I. SCOPE

This SOP outlines the appropriate steps to be taken when a clinical research study is permanently closed to ensure proper participant management, regulatory compliance, financial reconciliation and system closeout. This procedure includes the study completion and financial components needed to close a study.

II. PROCEDURES

A. Study Closeout Criteria
   1. Study meets one or more of the following closeout criteria:
      a. The study sponsor has formally notified the site (principal investigator and/or his/her designees) that the necessary procedures to terminate the site's participation in the study can begin.
      b. The department, division, institute and/or investigator determines that study participation is no longer feasible.
      c. For investigator initiated studies, the objectives and aims of the study have been met.

B. Study Closeout Process
   1. The designated member of the study team initiates the close out procedures utilizing the study close out checklist or a comparable checklist.
   2. The study team member files the completed checklist in the study folder in the research department's shared drive.
   3. The research department manager is responsible for the accuracy of the completed checklist.

III. REFERENCES

A. GCP/ICH Section 8

IV. ASSOCIATED DOCUMENTS AND FORMS

A. Study Closeout Checklist

V. APPROVALS

Katherine van Meter — 12/15/2020
LUMC Clinical Research — Date

Allison M. Fitzgerald, MD, MS — 12/17/2020
LUC Clinical Research Office — Date

Revision History

Effective Date	Summary of Changes
15/Aug/2016	Initial version
1/Jan/2021	Administrative updates; removed checklist items that are to be performed before close out

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Study Closeout Checklist

LU #: _____ Department: _____

Study Coordinator _____ Email: _____ Ext: _____

Initiate the following checklist when a clinical research study is permanently closed.
Submit the completed checklist to the research department manager.

Task	Task Completed	Date Completed	Comments	Validated By
General Information Confirm Permanent Closure Status based on closeout criteria.	YES ☐ NA ☐			
Notification Send notification that the study is undergoing closeout. • LUMC Clinical Research • Departmental Offices/PI • Research department manager	YES ☐ NA ☐ YES ☐ NA ☐ YES ☐ NA ☐			
Participant Status Verify research participants' accruals and statuses in departmental tracking systems and Epic.	YES ☐ NA ☐			
Recruitment Materials Confirm all advertisements and public study listings are appropriately removed or updated to reflect closure.	YES ☐ NA ☐			
Study Supplies and Equipment • Destroy all protocol-related materials (refer to CTA): – Research kits – Unused CRFs • Return any equipment on loan (refer to CTA): – ECG machines – Halter monitors – Blood pressure cuffs – Other_____ • Notify Biomedical Engineering / Purchasing, when the equipment is returned, if applicable (Ext 6-5286)	YES ☐ NA ☐ YES ☐ NA ☐ YES ☐ NA ☐ YES ☐ NA ☐ YES ☐ NA ☐ YES ☐ NA ☐ YES ☐ NA ☐			
Investigational Product (IP) • Confirm copies of DARFs and/or packing slips and shipment receipts are filed appropriately.	YES ☐ NA ☐			

Task	Task Completed	Date Completed	Comments	Validated By
Investigational Device • Return investigational devices and related equipment still on site to the sponsor or destroy as specified in the CTA. • Obtain original copies of Device Accountability Logs and/or packing slips and shipment receipts from LUMC CR	YES ☐ NA ☐ YES ☐ NA ☐			
Protocol Reconciliation / Closeout Visit • Ensure research participants' data is complete • Reconcile Regulatory files (1572, Delegation logs, Financial disclosure forms, etc.) • Schedule closeout visit • Submit termination letter and/or final report to the IRB	YES ☐ NA ☐ YES ☐ NA ☐ YES ☐ NA ☐ YES ☐ NA ☐			
Financial Reconciliation • Review the contract and budget to ensure all past due payments have been received and determine requirements for final payments (including internal payments and transfers). • Contact LUMC CR to request the outstanding Epic and non-patient care balance to reconcile • Contact Investigational Pharmacy to request the outstanding pharmacy balance to reconcile, if applicable • Verify the following in Lawson – Net balance – No open purchase orders – No current salaries allocated to the account – No account overdraft/ overdrafts are resolved • Complete the LUC-HSC Clinical Trial Project Closeout Form and email to SPA at grntcon@luc.edu with a copy of the IRB termination to signify the study has been closed. If applicable, provide a general development account on the form to move the residual balance. (SPA will transfer the residual and close the account in Lawson.)	YES ☐ NA ☐ YES ☐ NA ☐ YES ☐ NA ☐ YES ☐ NA ☐ YES ☐ NA ☐			

Task	Task Completed	Date Task Completed	Comments	Validated By
Information Systems Study is closed in: • Research Channel • Lawson • CCTO Website, if applicable • Remove copies of Protocols from clinics	YES ☐ NA ☐ YES ☐ NA ☐ YES ☐ NA ☐ YES ☐ NA ☐			
Record Retention Refer to CTA. Pack, catalogue and send protocol documents for long term storage. Document where the records are stored and the expected destruction date	YES ☐ NA ☐ YES ☐ NA ☐		Storage location: Expected destruction date:	