***TITLE: Study Close-Out***

***SOP Version #*** RM XX.XX

***Author(s):***

 ***Approved by Date***

***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

 ***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

***Approval:***

 ***Approved by Date***

 ***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

 ***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

***Annual Review of current version Review date Description***

 ***\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

 ***\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

***\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

**Instructions for modifying this template:**

1. This is a template and should be used as such. Please use this in the manner most appropriate for your research unit.
2. Anything in this template can and may be modified as appropriate for your area while accounting for your interpretation of the most current FDA Guidance.
3. After you have modified this SOP template, do not forget to remove the “Instructions for modifying this template” table.

**I. SCOPE/PURPOSE**

The purpose of this SOP is to describe site responsibilities related to the close out of a study at a UAB investigative site.

**II. ALLOWABLE EXCEPTIONS**

This SOP is meant to be followed without deviation. However, it is an allowable exception to follow procedures specified in a protocol or by the sponsor. If a deviation from this SOP occurs, a description of this event will be written and filed with this list of SOPs and the protocol.

**III. RELEVANT REGULATIONS/GCPS**

21 CFR 312.56

21 CFR 312.59

21 CFR 312.60

21 CFR 312.62

Probably more…

1. **DEFINITIONS/ACRONYMS**

CRF – Case Report Form

**V. RESPONSIBLE PERSONNEL**

This SOP applies to all Study Personnel.

1. **DETAILS**

Study close-out can be sponsor initiated or site initiated.

* Sponsors may contact the site investigator to arrange for a closeout visit after the last subject has concluded their participation.
* The participating UAB site may also reach out to a sponsor to request a close-out visit as long as all subject visits have occurred and the data has been analyzed at the site.
* For investigator-initiated trials, once all the subjects have been seen and the data has been analyzed, close-out can occur.

Before study close-out all of the following must be complete:

1. Subject study visits.
2. Case report forms and source documents
3. Resolve data queries.
4. Test articles/investigational product are collected, inventoried, discrepancies reconciled, and disposition per protocol.
5. Protocol specific equipment is returned in the manner specified by the sponsor.
6. Regulatory binder reconciled.
7. A final report is sent to the IRB for study closure per institutional requirements (UAB IRB or WIRB). A copy of this report is sent to the sponsor and a copy is retained in the regulatory binder.
8. All regulatory documentation is reviewed and attempts are made to recover any missing documentation. If documentation cannot be located the sponsor is notified and a note to file is placed in the regulatory binder.
9. Secure storage for CRFs, source documents, regulatory documentation is arranged per site standards and the sponsor is informed of the storage location.
10. **QA**

NA

1. **APPENDICES/ RESOURCES**

NA

**IX. RELATED SOPS**

NA