Procedure Name: **Format Requirements for Controlled Documents**
Effective Date: **February 26, 2010**
Revision: **01**
Initiating Department: **Office of Clinical Trials**
Procedure Number: **QA-001, Rev 1**
Application: **Office of Clinical Trials**

OBJECTIVE:

The objective of this procedure is to facilitate the approval of UNTHSC Office of Clinical Trials Controlled Documents by defining format requirements and providing a content guide.

SCOPE:

This procedure applies to all regulated documents and does not apply to documents that are not subject to regulatory oversight.

RESPONSIBILITY:

Initiators of a Controlled Document are responsible for following this procedure. OCT management is responsible for assuring that the provisions of this procedure are followed.

PROCEDURE:

Procedure Numbering:

OCT controlled procedures (Controlled Documents) are uniquely identified to provide for easy reference. Controlled Documents are numbered using a unit prefix followed by a unique 3-digit number. Numbers may be duplicated among units. OCT prefixes include:

RA – Regulatory Affairs
CR – Clinical Research
QA – Quality Assurance

Headers, Footers, Approval Blocks and Document Revision History

Document Header – Page 1:

Page 1 of each controlled document will contain a header containing the following information:

- UNT Logo or Graphic
- Procedure Name
- Effective Date
- Revision
- Initiating Department
- Procedure Number (unique number assigned sequentially by the OCT management)
- Application (i.e., who is affected by this procedure)

- Page x of y

Document titles are assigned by the initiator and confirmed during the change control process. Document numbers are assigned by the OCT management. Revision numbers are sequential, beginning with 0 for the original version of the document and incrementing each time a revised document is approved. Page numbering is sequential. Use of automatic page numbering is encouraged.

Effective dates are assigned by the OCT management following document approval. Effective dates are assigned based on the training requirements of the approved procedure and therefore may be somewhat later than the approval date.

Document Header – Page 2 and all subsequent pages

The document header for pages 2 through the end of the document contains a simplified version of the information presented on page 1. The page 2 header contains:

- UNTHSC Office of Clinical Trials:
- Document Title
- Document Number and revision
- Page x of y

Examples of Page 1 and Page 2 headers are illustrated in this document.

Footers

The footer notes that the subject document is a Controlled Copy, is confidential and proprietary and requires that the version is verified before use. Footers are illustrated in this document.

References:

Where applicable include a table of references which should follow the "Responsibility" section. Include references to external documents such as guidance documents and published regulatory requirements.

Document Organization:

Controlled documents shall include the following sections. Note that some of these are optional and should be utilized when applicable:

- Objective - Describe as briefly as possible the goal of the document
- Scope – Define the boundaries and/or limits of the procedure or document
- Responsibilities – List the applicable job titles and their specific responsibilities under the subject procedure
- References (optional) - include as applicable
- Definitions (optional) – include if the document contains terms or abbreviations which may not be known by the end users)
- Procedure – detail the procedure to be followed following the style recommendations described below.
- Attachments (optional) – include if the document contains attachments. The use of process flow diagrams is encouraged. Forms which are used in association with the procedure should be attached to the procedure.

Document Style

OCT documents should follow generally accepted styles which may be available in published style manuals. General recommendations for document style include:

- Font Types – Because OCT documents may need to be submitted to Regulatory Agencies, they will be prepared in Times Roman, font size 12 for general text. Headers and footers may utilize smaller fonts but not smaller than font size 8.
- Use **CAPITAL BOLD** for section heads (e.g., Objective, Scope, Procedure, etc).
- Use underlined section heads for subdivisions within a larger division.
- The use of outline numbering is encouraged. Generally, attempt to keep numbered subsections to three or less.

Literary Style

- Active vs. Passive voice - Use active voice to describe activities performed by the end-user(s) as much as possible. Do not use passive voice (e.g., the use of passive voice is to be avoided.)
- Procedural Description – Minimize the use of notes or comments that are not actions of the end-user. Where necessary, clearly identify the use of notes by starting the line or paragraph with "NOTE".
- Acronyms and Abbreviations - Minimize the use of acronyms and abbreviations. When used, define the abbreviation or acronym the first time it is used (e.g., Code of Federal Regulations (CFR); use the acronym or abbreviation thereafter in the document. Use the "Definitions" section to define acronyms that are not in common use.

Revision History:

The revision history appears on the last page of the procedure. It contains the following information:

- Revision number
- DCO # - The DCO is the **D**ocument **C**hange **O**rder number which is a tracking number assigned by the OCT management. The DCO provides traceability to the document history file maintained by the OCT management.
- Description of Change – This is a brief synopsis of the changes provided in the subject document. It is intended to be very brief; a more comprehensive description and rationale for changes is documented in the document history file (DCO forms). See SOP QA-002.
- Approval Signature – Signature of the member of OCT management approving the procedure.

REVISION HISTORY

Rev	DCO	Description of Change	Approved by
1	08-001	Edited for clarity and style.	Michael V.W. Bergamini