

Document Version Control

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

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

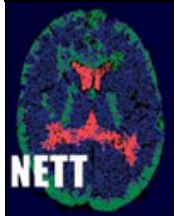
1. Definitions

- a. "NETT Document" includes the following:
 - i. Any document that will be provided to the Hub complexes (including GPSNJ-NETT) 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 NETT SOPs and process improvement documents.
 - iii. Any document under development or revision by a collaborative effort from the NETT.
- b. "GPSNJ-NETT Document" includes the following:
 - i. Any document that describes or guides network activities including GPSNJ-NETT SOPs and process improvement documents.
 - ii. Any document under development or revision by a collaborative effort from the GPSNJ-NETT.
- c. 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.
- d. "Approval" indicates the last step of the designated approval chain. The approval chain will be defined by the NETT working group or committee for NETT documents and the GPSNJ-NETT Hub for GPSNJ-NETT documents at the beginning of the document creation process. The approval process may vary between different types of documents or committees.
- e. Ctools is a shared NETT resource found at:
<http://www.nett.umich.edu/nett/resources>.

2. Procedure for Maintaining Version Control of Draft Documents

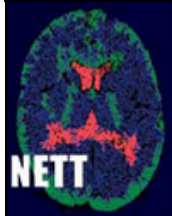
- a. NETT draft documents will be maintained on the collaborative worksite (CTools).
- b. GPSNJ-NETT draft documents will be maintained by the GPSNJ-NETT Hub team and available upon request by GPSNJ-NETT Spokes or NETT Clinical Coordinating Center.

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- c. 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.
- d. Title of document. The title should be brief and descriptive.
- e. 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.
- f. 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, “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.
- g. 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.
- h. Final document file names: A **final** document is labeled “title FINAL #”.
- i. The file name including document status number and letter should be included in the footer of the document.
- j. The flow of a GPSNJ-NETT document is as follows:
 - i. The GPSNJ-NETT controller (in most cases, the Hub Project Manager) will create an initial draft of the document and share it with the GPSNJ-NETT Hub team by email. Only the GPSNJ-NETT controller can create drafts.
 - ii. Revisions to a GPSNJ-NETT draft document can be created by any GPSNJ-NETT Hub team member. Starting with the most recent draft or most recent emailed revision, the team member should make all changes or comments using the “track changes” feature in Microsoft Word. The team member 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 shared by email to all GPSNJ-NETT Hub team members. 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 email it to all GPSNJ-NETT Hub team members. New drafts should be “clean”, i.e. all the suggested changes from the prior revisions should be accepted, rejected, or otherwise

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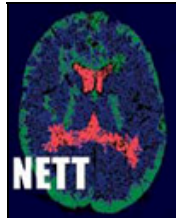


- addressed. Sequential drafts are not created using the track changes feature.
- v. Final, approved documents will be shared with GPSNJ-NETT Spokes by email and/or posting on the GPSNJ-NETT website:
www.med.upenn.edu/nett
- vi. Spokes may submit suggestions for SOPs to the GPSNJ-NETT Hub team for consideration. All suggested changes should be accepted, rejected, or otherwise addressed by the GPSNJ-NETT Hub team.
- k. The flow of a NETT document is demonstrated in the attached chart.
 - i. The NETT controller will post an initial draft of the document in the shared web folder (e.g. Ctools). Only the NETT controller can create drafts.
 - ii. Revisions to a NETT 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 NETT draft incorporates or addresses the changes made in prior revisions.
 - iv. Revisions to a NETT draft document should be posted to the shared web folder. After one or more revisions are created, the controller of the NETT 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.
 - v. To ensure the most current draft is being used at all times, and to preserve document security, all NETT document drafts and revisions should be placed in the shared web folder.
 - vi. NETT document drafts and revisions should generally not be shared by e-mail.

3. Procedure for Maintaining Version Control of Approved NETT and GPSNJ-NETT Documents

- a. A “final document” is a draft that is approved for use or distribution.
- b. Final NETT 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.
- c. Final GPSNJ-NETT documents must be approved by the GPSNJ-NETT Hub team. Verification of the approval will be provided by the GPSNJ-NETT Hub PI.
- d. Final documents will be labeled with the title of the document, the word “final”, a version number, and the date it was approved.
- e. Final documents will be assigned and display a version number prior to distribution. Version numbers of documents will begin with the number one (1).

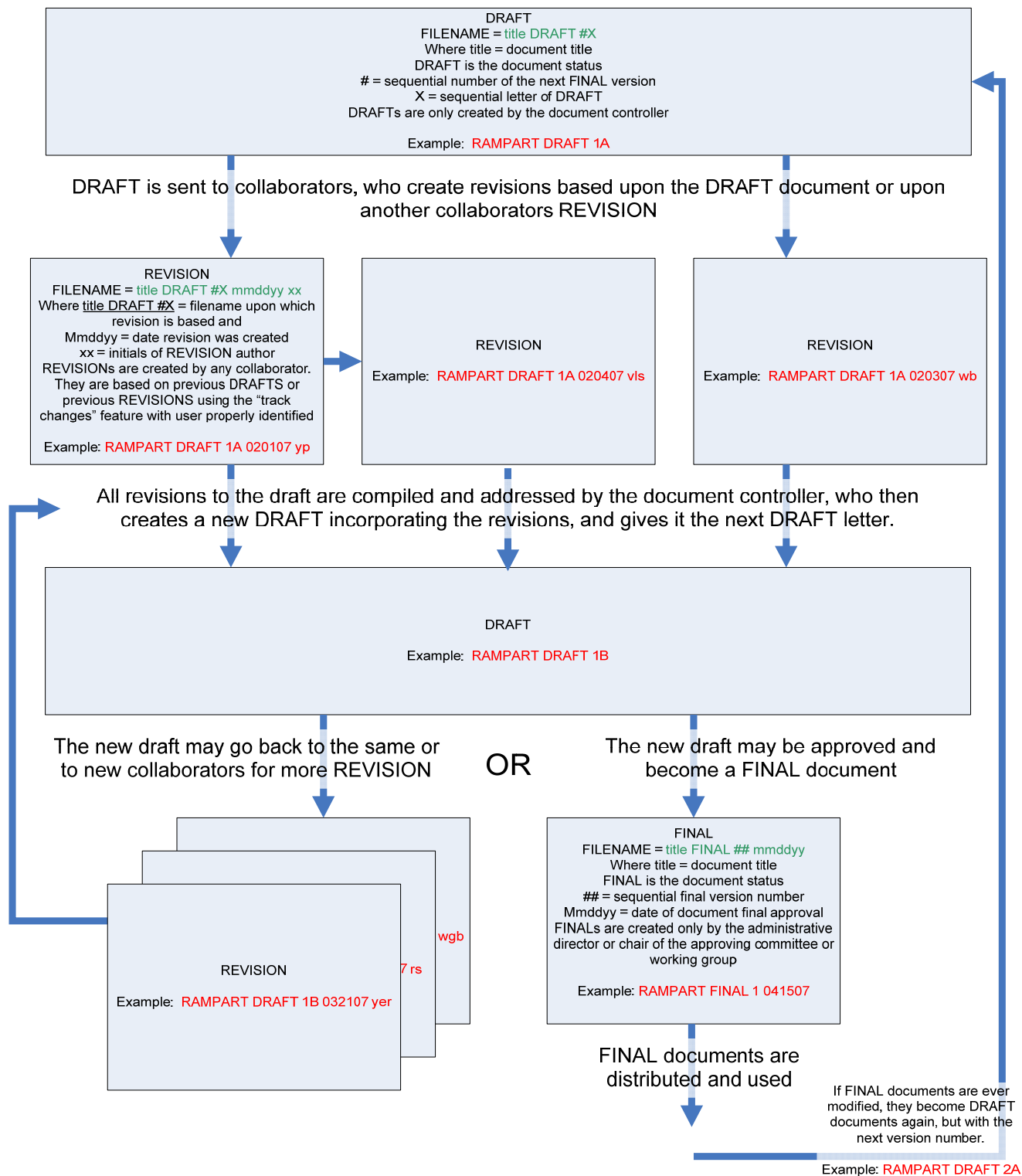
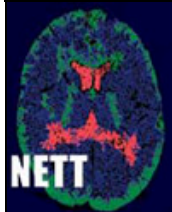
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Subsequent versions approved for distribution will be labeled with consecutive whole integers.

- i. Example: Title FINAL 1_030307
Title FINAL 2_060607
- f. Final versions of NETT and GPSNJ-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 or Spoke.
- g. A copy of a Word version of all NETT documents will be maintained on the collaborative Ctools site to facilitate future modifications.
- h. A copy of a Word version of all GPSNJ-NETT documents will be maintained by the GPSNJ-NETT Hub Project Manager and available upon request from a GPSNJ-NETT Hub or Spoke team member.

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