LSU HEALTH COORDINATOR COMPETENCIES

Study Closeout

Objectives

- Prepare studies for regulatory closeout as dictated by institutional and sponsor guidelines
- Recall the basics of document storage, including document retention
- Remind the team of the post-closure responsibilities

Closeout Procedures

Scientific

- Data query clean-up
- Case Report Form (CRF) clean-up
- IP accountability review
- Verification of study file completion
- Regulatory approval (IRB, IBC) closeout

Financial

- Submission of Closeout Certification and Closeout Request Form to Sponsored Projects

When Is A Study Closed?

Four different scenarios when a study might be closed:

1. Subject enrollment at the site is complete and all data is complete (*most common*)
2. Study is stopped due to safety issue or lack of efficacy
3. Poor investigator performance
4. Decision to withdraw by the investigator (*uncommon*)

Record Retention

At the completion of the study, all study documents need to be stored and maintained for a set period.

- There is language in the contract that will state how long the Sponsor requires study documents be retained
- Institutional Policy requires all study documents be kept for the life of the study plus 10 years

If the files are kept off-site (i.e., Iron Mountain, Vital Records, other long-term storage), a record of where they are stored must be readily available.

Post-Closeout PI Responsibilities

The Investigator continues to have responsibilities for a project even after the study is closed. These responsibilities, at a minimum, include:

- Retain records for the agreed upon time in accordance with the contract or institutional policy, whichever is longer
- Inform the Sponsor if contacted by the FDA for a site inspection
- Submit a final study report(s) to the Sponsor

Study Closeout Checklist

- ❑ Study documents are complete & filed
- ❑ Final report has been submitted to the Sponsor
- ❑ Close Request Application was submitted to IRB
- ❑ All Case Report Forms (CRFs) are complete & have been submitted
- ❑ All CRF corrections/queries have been addressed
- ❑ All source documentation is within the study files or location is noted in the study files
- ❑ Signed Informed Consent Forms are filed
- ❑ IP Dispensation & Disposition Log is complete
- ❑ IP has been returned to the Sponsor or destroyed at the direction of the Sponsor
- ❑ Any other study materials have been returned or destroyed
- ❑ Investigator Brochure has been filed with the other study documents
- ❑ Project Closeout Form has been submitted to Sponsored Projects

LSU Health Coordinator Competencies

- ✓ Onboarding
- ✓ Ethical Standards
- ✓ Protocol Compliance
- ❑ Informed Consent
- ❑ Patient Recruitment & Retention
- ❑ Management of Patients
- ❑ Documentation & Document Management
- ❑ Data Management & Information Technology
- ❑ Financial Stewardship
- ❑ Leadership & Professional Development