Procedure Name: **Non-Hospital Inpatient Trial Procedure – A to Z**
Effective Date: **March 30, 2010**
Revision: **01**
Initiating Department: **Office of Clinical Trials**
Procedure Number: **OCT-013**
Application: **Non-Hospital Inpatient Trial**

OBJECTIVE:

The objective of this procedure is to describe the steps occurring from the inception of an outpatient 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 feasibility questionnaire is received before the CDA).

C. The sponsor schedules a site pre-selection visit. If the HSC site is selected, protocol is received from the sponsor. CRC discusses enrollment strategies with the PI.

D. 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.)

E. Investigator's meeting is scheduled.

F. PI, CRC and/or CSAC, and the Director will review initial budget proposed by the sponsor for general acceptability.

G. After both the PI and the Director determine that initial proposed budget is at the very least feasible, Institutional Review Board (IRB) documentation submission is initiated. (Please note that new study packets are often submitted with draft budgets.)

H. OCT Financial Manager reviews the budget proposal and forwards it to the Director of Clinical Trials, who starts the budget negotiation process. The PI needs to be in agreement with the final budget proposal. (See Procedure Number OCT-011 for greater detail.)

I. The protocol is approved by the IRB and final contract is signed.

J. RA compiles regulatory binder and gives it to the CRC.

K. OCT Financial Manager sets up research account and enters the study in Study Manager.

L. Study initiation visit is scheduled.

M. Study drug is shipped by the sponsor to the PI/CRC unless it needs to be prepared by the UNTHSC Pharmacist (as in infusion trials) in which case it will be shipped directly to the UNTHSC Pharmacy. When received, the necessary party will log it appropriately.

N. CRC meets with the PI to re-discuss enrollment strategies and trial activities. This planning occurs throughout the trial.

O. CRC prepares source documentation if not provided by the sponsor. Should the study be an Electronic Data Capture trial, a laptop or other appropriate computing/storage device will be provided by the sponsor.

P. Screening and subject enrollment starts. (List of potential participants already may be in place).

Q. CRC or CSAC schedules subjects for visits.

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.)

S. All laboratory 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 report to the 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	10-113	Replacement of "policy" with "procedure"; update of procedures and addition of change history.	MVWB