Procedure Name: **Obtaining and Maintaining IRB Approval**
Effective Date: **March 1, 2010**
Revision: **01**
Initiating Department: **Office of Clinical Trials**
Procedure Number: **CR-006, Rev 1**
Application: **Principal Investigators, Clinical Coordinators**

OBJECTIVE:

Assure that IRB approval is obtained and maintained in compliance with regulatory requirements. Describe the process for obtaining IRB approval, documenting this approval and maintaining IRB approval throughout the course of the clinical study.

REFERENCES:

21 CFR 56	General Responsibilities of Investigators
21 CFR 312.66	Assurance of IRB Review
FDA	Guidance for Industry: Protecting the rights, Safety, and Welfare of Study Subjects – Supervisory Responsibility of the Investigators
21 CFR 812.64	IRB Continuing Review
I21CFR 812.100	General Responsibilities of the Investigator
21 CFR 812.110	Specific Responsibilities of the Investigator
UNTHSC-FW OPHS-IRB Website	Guidance or "How-to-pages" located at http://www.hsc.unt.edu/sites/OPHS-IRB/index.cfm?pageName=Instructional%20Guidelines#whatHSR
OPHS-IRB Manual Sections 5, 6 &7	Section 5: IRB Review and Types of Submissions Section 6: Submitting the Application to the IRB: Forms and Process Section 7: Reporting Requirements after IRB Approval

SCOPE:

US FDA regulations (21CFR 312.66) require that the Principal Investigator (PI) assures that an IRB that is in compliance with 21 CFR 56, will be responsible for the initial and on-going review and approval of the clinical trial. The regulation goes on to require that the PI will promptly report to the IRB all changes in the research activity and all unanticipated problems involving risk to the human subjects and that he/she will not make any changes in the research without IRB approval (except if necessary to mitigate an immediate hazard).

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One aspect of this regulation that is frequently over-looked is that the PI is responsible for the compliant operation of the IRB concerning his/her clinical study. This procedure details the requirements for obtaining initial IRB approval of any clinical study, maintaining on-going approval of the clinical study and assuring that the IRB operates in compliance with the requirements of 21 CFR 56.

RESPONSIBILITY:
It is Principal Investigator's (PI) responsibility to ensure that the IRB initially reviews, approves and periodically reviews and re-approves all clinical research, including all amendments and modifications to the protocol and consent documents and processes. Additionally, the PI is responsible for ensuring that the IRB operates in compliance with 21 CFR 56.

PROCEDURE:
Communication with the Office of Clinical Trials
Upon receipt of initial submission documents from the sponsor (i.e., study protocol, Investigator's Brochure, Informed Consent Form(s), handouts, recruitment materials, regulatory documents, etc.), the PI will forward said documents to Regulatory Affairs of the Office of Clinical Trials (OCT) to coordinate the submission of the protocol.

Communication with the IRB
The PI will obtain the UNTHSC IRB's current procedure and forms utilized for study and protocol initiation and review. In the event that the UNTHSC IRB authorizes the use of a commercial or central IRB for the study, the current procedures and forms of that alternate IRB will be used. For UNTHSC's IRB, the PI will refer to the below-listed resources for procedural guidance:

UNTHSC-FW OPHS-IRB Website	Guidance or "How-to-pages" located at http://www.hsc.unt.edu/sites/OPHS-IRB/index.cfm?pageName=Instructional%20Guidelines#whatHSR
OPHS-IRB Manual Sections 5, 6 &7	Section 5: IRB Review and Types of Submissions Section 6: Submitting the Application to the IRB: Forms and Process Section 7: Reporting Requirements after IRB Approval

In addition, the PI will:

1.0 Attend the IRB meeting held for initial review in order to answer questions from the IRB. If attendance is not possible, arrange for an informed research team member to attend.

2.0 Receive the IRB's disposition of the submission. If approved, will ensure that the Study Coordinator files the approval in the trial's Regulatory Binder. If the submission is not approved, will coordinate with Regulatory Affairs in OCT to address the IRB's concern(s) and follow the appropriate procedure to resubmit a revised application.

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3.0 Obtain the current list of IRB members and their qualifications and file the document in the trial's Regulatory Binder.

REVISION HISTORY

Rev	DCO	**Description of Change**	**Approved by**
1	08-014	Edited for clarity and style	Michael V.W. Bergamini

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