PM-305 Study Closeout for Sponsored Clinical Research

1. **PURPOSE:**
   To describe the procedures followed by research personnel engaged in clinical research at UTRGV during a close-out visit (COV) for a sponsored clinical study or trial. This applies from the time the monitor schedules the COV until all associated follow-up activities have been completed.

2. **SCOPE:**
   This SOP applies to key research personnel involved in arranging, managing, participating in, and/or resolving outstanding items resulting from the study COV.

3. **RESPONSIBLE INDIVIDUALS:** The Principal Investigator (PI), study coordinator, and/or other designated key personnel are responsible for study COVs.

4. **RELATED TERMS AND DEFINITIONS:**

   Case Report Form (CRF)
   Close Out Visit (COV)
   Investigational Product (IP)
   Key Personnel
   Monitoring
   Regulatory Binder

   Please reference the Standard Operating Procedures Glossary of Terms for complete definitions of terms in this SOP.

5. **POLICY STATEMENT:**
   This SOP will be used as a guide for study COVs of sponsored clinical research at UTRGV.

6. **PROCEDURES:**

   6.1 Preparing the Study Close-Out Visit**:**
   6.1.1 Use the Study Close-Out Checklist (see attachment section).

6.1.2 After the last patient has completed all scheduled visits associated with the study and all data has been collected and monitored from UTRGV, arrange a mutually convenient date and time for the study monitor to conduct the study COV.

6.1.3 The monitor should send a closeout confirmation letter and an agenda at least ten (10) business days prior to the scheduled visit.

6.1.4 If every element of close out has already been completed, the COV may be done by phone.

6.1.5 If the only elements of closeout remaining are within Florence or the sponsor's eCRF systems, the COV may be conducted remotely via Zoom, Teams, WebEx or another secure video communication platform.

6.1.6 Review the agenda from the monitor describing what is expected, what needs to be accomplished before visit takes place and to ensure that key personnel (pharmacists and or PI) will be available, if applicable.

6.1.7 Ensure that all regulatory documentation and case report forms (CRFs) not previously monitored are completed and ready for review. This should be a rare exception of last-minute changes or updates to documentation, as no COVs should even be scheduled if there is any data or regulatory that hasn't been previously monitored. For example, an investigator's medical license expired after the COV was scheduled and an updated one needs to be provided.

6.1.8 Ensure that all data queries received to date have been resolved and that the database has been locked.

6.1.9 Ensure the PI has access to the database **before** the COV and has done a review.

6.1.10 Have the monitor confirm if PI signatures are necessary prior to closeout. If so, obtain the necessary signatures. Sometimes the monitor prefers signatures to be obtained at the time of the close out visit instead of prior. Make sure all communication around this is clear and filed in the regulatory binder.

6.1.11 Encourage a separate pharmacy COV to take place prior to the site COV, when possible. Investigational pharmacy must inventory (IP)/ test article supply and complete final accountability records. If previously instructed, return, or dispose of any unused IP in accordance with the protocol and regulations. File copies of study packing slips and shipment receipts appropriately in regulatory binder for monitor review.

6.1.12 If the randomization code for any test article was broken for any reason (unblinding), ensure complete documentation has been filed.

6.1.13 Verify participant stipends have been distributed per the study budget, as outlined in the informed consent document.

6.1.14 Verify that all outstanding study invoices have been sent and payments have been received. (The exception being if there is a COV invoice/payment that must wait until the COV is completed.)

6.2 Managing the Study Close-Out Visit:

6.2.1 Continue the Study Close-Out Checklist.

6.2.2 Ensure all documentation is filed appropriately and ready for the monitor to review during the COV. Discuss any open study-related issues and what steps will be taken to resolve them in order to satisfy the sponsor/CRO requirement(s). There should be almost no remaining issues in order for the site to proceed with close-out.

6.2.3 Review any requirements for data retention and storage with the monitor.

6.2.4 Review any responsibilities for reporting serious adverse events and IND safety reports after formal termination of the study.

6.2.5 Review how the PI will ensure the appropriate follow-up for any participant experiencing an ongoing unanticipated problem (e.g., serious adverse event).

6.2.6 Review any ongoing conflict of interest reporting requirements.

6.2.7 Discuss processes regarding the possibility of a quality assurance (QA) audit and/or FDA audit.

6.2.8 If the study involved electronic data capture, discuss when copies of all CRFs will be provided to UTRGV. Establish how they will be sent.

6.2.9 Discuss the timelines and requirements for final payments, if applicable.

6.2.10 Ensure all documentation is complete with the necessary signatures. Often, the PI needs to sign off on the final copies of the delegation log, drug accountability log, site visit log, etc., during the COV.

6.2.11 Ensure return or destruction of all other study-related materials, such as unused lab kits and CRFs.

6.3 Follow-up after the Study Close-Out Visit:

6.3.1 The monitor will send a study close-out follow-up letter/report outlining what was accomplished during the visit and noting any items that need additional attention. Ensure that a copy of the report and follow-up letters are placed in the regulatory file.

6.3.2 If not previously instructed, ensure that any remaining IP is either returned to the sponsor/CRO per their requirements or if the sponsor allows remaining investigational drug to be disposed of at the site following the COV. (See Investigational Pharmacy SOPs)

6.3.3 Submit the Study Closure the UTRGV IRB. Provide the sponsor/CRO with a copy of the IRB closure letter and file one in the regulatory binder.
Note - once the study has been terminated with the IRB, no other work on the study may occur other than 6.3.4-6.3.7.

6.3.4 Complete Study Closeout Checklist and file in the regulatory binder.

6.3.5 If study records are in Florence eBinders™, ensure the study is labeled as closed within Florence. Contact clinicalresearch@utrgv.edu to request the study be moved into the Florence archives.

6.3.6 Arrange for transfer/ storage of paper study documents to secure, UTRGV approved storage location that was previously disclosed to the monitor.

6.3.7 Communicate the complete study closure with all affected departments and personnel (finance, sub-investigators, contracts, post approval monitoring, etc.).

7. REFERENCES:

- 21 CFR 312.50 General Responsibilities of Sponsors
- 21 CFR 312.59 Disposition of unused supply of investigational drug
- 21 CFR 312.60 General Responsibilities of Investigators
- 21 CFR 312.62 Investigator recordkeeping and record retention
- 21 CFR 312.64 Investigator reports
- 21 CFR 312.66 Assurance of IRB Review
- 21 CFR 312.68 Inspection of Investigator's Records and Reports
- UTRGV RA-205

8. FORMS OR ATTACHEMENTS

Study Closeout Checklist