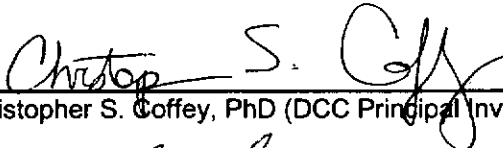



NeuroNEXT Network

Standard Operating Procedure (SOP) Document Development and Change Control Version 2.0 SOP NN GA 103

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NN GA 103

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR DOCUMENT DEVELOPMENT AND CHANGE CONTROL

SOP: NN GA 103 Version No.: 2.0 Effective Date: 21Oct2016	DOCUMENT DEVELOPMENT AND CHANGE CONTROL	Supersedes Document: Version 1.0 Effective Date: 21Apr2012
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1. POLICY

The NeuroNEXT Clinical Coordinating Center (CCC) and Data Coordinating Center (DCC) will ensure that critical documents are developed, approved, and modified in a manner that promotes systematic document development and change control. Substantive changes to critical documents constitute a revision, and may require a formal approval process.

For version-controlled critical documents that originate with the CCC and/or DCC, the NeuroNEXT Network requires that:

- only the currently approved version of a document is in use at any time;
- new documents are written using established templates as models where feasible and appropriate;
- all new or revised critical documents undergo review by appropriate personnel;
- changes to documents are properly incorporated and tracked;
- draft documents are versioned with a decimal number (e.g. 0.1), and the decimal is increased with each revision;
- final documents are versioned with a whole number (e.g.1.0); and
- final documents are reviewed and approved by the appropriate NeuroNEXT personnel.

Approval of study documents may be delegated by the Sponsor to the CCC, DCC, and/or the Study Team. The Study Team defines which documents may have delegated authority for review and signature approval and which may not. These decisions may be documented in a process map or similar document, depending on the requirements of the study. Clinical protocols and protocol amendments (if applicable to a study) must be signed by the Protocol Principal Investigator (PPI) and the Directors of the CCC and DCC.

Non-controlled documents, such as checklists, are management tools that do not carry regulatory weight and may require less rigorous change control.

Following the completion of the approval (signature) process, the document is considered issued. The effective date of the document is 30 days after the last required signature is obtained. The effective date is also the first day the new or revised document can be used.

The CCC and/or DCC maintain(s) complete files of all current and obsolete version-controlled documents and update(s) document revision histories (e.g. table of modifications or change document), if applicable.

2. SCOPE

This SOP has been developed to be in alignment with federal regulations and Good Clinical Practices (GCP) as set forth in the 1996 ICH E6 Consolidated Guidance. The policies and procedures described in this SOP apply to the NeuroNEXT Clinical Coordinating Center (CCC) and Data Coordinating Center (DCC) within the context of their oversight and advisory roles for the NeuroNEXT Network, and to all NeuroNEXT investigators, staff, subcontractors, or other entities associated with the NeuroNEXT Network who manage, oversee, and conduct research within the Network regulated by FDA and/or applicable review committees.

3. ROLES AND RESPONSIBILITIES

Each Study Team is responsible for developing team-specific documents and forms, using available templates where feasible and appropriate, and for following document development and change control procedures for version-controlled documents.

The CCC and/or DCC is/are responsible for maintaining complete files of all current and obsolete version-controlled documents, and for updating document revision histories, if applicable.

The responsibility to conduct any or all of these activities may be delegated at the discretion of the Sponsor to the NeuroNEXT CCC and/or DCC or to their subcontractors. Those individuals and entities take on responsibility for meeting regulatory requirements on behalf of the Sponsor, but the Sponsor has the ultimate responsibility and must therefore supervise those delegated activities effectively.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.50	General Responsibilities of Sponsors
21 CFR 312.57	Recordkeeping and Record Retention
ICH E6, 2.13	The Principles of ICH GCP
ICH E6, 5.1	Quality Assurance and Quality Control
ICH E6, 5.5	Trial Management, Data Handling and Recordkeeping

5. REFERENCES TO OTHER APPLICABLE SOPS

NN GA 101	Development and Maintenance of SOPs
NN GA 102	SOP Training
NN RA 202	Trial Master File Maintenance
NN PM 501	Communication

6. ATTACHMENTS AND REFERENCES

NN GA 103 – A	Document History
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7. TERMS AND ABBREVIATIONS

The following terms and abbreviations are used in this document:

CCC	Clinical Coordinating Center at Massachusetts General Hospital
DCC	Data Coordinating Center at The University of Iowa
FDA	U.S. Food and Drug Administration
GCP	Good Clinical Practices
ICH	International Council for Harmonisation
PPI	Protocol Principal Investigator
SOP	Standard Operating Procedure

8. SPECIFIC PROCEDURES

A. Development and Approval Procedures for Controlled Documents

#	Who	Task	Attachment	Related SOP
1.	CCC / DCC Leadership, PPI	Determine the need for a new version-controlled document (e.g., new SOP, clinical study materials, protocol).		
2.	CCC / DCC Leadership, PPI	Determine which individual will draft the first version of the new document and who must review and approve the draft of the new document.		
3.	CCC / DCC / Study Team designee	Use a template, when available, to initiate a new draft document.		
4.	CCC / DCC / Study Team designee	Circulate the draft as version 0.1 or a similar designation, and secure comments/suggestions from appropriate reviewers.		
5.	Reviewers	Provide edits or comments if needed, and re-version the document to the next incremental decimal with each subsequent review (e.g. 0.2, 0.3).		
6.	CCC / DCC / Study Team designee	Discuss and resolve any conflicting comments, and prepare the document for approval.		
7.	CCC / DCC / Study Team designee	Circulate the final draft to all signatories and request signatures to indicate approval of the final draft.		
8.	Study Team Signatories	Approve final draft using a signature page or by email confirmation, as appropriate.		
9.	CCC / DCC / Study Team designee	Give all newly-approved documents a version number (e.g. 1.0), an issue date, and an effective date (to be 30 calendar days after the issue date).		
10.	CCC / DCC / Study Team designee	Retain original document and corresponding Change Control Document as appropriate, and ensure proper training and review of document, if applicable.		
11.	CCC / DCC / Study Team designee	Update related indices (e.g., SOP List, Forms List) to reflect the addition of a new document or changes to the name of an existing document, if applicable.		

B. Change Procedures for Controlled Documents

#	Who	Task	Attachment	Related SOP
1.	CCC / DCC Leadership, PPI	Review documents and forms periodically or as needed by circumstances (e.g. new regulation).		
2.	CCC / DCC / Study Team designee	If revisions are not needed, indicate review on a Change Control Document, if applicable.		

#	Who	Task	Attachment	Related SOP
3.	CCC / DCC / Study Team designee	If revisions are needed, make the change(s) and circulate the revised draft (with revisions tracked). Document versioning increases incrementally by a decimal number (1.1, 1.2, etc.) for each revised draft document.		
4.	CCC / DCC / Study Team designee	Continue to give updated and revised documents a new version number, until all revisions are incorporated and ready for final signatures.		
5.	CCC / DCC / Study Team designee	Version the new document with the next consecutive whole number (2.0, 3.0, etc.), circulate to all signatories, and assign the issue date and the effective date.		
6.	CCC / DCC / Study Team designee	If applicable, create a table of modifications or a change document.		
7.	CCC / DCC / Study Team designee	Move obsolete documents to an archive file.		

C. Controlled Document Implementation

#	Who	Task	Attachment	Related SOP
1.	CCC / DCC / Study Team designee	As appropriate, notify all affected parties and regulatory authorities (if applicable) about changes to version-controlled documents, and provide new versions of documents to these parties.		
2.	CCC / DCC / Study Team designee	Train all affected personnel on the use of the new or revised document, if applicable.		NN GA 102
3.	CCC / DCC / Study Team designee	Record that document training was received by all affected personnel.		

Attachment NN GA 103 - A. Document History

NeuroNEXT Network Standard Operating Procedure (SOP) Document Development and Change Control SOP NN GA 103				
Version	Description of Modification	Reason or Justification for Modification	Issue Date	Effective Date
1.0	New	N/A	22Mar2012	21Apr2012
2.0	Updated the policy section and removed references to PWIs. Clarified that version-controlled documents originating with the CCC or DCC are subject to change control procedures, and that substantive changes to critical documents may require formal approval. Added policy for signature approval of clinical protocols and amendments. Simplified language in the specific procedures section regarding versioning, change histories, and archiving obsolete documents.	Updates for version 2.0.	21Sep2016	21Oct2016