Procedure Name: Hospital Inpatient Trial Procedure – A to Z

Effective Date: March 30, 2010

Revision: 01

Initiating Department: Office of Clinical Trials

Procedure Number: OCT-014

Application: Hospital Inpatient Trial

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OBJECTIVE:

The objective of this procedure is to describe the steps occurring from the inception of an inpatient clinical trial the close-out of the trial. Steps are enumerated in order to facilitate and define the day to day functions and duties of personnel involved in the conduct of clinical trial.

SCOPE:

This procedure applies to all proposed clinical trials governed by Office of Clinical Trials (OCT).

RESPONSIBILITY:

Principal Investigators (PIs), Clinical Research Coordinators (CRCs), Clinical Study Administration Coordinators (CSACs) and other key personnel associated with the research team are responsible for following this procedure. Steps A, D, G, H, I, J, K, U, and Z are the responsibility of OCT personnel.

PROCEDURE:

NOTE: THIS OUTLINE REPRESENTS THE OPTIMAL FLOW OF THE STEPS. SOME OF THE STEPS OCCUR SIMULTANEOUSLY, AND SOME MAY OCCUR IN A SLIGHTLY DIFFERENT ORDER THAN LISTED (DEPENDING ON THE SPONSOR'S OWN PROCEDURES AND THE TIMING OF THE PROTOCOL).

- A. The sponsor non-confidentially contacts the PI or vice versa to explore the possibility of UNTHSC becoming a site for a specific protocol. Once received from the sponsor, OCT sends the Confidentiality Disclosure Agreement (CDA) to UNTHSC's Legal Department (Legal) for review. After approval from the sponsor is received, OCT Regulatory Affairs (RA) routes CDA for signatures to be obtained. (See Procedure Number OCT-012 for greater detail.)
- **B.** Site feasibility questionnaire received from sponsor. PI, CRC and CSAC collaborate to complete it and return it to the sponsor and send a copy to RA. (Sometimes the site feasibility questionnaire is received before the CDA).

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- **C.** The sponsor schedules a site pre-selection visit. Key Personnel of the study need to have privileges with the hospital/hospitals where the trial procedures will be conducted.
- **D.** If the HSC site is selected, the protocol is received from the sponsor.
- **E.** Investigator's meeting is scheduled.
- **F.** OCT RA will initiate regulatory document and new study packet submission to the IRB. If the agreement has been made available, RA will begin the contract process. (See Procedure Number OCT-012 for greater detail.)
- **G.** PI, CRC and/or CSAC, and the Director will review initial budget proposed by the sponsor for general acceptability.
- **H.** OCT Financial Manager reviews the budget proposal and forwards it to the Director of Clinical Trials, who starts budget negotiation process. Hospital fee is also negotiated. The PI needs to be in agreement with the final budget proposal. (See Procedure Number OCT-011 for greater detail.)
- I. After negotiations on proposed budget are concluded and both the PI and the Director determine that proposed budget is acceptable, OCT RA will initiate documentation submission to both the UNTHSC and the hospital's Institutional Review Board (IRB). (Please note that new study packets are often submitted with draft budgets.)
- **J.** IRB approvals and final contract are received. CRC schedules in-service with the hospital personnel. Hospital personnel include: pharmacy, laboratory, radiology, operating room personnel, staff/nursing, and all supervisors.
- **K.** RA compiles regulatory binder and gives it to the CRC.
- **L.** CRC/CSAC meets with the PI to re-discuss enrollment strategies and trial activities. This planning occurs throughout the trial.
- **M.** Study initiation visit is scheduled.
- N. OCT Financial Manager sets up research account and enters the study in Study Manager.
- **O.** Study medication is shipped to the pharmacy who logs receipt appropriately.
- **P.** Enrollment starts and study participants are seen in the hospital.
- Q. CRC will submit requests for medical charts according to the hospital's time frame for such requests. CRC monitors and copies hospital notes/medical charts daily and they become source documentation for that subject unless otherwise specified by the sponsor.

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If the sponsor will not allow the use of medical charts as source documentation and has not provided any source documents, then the CRC will prepare such.

- **R.** All protocol specified procedures for each visit are performed in accordance with Good Clinical Practice guidelines. (See Procedure Numbers CR-001 through CR-010 for greater detail.) Should the study be an Electronic Data Capture trial, a laptop or other appropriate computing/storage device will be provided by the sponsor.
- **S.** All laboratory/other reports are reviewed and signed by the PI, adverse events and serious adverse events are assessed by the PI and reported to the sponsor and IRB in a timely manner.
- **T.** Sponsor monitoring visits are scheduled as often as the study requires.
- **U.** CRC and/or CSAC meets with OCT Financial Manager at the study start and on as needed basis throughout the trial.
- **V.** Clinical Trial is closed after all study visits have been performed according to the protocol; all data have been entered; all adverse events have been reported; all queries have been resolved; and the budget has been reconciled.
- W. Monitor comes for close out visit.
- **X.** The PI and CRC submit final reports to UNTHSC's IRB and to the hospital's/hospitals' IRB.
- **Y.** After IRB acknowledgement that the study has been closed is received, trial coordinator meets with the Financial Manager to plan the study account closure.
- **Z.** All research documents are kept and stored according to regulations and sponsor's request.

REVISION HISTORY

Rev	DCO	Description of Change	Approved by
1	10-114	Replacement of "policy" with "procedure"; update of procedures and addition of change history.	MVWB