned.”

Closure of studies after activation

3. At the time the IRB closure paperwork is submitted to the IRB, the Regulatory Owner will initiate the study closeout task list.
4. The PI or designee will confirm all subject visits in the CTMS are complete.
   4.1. Sponsors must approve closeout of the trial and confirm all queries are resolved, and all forms are locked.
5. The Regulatory Owner will compile necessary closeout reports (e.g., Serious Adverse Event report) as defined by Office of Research Integrity (“ORI”) and/or the study sponsor.
6. The Regulatory Owner will confirm all subjects are in a final status such as “Off Study” or “Screen Failure.”
7. The Regulatory Owner will ensure the IRB of record and any other applicable committee(s) have closed the study and enter closure details in the CTMS.
   7.1. The Regulatory Owner will record the IRB and FDA closeout information in the CTMS and notify the Budget Owner of closeout.
   7.2. If the study is using an external IRB, the Regulatory Owner will notify the UK IRB of study closure.
8. The PI or designee will update the study status in ClinicalTrial.gov as applicable (e.g. terminated, completed or withdrawn).
9. The Budget Owner will complete the study closeout in the CTMS, and mark tasks complete on the study closeout task list.
10. The Regulatory Owner will notify the study sponsor and FDA, if applicable, of study closure.
    10.1 If the study was terminated prematurely (e.g.closed for toxicity, lack of accrual, futility, etc.) the Regulatory Owner should update the study status to “Terminated” in the CTMS.
    10.2 If the study was completed as expected, the Regulatory Owner should update the study status to “IRB Study Closure” in the CTMS.
11. The Regulatory Owner should update the archive and notes in the CTMS with the date, archive type, and location.
12. The Budget Owner will coordinate account closure per OSPA and RFS written guidance and document the financial closure date in CTMS.

6. <u>ATTACHMENTS</u>

None

7. REFERENCES

Office of Sponsored Projects Administration (OSPA):

- ClinicalTrials.gov Registration and Results Reporting Guidance

University Financial Services: Business Procedures Manual

- E-21-5: Collections and Write Off Policy
- E-10-1: Fiscal Year-End Closing

Office of Research Integrity (ORI):

- Study Closure [C4.0200]
- Termination or Suspension of Research by the IRB [C2.0600]
- IRB/ORI Recordkeeping [C4.0250]

Protocol Close Out Work Instructions
Subject Admin Work Instructions