

PROCEDURES FOR CLOSING HUMAN RESEARCH STUDIES

1. **Objectives:** Outline activities performed to close a human research study.
2. **IRB and Atlanta VAMC Close Out Requirements:**
 - a) A study may be "closed" when the following conditions are met:
 - i. Research is permanently closed to enrollment at the Atlanta VAMC (AVAMC).
 - ii. All subjects enrolled at the AVAMC have completed all research related interventions and interactions.
 - iii. Collection of blood or tissue has ceased at the AVAMC.
 - iv. Data Collection is complete at the AVAMC. No additional identifiable private information about the subjects is being collected by the investigator.
 - v. Reportable events have been reported.
 - vi. Data analysis of personally identifiable information (PHI) is complete.
3. **IRB Close Out Procedures:**
 - a) Log In to eIRB and select the "Create Close-Out" button in My Activities section. Complete as directed. VA requires the upload of the VA closeout form located at http://www.atlanta.va.gov/Docs/Closeout_Summary_for_Human_Subjects_Research.docx for all VA protocols.
4. **AVAMC Close Out Procedures:** (done after the study is closed at the IRB):
 - a) VA records are the property of the VAMC and must remain under the control of VA. Arrangements to obtain a copy of data should be discussed with the Research Office. Do not destroy research records, keys, or data.
 - b) Store electronic research data on the secured research drive (contact the Director of Research Operations if one is already not created). Remove all research data from all other drives.
 - c) Data Key Storage:
 - I. Arrange for proper storage of data keys by contacting the Director of Research Operations or designee.
 - II. Electronic data keys should be sent to the AVAMC Research Office to be placed on the secured research drive.
 - III. Store paper data keys in regulatory binder.
 - d) Document the "End of Study Participation/Study Termination Note" in the Computerized Patient Record (CPRS). For subjects that do not have a CPRS record, please make a note in the subject's study record.

- e) Inactivate “Research Flags” in the CPRS for each study participant (if applicable).
- f) 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.
- g) Dispose of or return any study supplies (unused documents, specimen kits, shipping boxes, packaging materials, etc.) as specified by the study sponsor.
- h) For studies involving drugs, collect unused drug supplies from study subjects and deliver to research pharmacy for reconciliation, return to sponsor, and/or disposal (if required).
- i) File copies of the drug or device accountability logs, final inventory, and returned documents in the study binder (if applicable).
- j) Obtain study records from the Research Pharmacist to store with the Investigator’s files (if applicable).
- k) Audit the study binder for completeness and replace any missing documents.
- l) Close the study with the Atlanta VAMC Science Information Office by emailing the following:
 - I. A copy of the IRB Close Out approval letter.
 - II. The “Close Out Summary for Human Subject Research” form that has been uploaded in eIRB. Additional materials may be needed for Merit Awards.
- m) Notify Rodney Thompson, Research Compliance Officer (RCO), of study termination. He will perform a final audit of research records. His email is rodney.thompson2@va.gov.
- n) After the RCO audit, prepare study files for storage following the “Long Term Storage of Research Records” policy and by completing the “Long Term Storage of Research Records” form. These documents may be found on the Atlanta VAMC Research website.
- o) The CSC will provide storage boxes and coordinate storage and shipment per the VA Record Control Schedule.
- p) If your project is administered by AREF, send the AREF Clinical Trials Financial Analyst the completed “Clinical Trial Closeout” form. This form is located on the AREF website under “forms/AREFforms/AREFProject Management Forms”.
- q) Records are stored at the Atlanta Federal Records Center, 4712 Southpark Blvd, Ellenwood, GA 30294.