



Procedure Name: Controlled Document Change Management
Effective Date: February 26, 2010
Revision: 01
Initiating Department: Office of Clinical Trials
Procedure Number: QA-002, Rev 1
Application: Office of Clinical Trials
Page: 1 of 6

OBJECTIVE:

The objective of this procedure is to describe the process followed to create, modify, review, approve and implement Controlled Documents

SCOPE:

This procedure describes the system that governs the generation of Controlled Documents regulating the Office of Clinical Trials (OCT).

RESPONSIBILITY:

1. The initiator of a Controlled Document is responsible for the completeness and accuracy of the document submitted, including any supporting documentation.
2. Quality Assurance/Regulatory is responsible for:
 - Assigning document change order (DCO) numbers and managing the change control process
 - Assessing the potential regulatory impact of the proposed Controlled Document change to an already existing Controlled Document
 - Reviewing the content of new and revised Controlled Documents
 - Ensuring that all appropriate reviewers are included in the review process
 - Assuring that the same processes that approved the original Controlled Document review any revisions to that Controlled Document
 - Ensuring that all supporting documents are relevant and approved as necessary
 - Establishing effective dates upon approval or completion of training as appropriate
 - Updating the DCO database and filing the approved and effective Controlled Document into the “Approved” section of the electronic document system

ATTACHMENTS:

1. Document Change Order form

CONTROLLED COPY, Do Not Duplicate

CONFIDENTIAL and PROPRIETARY
VERIFY THAT THIS IS THE CORRECT VERSION BEFORE USE

PROCEDURE:

Creation/Revision of Controlled Documents

NOTE: Any qualified employee may initiate a new Controlled Document or a change to an existing Controlled Document by following the directions outlined in this procedure.

The initiator will:

1. Prepare a draft copy of a new or revised Controlled Document. Follow the format prescribed by the OCT procedure “Format Requirements for Controlled Documents” as applicable. For a revised Controlled Document, make a copy of the current version of the Controlled Document and modify the text appropriately (i.e., create a “red-line” version). When done electronically, use the change tracking tool of the word processing software to automatically identify the changes made.
2. SAVE the document to the user’s directory (i.e., a different directory than that used for approved documents).
3. Once drafted, request a pre-numbered DCO form from the OCT management.
4. Complete the pre-numbered DCO form as follows (Attachment 1):
 - Enter the title of the Controlled Document and revision # (the first revision is Rev 0).
 - Enter the rationale for either the change or the new Controlled Document as briefly and as accurately as possible. List any other Controlled Documents that may be impacted by the proposed change.
 - Attach any relevant documents (e.g., protocols and reports). If not physically possible (e.g., the supportive documentation is too voluminous), reference the documents.
 - Enter the personnel who will review and approve the Controlled Document. Generally this will include the initiator’s supervisor and the manager of the affected department.
 - Detail the training requirements on page 2 of the DCO form
5. Prepare the draft Controlled Document for review. Mark the Controlled Document as “DRAFT” and circulate:
 - A copy of the revised/new Controlled Document
 - The previously approved (red-line) Controlled Document if applicable
 - The DCO form
 - Any supporting documentation (i.e. summary reports, etc.). Assure that these supporting documents are approved where appropriate.
6. Distribute the Controlled Document to the reviewers as listed on page 1 of the DCO form (Attachment 1). Review may be performed sequentially or simultaneously (shotgun review).

CONTROLLED COPY, Do Not Duplicate

**CONFIDENTIAL and PROPRIETARY
VERIFY THAT THIS IS THE CORRECT VERSION BEFORE USE**

UNT-HSC OFFICE OF CLINICAL TRIALS
Controlled Document Change Process

QA-002

Page 3 of 6

7. Collect the review copies at the completion of the review period. Review each reviewer's comments and either incorporate the requested change in the draft Controlled Document or discuss the proposed revision with the appropriate reviewer.
8. Prepare the FINAL DRAFT of the Controlled Document.
9. Forward the Final Draft to the OCT management for final review and approval.

Reviewers will:

10. Perform an initial review of the draft Controlled Document. Mark the DCO form as either approving the draft Controlled Document "OK as is" or "OK with changes". When marking the later, provide the changes required to the requestor. When marking up an electronic draft Controlled Document, utilize "track changes", a different color font; utilize "comments" or some other method to differentiate required changes from the original text.
11. Following review, return the draft Controlled Document to the initiator.
12. Following preparation of a final draft, review the final draft and indicate either approval or rejection of the Controlled Document on page 2 of the DCO. If rejected, the initiator may prepare a new final draft and attach another copy of page 2 of the DCO.

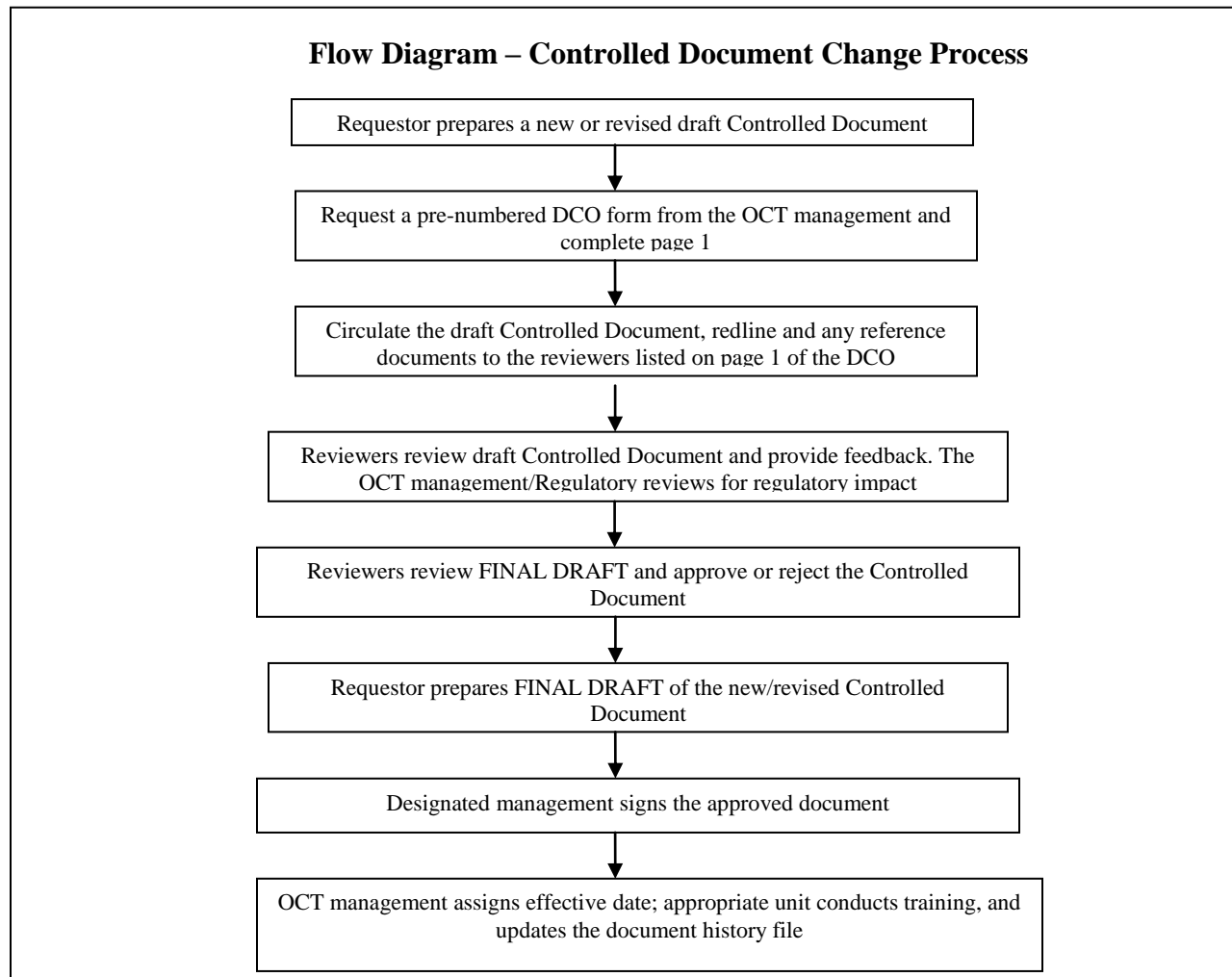
QA will:

13. Assign a DCO number and issue the numbered DCO form to the initiator. DCOs are sequentially numbered beginning with the year. For example, the first DCO issued for 2008 is numbered as 2008-001.
14. Review the draft procedure and assess any potential regulatory impact. Significant changes to product attributes or validated processes may trigger additional regulatory requirements.
15. If the Final Draft is acceptable, forward it to the same team members who reviewed the draft(s).
16. Upon receipt of a Controlled Document approved by the review process, assign the effective date and record it on the new/revised Controlled Document, the DCO form and the DCO database as applicable. Effective dates are generally set two work weeks from the date of approval to provide sufficient time to conduct and document training on the Controlled Document.
17. Upon reaching the effective date, create a "read-only" protected version of the approved Controlled Document (e.g. locked pdf document or other write-protected document) and place the new/revised document in the Approved Controlled Documents folder on the Q:/ drive.

CONTROLLED COPY, Do Not Duplicate

**CONFIDENTIAL and PROPRIETARY
VERIFY THAT THIS IS THE CORRECT VERSION BEFORE USE**

18. Electronically transmit notification to all involved parties alerting them to the newly approved Controlled Document. Remind all parties to eliminate any previous versions (hardcopies).
19. Update the Master Controlled Document file:
 - Place the newly approved Controlled Document and the approved DCO in the “current document” file.
 - Place the previous version (if applicable) and its’ associated DCO form in the Document History file.



REVISION HISTORY

Rev	DCO	Description of Change	Approved by
1	08-002	Edited for clarity and style.	Michael V.W. Bergamini

UNT-HSC OFFICE OF CLINICAL TRIALS
Controlled Document Change Process

QA-002

Page 5 of 6

DCO # _____	Date: _____
-------------	-------------

Document Title:

From version: _____

To version: _____

Synopsis of Change: Briefly summarize the changes and rationale for this change order. Attach additional pages if necessary. For a new document (rev 0), write "NEW DOCUMENT"

Required Reviewers: List the personnel required to review and approve this DCO. The originators' department, a member of OCT executive management should generally be included:

- _____
- _____
- _____
- _____

Initial Review		
OK as is	OK with changes	Name, Title and Date

UNT-HSC OFFICE OF CLINICAL TRIALS
Controlled Document Change Process

QA-002

Page 6 of 6

Training Requirements: Detail any specific training requirements for the new/revised Controlled Document.

Final Review

Approved	Rejected	Name, Title and Date

CONTROLLED COPY, Do Not Duplicate

CONFIDENTIAL and PROPRIETARY
VERIFY THAT THIS IS THE CORRECT VERSION BEFORE USE