

## **Appendix V: Closeout Procedures**

The Study Close Out will prompt the process of terminating a specific study and all related activity at SUNY Upstate. This includes completion of all documentation, complete final site visit, file archival, notify appropriate facilities, closeout Research Foundation study account to include process of determining receipt of any necessary funding from sponsor and payment of outstanding subject hospital billing.

- Study Close Out is defined as the termination of the conduct of the study at our site. This does not include a study that is no longer enrolling subjects as those studies may still follow subjects and receive payments. Study Close Out pertains to receipt of termination notice by the sponsor, closure of the study account which will transfer any remaining balance funding to a Multiple Sponsor Account in the PI's name and shipment of secure study files to the sponsor or to archival storage.
- Per the study agreement, the sponsor or site will determine study termination based on an agreed upon end date or process of study termination notification. At termination notification, the following offices will be notified with a copy of the termination notice:
  - IRB Office
  - Clinical Trials Office
  - Fiscal Services
  - IMT
  - RF Accounting/Budgeting

### PI/Coordinator:

- Notifies appropriate offices above of request for study closure.
- Coordinator or Billing Designate will verify that all subjects have been removed from the CAIS system.
- Review billing/funding to make certain all bills have been paid and funding received.
- Notify CTO if any funding is due from Sponsor with specific details.

### IRB:

- Submit *Termination Request Form* (on the IRB website- <http://www.upstate.edu/research/compliance/irb.shtml>).
- The IRB Office will terminate the study and forward a termination notice to the PI/coordinator.

### Fiscal (FSD)/Information Management (IMT)/Billing:

- The study will be removed from the MASTER CAIS system. If there are any BRIO Reports which are not completed, coordinator and PI will be notified that completed reports must be received within one week.
- IMT will forward to Fiscal a list of the patients that are on the study for their review.
- FSD will forward all outstanding accounts to the PI for review. FSD will notify the CTO of the amount due. All balances due to the Hospital shall be paid in full prior to closure of the study.
- Contact: Elaine Doughty 4-8078 (requests for bills); and Bobbi McBride 4-8092 (charges)

Post Award/Research Accounting:

- Post Award will require approval from the PI that all funding has been received and verify that the study balance may be transferred to a Multiple Sponsor Account in the PI's name.
- If any funding is owed from the sponsor, contact the CTO with details. CTO will follow up with sponsor and post award/accounting offices. Account termination will be placed on hold until completed.
- If any funding is owed back to the sponsor, PI will confirm with post award that the amount to be returned is accurate.
- At time of close out the Accounting Office will review and verify associated fees (IRB/CTO/Pharmacy). Appropriate adjustments will be made where necessary.
- Contact: Debora Weber 4- 4666