UTHealth Houston

Title: Study Initiation	Version: 2.0	Effective Date: 1 Jun 2011	Page 1 of 2

1. Purpose

1.1. To outline the process for study initiation at UTHealth Houston.

2. Scope and Responsibility

2.1. This SOP applies to all individuals participating in the conduct of clinical research at UTHealth. All staff to whom an investigator assigns a study task are required to follow this SOP.

3. Definitions

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

3.2. **Delegation of Responsibilities Log** is used by a study team to specify the names of individuals who will be responsible for implementing specified protocol activities.

4. Policy

4.1. It is the policy of UTHSC-H that prior to initiating the research study; all regulatory and institutional requirements approvals must be obtained.:

4.1.1. IND or IDE documentation (if applicable)

4.1.2. Fully Negotiated Clinical Trial Agreement (for industry sponsored trials)

4.1.3. Grant Approval Letter (for funded research)

4.1.4. Facility Approvals (Memorial Hermann Hospital Approval, Harris County Hospital District approval, etc.)

4.1.5. Other institutional approvals, if applicable (RCOI Committee, Institutional Biosafety Committee, Radiation Safety Committee etc.)

5. Procedures

5.1. The Principal Investigator (PI) should ensure that all study tasks are appropriately delegated to study team members. The study delegation log should be completed.

5.2. PI 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).

5.3. Delegated study team members involved in supervising, managing, or conducting study-related activities should have all required study documents available for review prior to study initiation.

5.4. The study team should start filing essential documents in the Regulatory Binder prior to start of the study according to policy on Regulatory Binder.

5.5. PI should ensure that 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.

5.6. 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.

5.7. The study team should develop tools to assist with study conduct such as flowsheets, checklists, study stamps, worksheets, etc.

5.8. **Site Initiation Visit** – The Site Initiation Visit (SIV) prepares the research site to conduct the research study.

5.8.1. **Industry Sponsored Trials:** Industry sponsored trials often have a site initiation visit prior to the start of the study. It is important for the PI and study team members to attend this meeting. If some members of the study team are not available at this meeting, it is the PI's responsibility to ensure that they receive the necessary information in a timely manner.

5.8.2. **Trials that are not Industry Sponsored:** Trials that are not industry sponsored may not have a formal site initiation visit organized by the study sponsor. These include investigator-initiated trials or federally funded multi-center trials led by other institutions. PIs for these types of trials should schedule a study initiation meeting to prepare the research site for conduct of the trial.

6. References

6.1. CPHS Training Requirements: https://www.uth.edu/cphs/for-researchers/training.htm

6.2. SOP Training

7. Appendices

7.1. Training Log

7.2. Delegation of Authority Log

7.3. Study Initiation Checklist

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

Document Number:	401-005
Developed by:	Good Clinical Practice SOP Workgroup
Approved by:	AVP, Research Compliance
Revision History:	1 Jun 2011 1 Jun 2023