NeuroNEXT Network

Standard Operating Procedure (SOP)

Study Materials Development

Version 4.0

SOP NN PM 503

Originators: NeuroNEXT CCC and DCC Personnel

Reviewed and Approved by:

Signature and Date: Christopher S. Coffey *Electronically signed by: Christopher S. Coffey Reason: I approve this document Date: Mar 7, 2024 14:53 CST* 07-Mar-2024
Name and Title: Christopher S. Coffey, PhD (DCC Principal Investigator)
Signature and Date: Merit Cudkowicz *Electronically signed by: Merit Cudkowicz Reason: I approve this document Date: Feb 22, 2024 17:04 CST* 22-Feb-2024
Name and Title: Merit E. Cudkowicz, MD MSc (CCC Principal Investigator)
Signature and Date: Marianne Chase *Electronically signed by: Marianne Chase Reason: I approve this document Date: Feb 22. 2024 15:15 EST* 22-Feb-2024
Name and Title: Marianne Chase, BA (CCC Senior Director of Clinical Trials Operations)

NN PM 503

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR STUDY MATERIALS DEVELOPMENT

SOP: NN PM 503 Version No.: 4.0 Issue Date: 01Mar2024 Effective Date: 15Apr2024	STUDY MATERIALS DEVELOPMENT	Supersedes Document Version : 3.0 Effective Date : 08Apr2023

Signature and Date:

Dixie Ecklund

Electronically signed by: Dixie Ecklund
Reason: I approve this document
Date: Feb 24, 2024 17:08 CST

24-Feb-2024

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

Signature and Date:

Electronically signed by: Stacey Grabert
Reason: I approve this document
Date: Feb 22, 2024 13:47 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 09:46 EDT

11-Mar-2024

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

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR STUDY MATERIALS DEVELOPMENT

SOP: NN PM 503 Version No.: 4.0 Issue Date: 01Mar2024 Effective Date: 15Apr2024	STUDY MATERIALS DEVELOPMENT	Supersedes Document Version : 3.0 Effective Date : 08Apr2023

1. POLICY

For all studies approved to be conducted within the NeuroNEXT Network, the Clinical Coordinating Center (CCC) will work with the Data Coordinating Center (DCC) and the Protocol Principal Investigator (PPI) or his/her designee to develop study-specific templates and other materials to be used by Clinical Study Sites (CSS) in the conduct of study-related activities. The CCC and DCC will collaborate to develop additional Network templates and materials that are used across NeuroNEXT studies, as needed. Study materials are posted to the internal study website and are accessible to all authorized NeuroNEXT personnel.

The following sections present examples of study materials that are typically developed for each NeuroNEXT study.

Manual of Operations (i.e. Manual of Procedures; MOP)

A MOP is a study-specific, version-controlled document that describes study processes and procedures. A MOP is developed for every NeuroNEXT study, and is used as a reference and a training tool for instructing CSS personnel on study conduct.

The study MOP incorporates an organizational plan that defines responsibilities, a study roster that contains contact information for the Study Team, and a communications plan that provides contact information for specific members of the Study Team who are directly involved with study management.

The MOP also includes a training plan, information on study logistics and procedures, a plan for recruitment and retention, and study enrollment procedures. Instructions related to protocol compliance, study medications, concomitant and prohibited medications, safety reporting, outcome measures, data collection and management, study closeout, and confidentiality and publication are also typically included in the study MOP. The MOP also may also describe laboratory procedures, including directions for processing and shipping laboratory specimens and directions for ordering/re-ordering study supplies and investigational product, as applicable.

The PPI, appropriate CCC and DCC personnel, and a representative from the Sponsor Company (if applicable) sign off on the study MOP and any subsequent revisions or amendments.

Other Study-Specific Materials

The following study-specific materials may be developed for use in a study (as applicable):

- Data collection templates and related materials
    - Source documents
    - Data entry templates
    - CRF forms grid
    - Assessment instruments (e.g. questionnaires, quizzes)
- Study-specific guidance documents, training manuals and materials, or user's manuals, such as:
    - Website and data entry user's manuals
    - Imaging manual and shipping instructions
    - Educational materials (e.g., videos, slide presentations)
    - Laboratory manuals
        - Specimen processing and tracking manual

- Temperature logs for freezers

- Pharmacy manuals
  - Site pharmacy manual
  - Study medication administration instructions
  - Study drug dispensing system user's manual
  - Study drug accountability log

Network Templates and Materials

- Standard Operating Procedures (SOPs)
- Study staff Delegation of Responsibilities (DOR) log template
- Study staff certification form
- Note to File template
- Data Change Request (DCR) form template

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 E6(R2).. The policies and procedures described in this SOP apply to the NeuroNEXT CCC and 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 regulated by FDA and/or applicable review committees.

3. ROLES AND RESPONSIBILITIES

The CCC, DCC, and PPI or his/her designee are responsible for developing a study-specific materials such as a MOP, source documents, and other materials and tools that may assist CSS in the conduct of the study.

The CCC and DCC are responsible for developing Network-wide templates and materials, when needed.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.50	General Responsibilities of Sponsors
ICH E6	The Principles of ICH GCP

5. REFERENCES TO OTHER APPLICABLE SOPS

NN GA 103	Document Development and Change Control

6. ATTACHMENTS AND REFERENCES

NN PM 502 – A	Document History

SOP: NN PM 503 Version No.: 4.0 Issue Date: 01Mar2024 Effective Date: 15Apr2024	STUDY MATERIALS DEVELOPMENT	Supersedes Document Version : 3.0 Effective Date : 08Apr2023

7. TERMS AND ABBREVIATIONS

The following terms and abbreviations are used in this document:

CCC	Clinical Coordinating Center at Massachusetts General Hospital
CSS	Clinical Study Site
DCC	Data Coordinating Center at The University of Iowa
FDA	U.S. Food and Drug Administration
ICH	International Council for Harmonisation
MOP	Manual of Operations (i.e. Manual of Procedures)
PPI	Protocol Principal Investigator

8. SPECIFIC PROCEDURES

A. Manual of Operations (MOP)

#	*Who*	*Task*	*Attachment / References*	*Related SOP*
1.	CCC, DCC, and PPI or designee	Draft a Manual of Operations (MOP) that describes study processes, procedures, and responsibilities of the CCC, DCC, study management personnel, and other key study personnel (if applicable).		NN GA 103
2.	PPI and applicable CCC and DCC personnel; Sponsor Company representative (if applicable)	Sign off on the final version of the MOP.		NN GA 103
3.	CCC, DCC	Provide each participating CSS access to the MOP on the internal study website.		
4.	PPI and applicable CCC and DCC personnel; Sponsor Company representative (if applicable)	Revise the MOP as necessary, and re-sign the revised version.		NN GA 103
5.	CCC, DCC	Provide each participating CSS access to the updated/amended MOP.		

B. Other Study Materials

#	*Who*	*Task*	*Attachment / References*	*Related SOP*
1.	CCC, DCC, and PPI or designee	Develop study-specific materials and tools as deemed appropriate for each study.		NN GA 103
2.	CCC, DCC	Provide each participating CSS access to study materials and tools on the internal study website.		
3.	CCC, DCC, and PPI or designee	Revise study materials and tools, as needed.		NN GA 103
4.	CCC, DCC	Provide each participating CSS access to updated study materials and tools on the internal study website, as needed.		

SOP: NN PM 503 Version No.: 4.0 Issue Date: 01Mar2024 Effective Date: 15Apr2024	STUDY MATERIALS DEVELOPMENT	Supersedes Document Version : 3.0 Effective Date : 08Apr2023

Attachment NN PM 503 - A. Document History

NeuroNEXT Network Standard Operating Procedure (SOP) Study Materials Development SOP NN PM 503					
Version	**Description of Modification**	**Reason or Justification for Modification**	**Issue Date**	**Effective Date**	**Reviewer(s)**
1.0	New	N/A	06Apr2012	06May2012	N/A
2.0	Extensively revised to include a description of the study Manual of Operations (i.e. Manual of Procedures; MOP), and listings of other study-specific and Network materials that may be developed to assist CSS with proper study conduct. Removed references to a study manual for CSS.	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.	Updated for version 3.0			Catherine Gladden
4.0	Minor edits for clarity	Periodic review	01Mar2024	15Apr2024	Preeti Paul

NN PM 503 Study Materials Development v4.0 clean

Final Audit Report 2024-03-11

Created:	2024-02-22
By:	Tania Leeder (tleeder@mgb.org)
Status:	Signed
Transaction ID:	CBJCHBCAABAARrujHhLwKZcxx1AwJqCxEpd6Pi3LY8kx
Number of Documents:	1
Document page count:	7
Number of supporting files:	0
Supporting files page count:	0

"NN PM 503 Study Materials Development v4.0 clean" History

Document created by Tania Leeder (tleeder@mgb.org)
2024-02-22 - 6:45:11 PM GMT

Document emailed to christopher-coffey@uiowa.edu for signature
2024-02-22 - 6:47:00 PM GMT

Document emailed to cudkowicz.merit@mgh.harvard.edu for signature
2024-02-22 - 6:47:01 PM GMT

Document emailed to Marianne Chase (mchase@mgh.harvard.edu) for signature
2024-02-22 - 6:47:01 PM GMT

Document emailed to dixie-ecklund@uiowa.edu for signature
2024-02-22 - 6:47:01 PM GMT

Document emailed to Stacey Grabert (SGrabert@mgh.harvard.edu) for signature
2024-02-22 - 6:47:01 PM GMT

Document emailed to ohayonj@ninds.nih.gov for signature
2024-02-22 - 6:47:01 PM GMT

Stacey Grabert (SGrabert@mgh.harvard.edu) authenticated with Adobe Acrobat Sign.
Challenge: The user opened the agreement.
2024-02-22 - 6:47:44 PM GMT

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

Signing reason: I approve this document

Signature Date: 2024-02-22 - 6:47:58 PM GMT - Time Source: server

Email viewed by christopher-coffey@uiowa.edu

2024-02-22 - 7:55:47 PM GMT

Marianne Chase (mchase@mgh.harvard.edu) authenticated with Adobe Acrobat Sign.

Challenge: The user opened the agreement.

2024-02-22 - 8:14:56 PM GMT

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

Signing reason: I approve this document

Signature Date: 2024-02-22 - 8:15:11 PM GMT - Time Source: server

Email viewed by cudkowicz.merit@mgh.harvard.edu

2024-02-22 - 11:04:26 PM GMT

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

Challenge: The user opened the agreement.

2024-02-22 - 11:04:42 PM GMT

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

2024-02-22 - 11:04:54 PM GMT

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

Signing reason: I approve this document

Signature Date: 2024-02-22 - 11:04:56 PM GMT - Time Source: server

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 - 7:01:08 PM GMT

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

2024-02-23 - 7:01:08 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 - 7:01:17 PM GMT

Document emailed to ecklundd@uiowa.edu for signature

2024-02-23 - 7:01:17 PM GMT

Email viewed by cscoffey@iowa.uiowa.edu

2024-02-23 - 7:14:13 PM GMT

Email viewed by ecklundd@uiowa.edu

2024-02-24 - 11:07:49 PM GMT

ecklundd@uiowa.edu authenticated with Adobe Acrobat Sign.

Challenge: The user opened the agreement.

2024-02-24 - 11:08:01 PM GMT

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

2024-02-24 - 11:08:18 PM GMT

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

Signing reason: I approve this document

Signature Date: 2024-02-24 - 11:08:21 PM GMT - Time Source: server

Email viewed by cscoffey@iowa.uiowa.edu

2024-03-07 - 8:53:23 PM GMT- IP address: 128.255.113.139

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

Challenge: The user opened the agreement.

2024-03-07 - 8:53:37 PM GMT

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

2024-03-07 - 8:53:51 PM GMT- IP address: 128.255.113.139

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

Signing reason: I approve this document

Signature Date: 2024-03-07 - 8:53:54 PM GMT - Time Source: server- IP address: 128.255.113.139

Email viewed by ohayonj@ninds.nih.gov

2024-03-11 - 1:45:36 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 - 1:45:45 PM GMT

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

2024-03-11 - 1:45:58 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 - 1:46:00 PM GMT - Time Source: server- IP address: 72.83.187.43

Agreement completed.

2024-03-11 - 1:46:00 PM GMT