UC San Diego Senior Associate Vice Chancellor in Health Sciences Office of Clinical Research	SOP Number	OCR:013 Page 1 of 2
	Date:	04/02/2025
	Author:	T. Graham
	Approved by:	S. Little
SOP TITLE: STUDY CLOSEOUT AND REPORTING		

1 PURPOSE

1.1 This procedure establishes the process for Principal Investigators (PIs) and study personnel under the PI's supervision to follow to close a study with the IRB once all study activities have been completed.

1.2 The process begins when the PI or designee becomes aware that the study meets criteria for closure.

1.3 The process ends when the IRB closure acceptance letter has been received.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 REQUIREMENTS

3.1 A clinical study may be closed once all the following conditions are met:

- 3.1.1 All recruitment and enrollment activities are complete
- 3.1.2 All study procedures are complete
- 3.1.3 All participant follow-up, including participant contact and/or review of medical records for research purposes, is complete
- 3.1.4 All data analysis and manuscript preparation are complete
  - 3.1.4.1 If manuscript preparation involves analyzing data that includes identifiable private information, the study must remain open under IRB oversight. Continued use of identifiable data is considered human subjects research.
  - 3.1.4.2 If identifiers remain in existence and can be linked to the data to re-identify it, meaning if a code or link to direct identifiers exists, this is still human subjects research and requires IRB oversight.
  - 3.1.4.3 "De-identified" in the HIPAA context means that all 18 HIPAA identifiers, including all elements of dates, have been removed. "De-identified" in the IRB regulatory context means that data is not "readily" identifiable/cannot be linked to the individual from whom the data was collected.
- 3.1.5 Analysis or research on identifiable biological specimens that are being maintained in a repository approved for the study is complete
- 3.1.6 For sponsored research, the sponsor has given permission to close the study and, if applicable, has conducted the close out monitoring visit

3.2 OIA-103 IRB Handbook "How do I close out a study?" describes the process for submitting a closure request in the Kuali IRB electronic submission system. The Knowledge Base Article "Steps to Submitting a Closure" describes each step in the process.

3.3 The study closure request must be submitted at least 30 days before the IRB expiration date.

4 RESPONSIBILITIES

4.1 The PI or designee is responsible for tracking study activities to ensure that a timely study closure request is submitted to the IRB.

5 PROCEDURE

5.1 Confirm that the study is ready for closure.

5.1.1 Confirm that all source data have been verified, case report forms are complete, and relevant participant logs have been transmitted to the sponsor, if applicable.

5.1.2 Verify that all data has been entered in the study database and that all data queries have been resolved.

5.1.3 Verify that investigational product accountability is complete and accurate.

5.1.4 Verify that investigational product has been returned to the sponsor, if applicable, or destroyed in accordance with the study protocol and the study contractual agreement, if applicable.

5.1.5 For investigator-initiated studies, verify that any required results reporting in clinicaltrials.gov has been submitted and accepted in the Protocol Registration and Results System (PRS), as applicable.

5.1.6 Ensure that all applicable activities in OCR-112- Sample Closeout Checklist have been completed.

5.2 Submit the closure request in the IRB electronic submission system prior to study expiration.

5.2.1 For sponsored research, submit the sponsor's documentation giving permission to close the study.

5.2.2 If UC San Diego IRB is relying on another IRB, submit the closure letter from the IRB of record with the UC San Diego IRB closure request.

5.3 File the IRB closure acceptance letter in the study file.

6 MATERIALS

6.1 OCR-112 – Sample Closeout Checklist

7 REFERENCES

7.1 OIA-103 IRB Handbook "How do I close out a study?"

7.2 Knowledge Base Article "Steps to Submitting a Closure"