**Guidance: Study Initiation**

**Policy:** It is the policy of UTHSC-H that prior to initiating the research study; all regulatory and institutional requirements must be met. In addition, the research staff and others involved in recruitment, selection of subjects and enrollment must receive appropriate training.

**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.

**Essential Documents**: Prior to initiating the study, the Principal Investigator must ensure that the following are available:

* + 1. CPHS Approval Letter
		2. IND or IDE documentation (if applicable)
		3. Signed Clinical Trial Agreement (for industry sponsored trials)
		4. Grant Approval Letter (for funded research)
		5. Facility Approvals (Memorial Hermann Hospital Approval, Harris County Hospital District approval, etc.)
		6. Other institutional approvals (Institutional Biosafety Committee, Radiation Safety Committee etc.)

The Principal Investigator should ensure that all necessary clinical trial supplies are already at site, or assurance that they will be available before the first subject needs the supplies. This includes study drug / device, lab kits, case report forms, subject diaries, questionnaires etc.

The Principal Investigator should assign study responsibilities to members of the study team. It is a good practice to have a study responsibility log signed by all study team members prior to start of the study.

The Principal Investigator must ensure that all members of the study team are trained for their role in the study. At the minimum, all the study team members should be informed of their role in study (as documented in the study responsibility log) and must have access to the current approved study protocol and consent document.

The Principal Investigator or Study Coordinator should start filing essential documents in the Regulatory Binder prior to start of the study according to policy on Regulatory Binder.

The study team should discuss the step by step conduct of the clinical trial going through all the study related procedures from recruitment to how subject visits will be handled. The study team may develop various tools to assist with study conduct such as flowsheets, checklists, study stamps, worksheets, etc.

**Site Initiation Visit** – Monitors for industry sponsored protocols schedule a site initiation visit prior to the start of the study. It is important for the Principal Investigator and the Study Coordinator to attend this meeting. It is highly encouraged that all Key Study Personnel attend this important meeting. If some members of the study team are not available at this meeting, it is the Principal Investigator’s responsibility to ensure that they receive the necessary information in a timely manner.

**Applicable Regulations and Guidelines**

* 21 CFR 56.109 IRB review of research
* 21 CFR 312.23 IND content and format
* ICH Good Clinical Practice: Consolidated Guideline

**Applicable Institutional Policies and Procedures**

* None

**Attachments**

* Study Responsibility Log
* Regulatory Binder Contents Template

**If you find errors in this document, contact** **clinicaltrials@uth.tmc.edu**

|  |  |
| --- | --- |
| **Document Number:** | 402-005 |
| **Author:** | Clinical Trials Resource Center |
| **Effective:** | June 1, 2011 |
| **Revision History:** | None |
|  |  |
|  |  |