NeuroNEXT Network

Standard Operating Procedure (SOP)

Corrective and Preventative Action Management

Version 1.0

SOP NN QA 803

Originators: NeuroNEXT CCC and DCC Personnel

Signature and Date: DocuSigned by Christopher Coffey Christopher Coffey | I approve this document 16-Feb-2023 | 11:01:17 AM PST C68AC8DD80334CF982AED1200765F147 16-Feb-2023
Name and Title: Christopher S. Coffey, PhD (DCC Principal Investigator)
Signature and Date: DocuSigned by Merit Cudkowicz Merit Cudkowicz | I approve this document 17-Feb-2023 | 8:28:16 AM EST 9F8FE4180E504C6AB0A67B835E80C644 17-Feb-2023
Name and Title: Merit E. Cudkowicz, MD MSc (CCC Principal Investigator)
Signature and Date: DocuSigned by Marianne Chase Marianne Chase | I approve this document 17-Feb-2023 | 1:37:32 PM EST 58FE690F6BCA4F2390E3DA15BCE3F578 17-Feb-2023
Name and Title: Marianne Chase, BA (CCC Senior Director of Clinical Trials Operations)

Signature and Date:

DocuSigned by DIXIE ECKLUND

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

Signature and Date:

DocuSigned by Stacey Grabert

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22-Feb-2023

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

Signature and Date:

DocuSigned by Joan Ohayon

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16-Feb-2023

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

NN QA 803

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR CORRECTIVE AND PREVENTIVE ACTION PLAN MANAGEMENT

1. POLICY

The NeuroNEXT Data Coordinating Center (DCC) at the University of Iowa Clinical Trials Statistical and Data Management Center (CTSDMC) and Clinical Coordinating Center (CCC) at the Massachusetts General Hospital Neurology Clinical Research Institute (NCRI) will initiate the corrective and preventive action (CAPA) process in response to deviations and unexpected events that result in noncompliance with Network SOPs, have an impact on subject welfare and safety, and/or the integrity of the research data.

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.

The NeuroNEXT Network adheres to a quality management system based on SOPs for key research-related processes. The purpose of this SOP is to provide guidance on the corrective and preventive action (CAPA) process to NeuroNEXT DCC and CCC for drafting a plan addressing existing or potential issues of noncompliance with NeuroNEXT SOPs identified during the conduct of research, and to prevent reoccurrence.

3. ROLES AND RESPONSIBILITIES

The CCC and/or DCC are responsible for identifying noncompliance with a NeuroNEXT SOP and determining if the CAPA process should be initiated and if immediate corrections need to be implemented.

Where applicable, the CCC Quality Assurance (QA) team will identify the individual(s) responsible for developing and implementing the CAPA plan, as well as training appropriate staff and evaluating the CAPA plan to determine/verify that is resolved the issue(s).

In the case of clinical trials sponsored by commercial sponsors, the Sponsor's SOPs may supersede this procedure, as appropriate, and will be documented to indicate as such. If a Sponsor's SOP is to be utilized and implemented by NeuroNEXT personnel, the SOP must be made available to the appropriate individuals for training and implementation.

4. APPLICABLE REGULATIONSAND GUIDELINES

ICH GCP E6	2.13, 5.1.1
FDA Regulations	21 CFR 820.100 and 21 CFR 211
FDA Guidance	Guidance for Industry Investigator Responsibilities

5. REFERENCES TO OTHER APPLICABLE SOPS

This SOP applies to all NeuroNEXT Network SOPs and/or Sponsor SOPs as described in section 3 above

6. ATTACHMENTS AND REFERENCES

NN QA 803 - A Document History

7. TERMS AND ABBREVIATIONS

The following terms and abbreviations are used in this document:

CAPA Corrective and Preventive Action Plan

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

QA Quality Assurance

RCA Root Cause Analysis

SOP Standard Operating Procedure

8. SPECIFIC PROCEDURES

A. Assess risk and make immediate corrections

#	*Who*	*Task*	*Attachment/ Reference*	*Related SOP*
1.	CCC/DCC Personnel	Contact PPI, Sponsor, and/or Study Team, as appropriate and inform of noncompliance		NN PM 501
2.	CCC/DCC Personnel and CCC QA Staff	Determine if the CAPA process should be initiated and if immediate corrections need to be implemented.		
3.	CCC QA Staff	Identify the individual(s) responsible for: - Implementing immediate corrections - Developing the CAPA plan - Implementing the CAPA plan - Training staff on the CAPA plan - Evaluating results of the CAPA plan		
4.	CCC/DCC Personnel	Make immediate corrections to resolve the issue, if necessary		

B. Perform root cause analysis and develop CAPA

#	*Who*	*Task*	*Attachment/ Reference*	*Related SOP*
1.	CCC QA Staff	Perform a root cause analysis and document findings		
2.	CCC/DCC Personnel and CCC QA Staff	Develop and document a CAPA plan to identify the actions needed to correct and prevent issue		
3.	CCC/DCC Personnel and CCC QA Staff	Send a copy of the final CAPA plan to the PPI or designee for review and approval		
4.	PPI or designee	Review and approve CAPA		
5.	CCC/DCC Personnel and CCC QA Staff	Develop or modify processes/ procedures, SOPs to address the root cause of the issue		
6.	CCC/DCC Personnel and CCC QA Staff	Communicate CAPA plan and changes to the processes/procedures, SOPs to those affected		
7.	CCC/DCC Personnel and CCC QA Staff	Train study staff on CAPA plan and new/revised SOPs, and training documents		

C. Effectiveness check

#	*Who*	*Task*	*Attachment/ Reference*	*Related SOP*
1.	CCC QA Staff	Evaluate CAPA to determine/verify that the CAPA plan resolved the issue		
2.	CCC QA Staff	If the CAPA plan did not address the root case, amend the plan, and re-evaluate		
3.	CCC QA Staff	Document closure of the CAPA and file it in the appropriate location		

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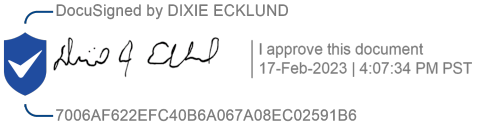
DIXIE ECKLUND dixie-ecklund@uiowa.edu Security Level: Email, Account Authentication (Required), Login with SSO	 Signature Adoption: Drawn on Device Signature ID: 7006AF62-2EFC-40B6-A067-A08EC02591B6 Using IP Address: 128.255.112.230 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 2/16/2023 9:31:13 AM Viewed: 2/17/2023 7:06:33 PM Signed: 2/17/2023 7:07:36 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: 2/16/2023 9:31:13 AM Viewed: 2/17/2023 1:37:14 PM Signed: 2/17/2023 1:37:35 PM
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