**Guidance: Study Closure**

**Policy:** It is the policy of UTHSC-H that that at the end of a clinical research study, the Principal Investigator should formally close the study site.

**Key Terms**

**Essential Documents:** Essential documents are those documents which individually and collectively permit evaluation of the conduct of research and the quality of data produced.

**Last Patient Last Visit:** The date when the last study participant in the research study completes the final study visit.

When the last patient has completed the last visit and individually identifiable data will not be used any longer, the PI or delegate should formally close the study at the site.

**Site Closure Visit** – After the last patient has completed all study activities and all outstanding data queries have been resolved, industry sponsored clinical trials schedule a formal site closure visit from the trial monitor to close the site.

For clinical trials with no outside monitor, the research team should ensure that the study is properly closed at the site. Some of the tasks that need to be completed include:

1. The Study Closure Report should be completed and submitted to CPHS via iRIS. If a manuscript has been accepted or published, include this with the submission.
2. Case report forms (or data collection forms) should be complete for all enrolled subjects. Where applicable, PI or delegate should ensure that copies of all the forms have been sent to the sponsor or data coordinating center. Ensure that all outstanding data queries have been resolved.
3. If drugs are being stored at IDS, the study pharmacist should be informed of the scheduled site close-out visit so that study drug can be inventoried and drug accountability records can be completed. Arrangement should be made for disposal of unused study drugs.
4. Inventory trial supplies including lab kits, diary cards, unused case report forms etc. These should be returned to the sponsor, data coordinating center or properly disposed. Disposal records should be kept in the regulatory files.
5. For industry sponsored trials, the PI or delegate should discuss with the monitor the sponsor’s requirements for patient follow-up for serious adverse events after formal termination from the study.
6. The PI or delegate must ensure that all payments have been made to the institution and arrange to close the research account after all transfers are made.
7. If research results are going to be returned to subjects, the PI or delegate should plan how this will be accomplished. CPHS should be informed of this plan.
8. Copies of source documents should be obtained for archival or plans should be made to ensure that medical records are not destroyed until the end of the retention period.
9. Regulatory files should be carefully reviewed to ensure they are complete. This could be achieved by checking off the list under the essential documents in the ICH GCP Guidelines. The PI or delegate should ensure that all the signed consent forms and HIPAA forms are present.
10. For industry sponsored studies, refer to the contract or talk to the monitor to ensure that documents are stored for the required period of time. For other studies follow the UT Houston guidance for records retention. Arrange for transfer of study documents to secure storage. Maintain details of documents stored in a log so that individual files can be quickly retrieved in the event of an audit or inspection.

**Applicable Regulations and Guidelines**

* ICH Good Clinical Practice: Consolidated Guideline

**Applicable Institutional Policies and Procedures**

* None

**Attachments**

* Regulatory Binder Contents Template

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