

NeuroNEXT Network

Standard Operating Procedure (SOP)

Clinical Protocol Development and Maintenance for Grant Submission

Version 2.0

SOP NN PD 303

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: Mar 7, 2024 14:49 CST</small>		07-Mar-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 17:01 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 15:06 EST</small>		22-Feb-2024
Name and Title: Marianne Chase, BA (CCC Senior Director of Clinical Trials Operations)		

NN PD 303

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR CLINICAL PROTOCOL DEVELOPMENT AND MAINTENANCE FOR GRANT SUBMISSION

SOP: NN PD 303 Version No.: 2.0 Issue Date: 01Mar2024 Effective Date: 15Apr2024	CLINICAL PROTOCOL DEVELOPMENT AND MAINTENANCE FOR GRANT SUBMISSION	Supersedes Document Version : 1.0 Effective Date : 08Apr2023
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Signature and Date: <i>Dixie Ecklund</i> <small>Electronically signed by: Dixie Ecklund Reason: I approve this document Date: Feb 24, 2024 17:05 CST</small> 24-Feb-2024	
Name and Title: Dixie J. Ecklund, RN MSN MBA (DCC Associate Director)	
Signature and Date:  <small>Electronically signed by: Stacey Grabert Reason: I approve this document Date: Feb 22, 2024 13:49 EST</small> 22-Feb-2024	
Name and Title: Stacey Grabert, Pharm.D, MS, (CCC Director of Quality Assurance)	
Signature and Date: <i>Joan Ohayon</i> <small>Electronically signed by: Joan Ohayon Reason: I approve this document Date: Mar 11, 2024 09:42 EDT</small> 11-Mar-2024	
Name and Title: Joan Ohayon, RN, MSN, CRNP, MSCN (NINDS, NeuroNEXT Program Official)	

**NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR
CLINICAL PROTOCOL DEVELOPMENT AND MAINTENANCE FOR GRANT SUBMISSION**

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1. POLICY

This policy is intended to provide guidance for NeuroNEXT Network personnel who participate in the development of clinical study protocols prior to grant submission. These procedures have been developed based on NINDS and regulatory requirements of a clinical protocol and reflect ICH guidelines on protocol development.

It is the policy that each clinical study protocol developed by the NeuroNEXT Network will incorporate all applicable regulatory requirements and guidance documents that are available to the Protocol Principal Investigator (PPI), Clinical Coordinating Center (CCC) and Data Coordinating Center (DCC), as well as counsel from appropriate individuals who are experts in the subject matter pertaining to the protocol. The clinical protocol should be included in the grant submission and uploaded as “other attachment” (item 12 of 4.4 ‘Other Project Information Component’).

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). 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 PPI is responsible for working with the appropriate Protocol Working Group (PWG) to develop the clinical study protocol, and submit with the full grant submission, in compliance with the application specifications. If an IND is required, the protocol PI will submit the protocol with an IND application at least 31 days prior to full grant submission. Prior to grant submission, the final protocol will undergo review by the CCC, DCC and NeuroNEXT Executive Committee (NEC).

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.20	Requirements for an IND
21 CFR 312.21	Phases of an Investigation
21 CFR 312.23	IND Content and Format
21 CFR 314.126	Adequate and Well-Controlled Studies
ICH E6 2.2, 2.4 – 2.6	The Principles of ICH GCP
ICH E6, 2.10, 2.11	The Principles of ICH GCP
ICH E6, 5.4	Trial Design
ICH E6, 5.23	Multicentre Trials
ICH E6, 6.0	Clinical Trial Protocol and Protocol Amendment(s)
ICH E8	General Considerations for Clinical Trials (December 1997)
ICH E9	Statistical Principles for Clinical Trials (September 1998)
ICH E10	Choice of Control Group and Related Issues in Clinical Trials (May 2001)

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5. REFERENCES TO OTHER APPLICABLE SOPS

NN GA 102	Document Development and Change Control
NN RA 201	Regulatory Authority Submissions and FDA Contact
NN PD 301	Proposal Feasibility
NN PD 302	Protocol Synopsis Development

6. ATTACHMENTS AND REFERENCES

NN PD 301-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
ESC	Extramural Science Committee
FDA	U.S. Food and Drug Administration
GCP	Good Clinical Practice
ICH	International Conference for Harmonisation
IDE	Investigational Device Exemption
IND	Investigational New Drug application
NEC	NeuroNEXT Executive Committee
PPI	Protocol Principal Investigator
PSC	Protocol Steering Committee
PWG	Protocol Working Group

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8. SPECIFIC PROCEDURES

A. Clinical Protocol Development

#	Who	Task	Attachment/ References	Related SOP
1.	PPI	Work with appropriate PWG members to draft the full protocol using a template such as the NINDS Protocol Template	21 CFR 312	NN GA 102
2.	PPI/PWG Members	Review the draft protocol to ensure that it meets all regulatory requirements.	ICH E6	NN RA 201
3.	PPI	If required, include the final draft of the protocol in IND application to FDA at least 31 days prior to grant submission deadline.	21 CFR 312	NN RA 201
4.	PPI	Include the final draft of the protocol in the grant submission.		

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Attachment NN PD 303 - A. Document History

NeuroNEXT Network Standard Operating Procedure (SOP) SOP NN PD 303 Protocol Development and Maintenance					
Version	Description of Modification	Reason or Justification for Modification	Issue Date	Effective Date	Reviewer(s)
1.0	New	N/A	22Feb2023	08Apr2023	Catherine Gladden
2.0	Minor edits foe clarity	Periodic review	01Mar2024	15Apr2024	Preeti Paul

NN PD 303 Protocol Development and Maintenance for Grant Submission v2.0








2feb2024 clean

Final Audit Report

2024-03-11

Created:	2024-02-22
By:	Tania Leeder (tleeder@mgb.org)
Status:	Signed
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Document page count:	6
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-  Document created by Tania Leeder (tleeder@mgb.org)
2024-02-22 - 6:21:59 PM GMT
-  Document emailed to christopher-coffey@uiowa.edu for signature
2024-02-22 - 6:23:33 PM GMT
-  Document emailed to cudkowicz.merit@mgh.harvard.edu for signature
2024-02-22 - 6:23:33 PM GMT
-  Document emailed to Marianne Chase (mchase@mgh.harvard.edu) for signature
2024-02-22 - 6:23:34 PM GMT
-  Document emailed to dixie-ecklund@uiowa.edu for signature
2024-02-22 - 6:23:34 PM GMT
-  Document emailed to Stacey Grabert (SGrabert@mgh.harvard.edu) for signature
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-  Document emailed to ohayonj@ninds.nih.gov for signature
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