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## SOP 14

### STUDY CLOSE-OUT ACTIVITIES

#### **1.0 PURPOSE AND SCOPE**

##### **1.1 Purpose and Scope**

This SOP specifies the requirements for the activities performed to complete a research study.

#### **2.0 RESPONSIBILITIES**

- 2.1 The PI is responsible to ensure the study is closed out according to the requirements specified in this SOP.

#### **3.0 REQUIREMENTS**

- 3.1 All the following activities must be completed to close the study:
- 1) All subjects must complete all study visits and follow-ups.
  - 2) Complete all CRF and source documents.
  - 3) Complete all requests for data corrections or verifications on the CRF.
  - 4) All drugs are collected from all the study subjects. Inventory all used and unused drugs.
  - 5) The used and unused drug supplies are returned to the Sponsor in the manner specified. All containers are returned to the Sponsor. Shipping documentation is retained.
  - 6) Copies of the drug logs, final inventory, and return documents are filed in the regulatory binder.
  - 7) All other Sponsor required reports are completed. A copy is filed in the regulatory binder.
  - 8) The PI completes an IRB annual renewal indicating closure/final and provides a short narrative summary of the conclusion of the study to the IRB. Include comments on any AE that occurred and the significance that the AE had on the study conclusions. A copy of the report is sent to the Sponsor and filed in the regulatory binder.

9) Review the regulatory binder and recovers any missing documents or places a waiver in the binder.

10) Store all applicable study documentation.

11) Document in the subject's research/medical records the completion of study participation.



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