

PROCEDURES FOR CLOSING RESEARCH STUDIES

1. **OBJECTIVES:** Outline activities performed to closeout a research study.
2. **DEFINITION:** A study is "closed" when all of the following conditions are met:
 - a) All subjects have completed study participation
 - b) Data collection is complete
 - c) The sponsor decides to terminate the study and/or completes a Study Close Out Visit
 - d) Data analysis is complete (Note: this is different for IRB and R&D, see 4a and 4b below)
3. **REQUIREMENTS:**
 - a) All of the following are required prior to closing a research study with the IRB:
 - I. Complete all subject study visits and/or follow up
 - II. Complete all study data collection and query resolution
 - III. All data has been de-identified and the key destroyed.
 - IV. For drug studies, drug accountability must be reconciled and all study drug (full or empty) should be returned to the sponsor or destroyed according to policy or sponsor's specification
 - b) In addition to the above, study data analysis must be completed prior to closing a research study with R&D.
4. **PROCEDURES:**
 - a) Document the "end of study participation/study termination" in the subject's medical record, if applicable.
 - b) Inactivate "Research Flags" in the Computerized Patient Record (CPRS) for study participants that have completed study participation (if applicable).
 - c) For studies involving drugs, collect opened used/unused drug supplies from study subjects as specified by the study sponsor and dispose of them or return them according to the sponsor's procedures (as applicable).
 - d) Dispose of any other study supplies (unused documents, specimen kits, shipping boxes, packaging materials, etc.) as specified by the study sponsor.
 - e) File copies of the drug or device accountability logs, final inventory, and returned documents in the study binder, if applicable.

- f) Audit the study binder for completeness and replace any missing documents.
- g) For subjects participating in studies involving a clinical intervention (Drug/device, etc.), notify the primary healthcare provider of the end of the subject's study participation.
- h) Submit the "Protocol Termination Report Form" to Emory IRB for paper submissions; for eIRB, select "Create Close-out" from the "My Activities" section.
- i) Close the study with the Research Office once all data analysis has been completed by turning in the following:
 - I. A copy of the IRB Close Out approval letter
 - II. An end of study summary abstract (additional materials may be needed for Merit Awards)
 - III. Include both of the above in an email notification of the study closing to the Research Office
- j) Obtain study records from the Research Pharmacist to store with the Investigator's files if applicable.
- k) Prepare study files for storage following the Short Term or Long Term Storage Procedures.
- l) Ensure that all electronic study identifying information has been saved on the secure research server.
- m) Send the AREF Contracts/ Grants Administrator an e-mail regarding project closeout.