NeuroNEXT Network

Standard Operating Procedure (SOP)

Clinical Protocol Development and Maintenance for Grant Submission

Version 1.0

SOP NN PD 303

Originators: NeuroNEXT CCC and DCC Personnel

Reviewed and Approved by:

Signature and Date: DocuSigned by Christopher Coffey Christopher Coffey | I approve this document 14-Feb-2023 | 12:36:07 PM PST C68AC8DD80334CF982AED1200765F147 14-Feb-2023
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Name and Title: Merit E. Cudkowicz, MD MSc (CCC Principal Investigator)
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14-Feb-2023

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NN PD 303

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

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)

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

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 on 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

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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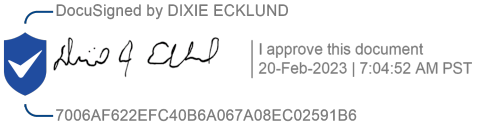
DIXIE ECKLUND dixie-ecklund@uiowa.edu Security Level: Email, Account Authentication (Required)	 Signature Adoption: Drawn on Device Signature ID: 7006AF62-2EFC-40B6-A067-A08EC02591B6 Using IP Address: 173.19.231.252 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 2/14/2023 9:40:41 AM Viewed: 2/20/2023 10:04:37 AM Signed: 2/20/2023 10:04:56 AM
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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: 2/14/2023 9:40:42 AM Viewed: 2/14/2023 12:37:29 PM Signed: 2/14/2023 12:37:56 PM
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Marianne Chase MCHASE@mgh.harvard.edu Sr Director, Clinical Trial Operations Insight OBO The Massachusetts General Hospital Security Level: Email, Account Authentication (Required), Logged in	 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: 2/14/2023 9:40:41 AM Viewed: 2/14/2023 9:42:55 AM Signed: 2/14/2023 9:43:27 AM
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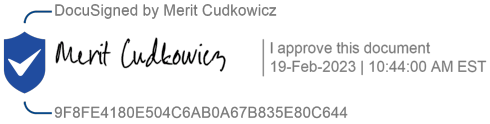
Merit Cudkowicz cudkowicz.merit@mgh.harvard.edu Chief of Neurology Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: 9F8FE418-0E50-4C6A-B0A6-7B835E80C644 Using IP Address: 68.239.56.73 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 2/14/2023 9:40:42 AM Viewed: 2/19/2023 10:43:50 AM Signed: 2/19/2023 10:44:02 AM
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