NeuroNEXT Network

Standard Operating Procedure (SOP)

Study Materials Development

Version 3.0

SOP NN PM 503

Originators: NeuroNEXT CCC and DCC Personnel

Reviewed and Approved by:

Signature and Date: DocuSigned by Christopher Coffey Christopher Coffey | I approve this document 15-Feb-2023 | 8:18:37 AM PST C68AC8DD80334CF982AED1200765F147 15-Feb-2023
Name and Title: Christopher S. Coffey, PhD (DCC Principal Investigator)
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NN PM 503

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR STUDY MATERIALS DEVELOPMENT

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

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.		

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DIXIE ECKLUND dixie-ecklund@uiowa.edu Security Level: Email, Account Authentication (Required), Login with SSO	 Signature Adoption: Drawn on Device Signature ID: 7006AF62-2EFC-40B6-A067-A08EC02591B6 Using IP Address: 128.255.112.230 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 2/15/2023 8:29:54 AM Viewed: 2/15/2023 2:43:33 PM Signed: 2/15/2023 2:48:19 PM
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Joan Ohayon ohayonj@ninds.nih.gov Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: 72C6AAFD-8CC4-4855-82AC-A0700072901A Using IP Address: 156.40.137.188 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 2/15/2023 8:29:56 AM Viewed: 2/15/2023 12:02:32 PM Signed: 2/15/2023 12:02:51 PM
Electronic Record and Signature Disclosure: Accepted: 2/13/2023 2:03:22 PM ID: 385a0a53-0f0c-4395-88f6-d5700c36e050		
Marianne Chase MCHASE@mgh.harvard.edu Sr Director, Clinical Trial Operations Insight OBO The Massachusetts General Hospital Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: 58FE690F-6BCA-4F23-90E3-DA15BCE3F578 Using IP Address: 73.114.253.109 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 2/15/2023 8:29:55 AM Viewed: 2/15/2023 8:45:58 PM Signed: 2/15/2023 8:46:31 PM
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Merit Cudkowicz cudkowicz.merit@mgh.harvard.edu Chief of Neurology Security Level: Email, Account Authentication (Required), Logged in	 DocuSigned by Merit Cudkowicz I approve this document 17-Feb-2023 | 9:39:54 AM EST 9F8FE4180E504C6AB0A67B835E80C644 Signature Adoption: Pre-selected Style Signature ID: 9F8FE418-0E50-4C6A-B0A6-7B835E80C644 Using IP Address: 68.239.56.73 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 2/15/2023 8:29:55 AM Viewed: 2/17/2023 9:39:44 AM Signed: 2/17/2023 9:39:56 AM
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Stacey Grabert sgrabert@mgh.harvard.edu Director QA Stacey Grabert Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: 60CC52B0-747A-44E6-B220-8D8D880698C0 Using IP Address: 132.183.56.49 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 2/15/2023 8:29:56 AM Viewed: 2/22/2023 11:22:58 AM Signed: 2/22/2023 11:23:10 AM
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