

<b>OFFICE FOR EDUCATION &amp; QUALITY IN CLINICAL RESEARCH</b>	<b>CATEGORY</b>	<b>Clinical Research: Study Management</b>
	<b>SUBJECT</b>	<b>Study Close Out</b>
	<b>SOP #</b>	<b>2.12</b>
	<b>EFFECTIVE DATE</b>	<b>August 6, 2008</b>
	<b>REVISION DATE</b>	<b>January 15, 2018</b>

**OBJECTIVE**

Describe the activities for a study close out of a clinical research study. These procedures apply to all clinical research activities approved by the Office for Human Subjects Research conducted within the Hennepin County Medical Center campus.

**APPLICABLE REGULATIONS AND GUIDELINES**

45 CFR 46	Protection of Human Subjects
21 CFR 50	Protection of Human Subjects
21 CFR 56	Institutional Review Boards
21 CFR 312	Investigational New Drug Application
21 CFR 812	Investigational Device Exemptions
FDA Guidance	Oversight of Clinical Investigations-A Risk –Based Approach to Monitoring

**REFERENCES TO RELATED SOPs**

SOP 2.1  
SOP 2.10  
SOP 3.4  
SOP 4.4  
SOP 4.5

**ATTACHMENTS**

None

- 1) Arrange a mutually convenient date and time for the sponsor/CRO study close out visit.
  - a) Ensure that all regulatory documents and case report forms are present and completed.
  - b) Ensure that all data queries to date have been resolved to the extent possible.
  - c) Ensure that all investigational product accountability records are completed.
  - d) Notify research pharmacist of study termination (if applicable).
  - e) Establish specific procedures for addressing any additional queries that develop during sponsor/CRO processing of case report forms and data review.
  - f) Discuss the sponsor/CRO requirements for subject follow-up for serious adverse events after closure of the study.
  
- 2) Dispose of investigational product and investigational supplies per sponsor/CRO instructions.
  - a) The Clinical Research Associate (monitor) will likely pack and ship investigational product; if not research personnel are responsible for return of the investigational product to the sponsor.
  - b) Consult the HCMC investigational pharmacy if sponsor/CRO directs research team to dispose of investigational drug.

- c) Retain copies of investigational product shipping slips and shipment receipts with study records.
  - d) Return or destroy all other study-related materials as directed by the sponsor/CRO.
- 3) Inform ancillary departments of study closure.
- 4) Notify the Human Subjects Research Committee by completing and submitting study closure report.
- 5) Arrange for study record storage.
- a) Destroy any unneeded protected health information by disposing in commercial shredding container or by personally shredding with a (preferably) crosscut shredder.
  - b) Collect all documents, or document their location (place location documentation in the regulatory binder) the location(s) of all source documents that must be retained per applicable FDA regulations. These include, but are not limited to:
    - i) Case report forms
    - ii) Signed informed consent
    - iii) Study drug/device accountability records
    - iv) Subject diaries
    - v) Regulatory files
    - vi) Medical files
  - c) If the sponsor/CRO employed electronic data capture, a means to accessing the site's case report forms must be given to the site by the sponsor/CRO.
  - d) Notify the sponsor/CRO of any change in record location.
  - e) Notify the sponsor/CRO of any change in responsibility for study files. If the principal investigator leaves the institution, the responsibility must be delegated to another investigator and the sponsor/CRO notified.
  - f) Retain documents for no less than the amount of time required by federal regulations.
  - g) Obtain written authorization from the sponsor/CRO before destroying any records. Check with the appropriate Grant Administrator for contractual obligations.
  - h) If study is Investigator Initiated, clinical trial consent forms should be posted on [clinicaltrials.gov](http://clinicaltrials.gov). One consent form for the clinical trial must be posted on the federal website after the trial is closed to recruitment and no later than 60 days after the last study visit by any subject.