Procedure Name:	**Qualification and Training Requirements for the Office of Clinical Trials Personnel**
Effective Date:	**March 2, 2010**
Revision:	**01**
Initiating Department:	**Office of Clinical Trials**
Procedure Number:	**QA-003, Rev 1**
Application:	**Office of Clinical Trials**
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OBJECTIVE:

Good Clinical Practice requires that clinical research personnel be qualified by means of background, education, training and experience to perform their assigned duties. This procedure documents the methods that the Office of Clinical Trials (OCT) utilizes to establish and document minimum qualifications for each applicable position, document that both incumbent and newly hired individuals meet those requirements, establish training requirements for each applicable position and document the training conducted.

REFERENCES:

ICH E-6	Good Clinical Practice
UNTHSC-FW	Human Resources Policies and Procedures

SCOPE:

This procedure applies to all OCT personnel and to Key Personnel conducting clinical trials.

RESPONSIBILITY:

1. Managers are responsible for identifying the minimum qualifications of personnel in their departments, defining training requirements, assuring that required training is conducted and documenting training conducted per the requirements of this procedure.

2. Office of Clinical Trials management is responsible for auditing training records per the requirements of this procedure.

DEFINITIONS:

"Manager" in this procedure refers to the highest ranking member of management in a given unit, regardless of actual title. The procedures detailed in this procedure may be delegated to other members of management at the discretion of the "manager".

"Full-time position" includes full-time employees, contract employees such as research nurses, consultants or contractors who may be fulfilling those roles.

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ATTACHMENTS:

1. Illustration of a Training Record

PROCEDURE:

Establishing Minimum Qualifications

Managers will prepare a written position description for each full-time position. The position description will define the minimum combination of training, experience and education to assure that the candidate can fulfill his/her responsibilities. Position descriptions are subject to Document Change Control as defined in policy and procedures. Approved position descriptions will be filed in the respective employee's training folder.

Establishing Training Requirements

Department managers will establish training requirements for each full time position. These training requirements will be documented such that the established requirements and their subsequent completion can be reviewed. An illustration of a training record that meets this requirement can be seen in Attachment 1. For some positions and at the manager's discretion, professional certification may provide documentation that specified training requirements are met [i.e., Certified Clinical Research Coordinator (CCRC), Collaborative Institutional Training Initiative (CITI)].

Documenting Training

Training conducted in response to the requirements established above must be documented and maintained in the training file. An illustration of a training record that meets this requirement is presented in Attachment 1.

Assessing Training Effectiveness:

Training programs may be developed or purchased to cover specific relevant topics. Such programs should include an objective assessment as applicable. Assessment can include a written test, oral evaluation, hands-on demonstration or other assessment. The intent of this requirement is to include a relevant form of assessment in contrast to requiring that a trainee read a procedure to be considered trained. Where utilized, a copy of the completed assessment instrument is to be maintained in the training file.

Training on Internal Procedures:

Most procedures require training either before or following implementation. Such training will be documented and assessed as described above. Note that the individuals who authored, edited, reviewed and approved the procedure are not required to complete and document training for that procedure.

Training Files:

Training files containing the position description, training requirements and documentation of applicable training conducted may be maintained either electronically or in hardcopy. Regardless of the method used, training records must be protected from alteration and available for review by the OCT management or external auditors/investigators.

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REVISION HISTORY

Rev	DCO	Description of Change	Approved by
1	08-003	Edited for clarity	MVWB

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TRAINING RECORD – TEMPLATE

The following training record is provided as an illustration. Other forms may be used at the manager's discretion provided that the requirements established in the Training SOP are met.

Employee:_____ Position:_____

Training Requirement	**Training Conducted**
UNTHSC Research and IRB Policies and the OCT Procedures	
	Date & reference to assessment
QA-001 – Format Requirements for OCT Documents	
QA-002 – Document Change Control	
QA-003 – Requirements for Research Personnel Training	
Other Training	
UNTHSC Orientation	
Fundamental GCP	
Medical training programs	
CITI	
CCRC	