

## Document Version Control

**Procedure Overview:** This policy describes the procedures to be followed when creating, editing, and distributing NETT related documents.

**Participating individuals:** Any member of the NETT network involved in the creating, editing and/or distributing process of NETT documents.

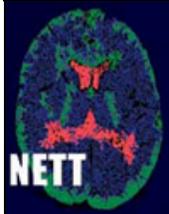
### 1. Definitions

- a. "NETT Document" includes the following:
  - i. Any document that will be provided to the Hub complexes for regulatory purposes such as IRB submissions, including clinical trial protocols, protocol amendments, and sponsor progress reports.
  - ii. Any document that describes or guides network activities including SOPs and process improvement documents.
  - iii. Any document under development or revision by a collaborative effort of a NETT committee or working group.
- b. Documents are considered to have three different states:
  - i. "**Draft**" is a document created by controller of the document. Documents remain drafts until all revisions and edits are completed and the document is approved.
  - ii. "**Revision**" is a document created by a collaborator by modifying a draft using the track changes feature. Revisions are then used by controllers to create new drafts.
  - iii. "**Final**" is a document that has been approved for use and distribution. No further edits or revisions are considered on finalized documents.
- c. "Approval" indicates the last step of the designated approval chain. The approval chain will be defined by the working group or committee at the beginning of the document creation process. The approval process may vary between different types of documents or committees.

### 2. Procedure for Maintaining Version Control of Draft Documents

- a. Draft documents will be maintained on the collaborative worksite (CTools).
- b. A single individual will be designated as the controller of any draft document. The controller will be designated ad hoc at the time a document is first created by the group charged with creating the document.
- c. Title of document. The title should be brief and descriptive.
- d. Documents are described with sequential numbers and letters. Numbers indicate the version of the resulting **final** document. Letters indicate the sequential **drafts** that precede a final document. New documents are given the number 1 when first created. The first draft will be DRAFT 1A. The second draft will be DRAFT 1B. The approved final document will be FINAL 1. If the approved document is modified in the future, the first draft of the modified document will be DRAFT 2A, and so on.
- e. Draft file names: A **draft** of the document created or updated by the controller is labeled "*title* draft #X" where *title* is the title of the document,

Version Number: FINAL 01	Release Date: 3/7/2007
Original Approval Date: 3/1/2007	Revision Date: NA
Policy Number: TBD	Page 1 of 4



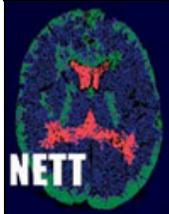
“draft” labels the document as a draft, # is a sequential number that is advanced only when creating a new draft of a previously approved document, and X is a sequential letter that is advanced when the controller updates the draft. Please refer to the attached chart.

- f. Revision file names: A **revision** has the same name as the draft upon which it is based except that the date of the revision and the initials of the person creating the revision are appended. For example, after the controller of a document releases ‘title DRAFT 1A’ a collaborator uses track changes to add comments and creates a revision ‘title DRAFT 1A 012307 rs’ where 012307 is the date the revision was created and rs is the initials of the person creating the revision.
- g. Final document file names: A **final** document is labeled “title FINAL #”.
- h. The file name including document status number and letter should be included in the footer of the document.
- i. The flow of a document is demonstrated in the chart.
  - i. The controller will post an initial draft of the document in the shared web folder (e.g. Ctools). Only the controller can create drafts.
  - ii. Revisions to a draft document can be created by any user. Starting with the most recent draft or most recent posted revision, the user should make all changes or comments using the “track changes” feature in Microsoft Word. The user must make certain that their user name is set in Word under tools/options/user information so that changes they make using “track changes” will be properly attributed to them.
  - iii. Each sequential draft incorporates or addresses the changes made in prior revisions.
  - iv. Revisions to a draft document should be posted to the shared web folder. After one or more revisions are created, the controller of the document will combine the revisions and create a new draft with the next draft letter and post it to the shared folder. New drafts should be “clean”, i.e. all the suggested changes from the prior revisions should be accepted, rejected, or otherwise addressed. Sequential drafts are not created using the track changes feature.
- j. To ensure the most current draft is being used at all times, and to preserve document security, all drafts and revisions should be placed in the shared web folder.
- k. Drafts and revisions should generally not be shared by e-mail.

### 3. Procedure for Maintaining Version Control of Approved NETT Documents

- a. A “final document” is a draft that is approved for use or distribution. Final documents must be approved by the appropriate NETT committee or working group. Verification of the approval will be provided by the Chairperson or designated leader of the committee or working group to the NETT Administrative Director.
- b. Final documents will be labeled with the title of the document, the word “final”, a version number, and the date it was approved.

Version Number: FINAL 01	Release Date: 3/7/2007
Original Approval Date: 3/1/2007	Revision Date: NA
Policy Number: TBD	Page 2 of 4



- c. Final documents will be assigned and display a version number prior to distribution. Version numbers of documents will begin with the number one (1). Subsequent versions approved for distribution will be labeled with consecutive whole integers.
  - i. Example: Title FINAL 1\_030307  
Title FINAL 2\_060607
- d. Final versions of NETT documents will be converted to Adobe PDF documents prior to posting and/or distribution.
  - i. An exception to this directive is an informed consent document template that may require modification at the Hub complex.
- e. A copy of a Word version of all documents will be maintained on the collaborative Ctools site to facilitate future modifications.

Version Number: FINAL 01	Release Date: 3/7/2007
Original Approval Date: 3/1/2007	Revision Date: NA
Policy Number: TBD	Page 3 of 4

DRAFT  
FILENAME = title DRAFT #X  
Where title = document title  
DRAFT is the document status  
# = sequential number of the next FINAL version  
X = sequential letter of DRAFT  
DRAFTs are only created by the document controller  
Example: RAMPART DRAFT 1A

DRAFT is sent to collaborators, who create revisions based upon the DRAFT document or upon another collaborators REVISION

REVISION  
FILENAME = title DRAFT #X mmddyy xx  
Where title DRAFT #X = filename upon which revision is based and  
Mmddyy = date revision was created  
xx = initials of REVISION author  
REVISIONs are created by any collaborator. They are based on previous DRAFTs or previous REVISIONs using the "track changes" feature with user properly identified  
Example: RAMPART DRAFT 1A 020107 yp

REVISION  
Example: RAMPART DRAFT 1A 020407 vls

REVISION  
Example: RAMPART DRAFT 1A 020307 wlb

All revisions to the draft are compiled and addressed by the document controller, who then creates a new DRAFT incorporating the revisions, and gives it the next DRAFT letter.

DRAFT  
Example: RAMPART DRAFT 1B

The new draft may go back to the same or to new collaborators for more REVISION

OR

The new draft may be approved and become a FINAL document

REVISION  
Example: RAMPART DRAFT 1B 032107 yer  
7 rs  
wgb

FINAL  
FILENAME = title FINAL ## mmddyy  
Where title = document title  
FINAL is the document status  
## = sequential final version number  
Mmddyy = date of document final approval  
FINALS are created only by the administrative director or chair of the approving committee or working group  
Example: RAMPART FINAL 1 041507

FINAL documents are distributed and used

If FINAL documents are ever modified, they become DRAFT documents again, but with the next version number.

Example: RAMPART DRAFT 2A