

NeuroNEXT Network

Standard Operating Procedure (SOP) Document Development and Change Control Version 4.0 SOP NN GA 103

Originators: NeuroNEXT CCC and DCC Personnel

Reviewed and Approved by:

Signature and Date: <i>Christopher S. Coffey</i> <small>Electronically signed by: Christopher S. Coffey Reason: I approve this document Date: Feb 23, 2024 13:47 CST</small>	23-Feb-2024
Name and Title: Christopher S. Coffey, PhD (DCC Principal Investigator)	
Signature and Date: <i>Merit Cudkowicz</i> <small>Electronically signed by: Merit Cudkowicz Reason: I approve this document Date: Feb 22, 2024 11:48 CST</small>	22-Feb-2024
Name and Title: Merit E. Cudkowicz, MD MSc (CCC Principal Investigator)	
Signature and Date: <i>Marianne Chase</i> <small>Electronically signed by: Marianne Chase Reason: I approve this document Date: Feb 22, 2024 12:54 EST</small>	22-Feb-2024
Name and Title: Marianne Chase, BA (CCC Senior Director of Clinical Trials Operations)	

NN GA 103
NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR
DOCUMENT DEVELOPMENT AND CHANGE CONTROL

SOP: NN GA 103 Version No.: 4.0 Issue Date: 01Mar2024 Effective Date: 15Apr2024	DOCUMENT DEVELOPMENT AND CHANGE CONTROL	Supersedes Document : Version 3.0 Effective Date : 08Apr2023
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Signature and Date:

Dixie Ecklund

Electronically signed by: Dixie Ecklund
Reason: I approve this document
Date: Feb 24, 2024 17:01 CST

24-Feb-2024

Name and Title: Dixie J. Ecklund, RN MSN MBA (DCC Associate Director)

Signature and Date:

Stacey Grabert

Electronically signed by: Stacey Grabert
Reason: I approve this document
Date: Feb 22, 2024 13:58 EST

22-Feb-2024

Name and Title: Stacey Grabert, Pharm.D, MS, (CCC Director of Quality Assurance)

Signature and Date:

Joan Ohayon

Electronically signed by: Joan Ohayon
Reason: I approve this document
Date: Mar 11, 2024 09:39 EDT

11-Mar-2024

Name and Title: Joan Ohayon, RN, MSN, CRNP, MSCN (NINDS, NeuroNEXT Program Official)

NN GA 103
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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 such as clinical protocol and consent forms 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.

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. Approval of other 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.

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

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 2016 Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E (R2).e. 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.

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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

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

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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.		

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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.		
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	Reviewer(s)
1.0	New	N/A	22Mar2012	21Apr2012	N/A
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	N/A
3.0	Updated "1996 ICH E6 Consolidated Guidance" to "2016 Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)". Updated signature block to accommodate for electronic signatures. Additional minor updates throughout	Updates for version 3.0	22Feb2023	08Apr2023	Catherine Gladden
4.0	Added definition of controlled document, and formatting requirements for a controlled document.	Periodic Review	01Mar2024	15Apr2024	Preeti Paul









NN GA 103 Document Development and Change Control v4.0 clean

Final Audit Report

2024-03-11

Created:	2024-02-22
By:	Tania Leeder (tleeder@mgb.org)
Status:	Signed
Transaction ID:	CBJCHBCAABAAliecsHWkZEqG_E-oLuPkPqAl-ZZ7XqRU
Number of Documents:	1
Document page count:	7
Number of supporting files:	0
Supporting files page count:	0

"NN GA 103 Document Development and Change Control v4.0 clean" History

-  Document created by Tania Leeder (tleeder@mgb.org)
2024-02-22 - 5:43:14 PM GMT
-  Document emailed to christopher-coffey@uiowa.edu for signature
2024-02-22 - 5:45:01 PM GMT
-  Document emailed to cudkowicz.merit@mgh.harvard.edu for signature
2024-02-22 - 5:45:01 PM GMT
-  Document emailed to mchase@mgh.harvard.edu for signature
2024-02-22 - 5:45:01 PM GMT
-  Document emailed to dixie-ecklund@uiowa.edu for signature
2024-02-22 - 5:45:02 PM GMT
-  Document emailed to Stacey Grabert (SGrabert@mgh.harvard.edu) for signature
2024-02-22 - 5:45:02 PM GMT
-  Document emailed to ohayonj@ninds.nih.gov for signature
2024-02-22 - 5:45:02 PM GMT
-  Email viewed by cudkowicz.merit@mgh.harvard.edu
2024-02-22 - 5:46:55 PM GMT

✓ cudkowicz.merit@mgh.harvard.edu authenticated with Adobe Acrobat Sign.

Challenge: The user opened the agreement.

2024-02-22 - 5:48:10 PM GMT

📄 Signer cudkowicz.merit@mgh.harvard.edu entered name at signing as Merit Cudkowicz

2024-02-22 - 5:48:41 PM GMT

📄 Document e-signed by Merit Cudkowicz (cudkowicz.merit@mgh.harvard.edu)

Signing reason: I approve this document

Signature Date: 2024-02-22 - 5:48:43 PM GMT - Time Source: server

📄 Email viewed by mchase@mgh.harvard.edu

2024-02-22 - 5:54:00 PM GMT

✓ mchase@mgh.harvard.edu authenticated with Adobe Acrobat Sign.

Challenge: The user opened the agreement.

2024-02-22 - 5:54:17 PM GMT

📄 Signer mchase@mgh.harvard.edu entered name at signing as Marianne Chase

2024-02-22 - 5:54:43 PM GMT

📄 Document e-signed by Marianne Chase (mchase@mgh.harvard.edu)

Signing reason: I approve this document

Signature Date: 2024-02-22 - 5:54:45 PM GMT - Time Source: server

✓ Stacey Grabert (SGrabert@mgh.harvard.edu) authenticated with Adobe Acrobat Sign.

Challenge: The user opened the agreement.

2024-02-22 - 6:58:35 PM GMT

📄 Document e-signed by Stacey Grabert (SGrabert@mgh.harvard.edu)

Signing reason: I approve this document

Signature Date: 2024-02-22 - 6:58:44 PM GMT - Time Source: server

📄 Email viewed by christopher-coffey@uiowa.edu

2024-02-22 - 7:55:15 PM GMT

📄 Tania Leeder (tleeder@mgb.org) added alternate signer cscoffey@iowa.uiowa.edu. The original signer christopher-coffey@uiowa.edu can still sign.

2024-02-23 - 7:05:48 PM GMT

📄 Document emailed to cscoffey@iowa.uiowa.edu for signature

2024-02-23 - 7:05:48 PM GMT

📄 Tania Leeder (tleeder@mgb.org) added alternate signer ecklundd@uiowa.edu. The original signer dixie-ecklund@uiowa.edu can still sign.

2024-02-23 - 7:06:21 PM GMT

 Document emailed to ecklundd@uiowa.edu for signature

2024-02-23 - 7:06:21 PM GMT

 Email viewed by cscoffey@iowa.uiowa.edu

2024-02-23 - 7:14:14 PM GMT


 cscoffey@iowa.uiowa.edu authenticated with Adobe Acrobat Sign.

Challenge: The user opened the agreement.

2024-02-23 - 7:47:16 PM GMT


 Signer cscoffey@iowa.uiowa.edu entered name at signing as Christopher S. Coffey

2024-02-23 - 7:47:31 PM GMT


 Document e-signed by Christopher S. Coffey (cscoffey@iowa.uiowa.edu)

Signing reason: I approve this document

Signature Date: 2024-02-23 - 7:47:34 PM GMT - Time Source: server

 Email viewed by ecklundd@uiowa.edu

2024-02-24 - 11:01:25 PM GMT

 ecklundd@uiowa.edu authenticated with Adobe Acrobat Sign.

Challenge: The user opened the agreement.

2024-02-24 - 11:01:37 PM GMT


 Signer ecklundd@uiowa.edu entered name at signing as Dixie Ecklund

2024-02-24 - 11:01:51 PM GMT

 Document e-signed by Dixie Ecklund (ecklundd@uiowa.edu)

Signing reason: I approve this document

Signature Date: 2024-02-24 - 11:01:53 PM GMT - Time Source: server

 Email viewed by ohayonj@ninds.nih.gov

2024-03-11 - 1:39:13 PM GMT- IP address: 104.47.64.254

 ohayonj@ninds.nih.gov authenticated with Adobe Acrobat Sign.

Challenge: The user opened the agreement.

2024-03-11 - 1:39:23 PM GMT

 Signer ohayonj@ninds.nih.gov entered name at signing as Joan Ohayon

2024-03-11 - 1:39:35 PM GMT- IP address: 72.83.187.43

 Document e-signed by Joan Ohayon (ohayonj@ninds.nih.gov)

Signing reason: I approve this document

Signature Date: 2024-03-11 - 1:39:37 PM GMT - Time Source: server- IP address: 72.83.187.43

 Agreement completed.

2024-03-11 - 1:39:37 PM GMT