NeuroNEXT Network

Standard Operating Procedure (SOP)

Site Performance Monitoring

Version 2.0

SOP NN SS 404

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 | 8:21:40 AM PST C68AC8DD80334CF982AED1200765F147 15-Feb-2023
Name and Title: Christopher S. Coffey, PhD (DCC Principal Investigator)
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15-Feb-2023

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NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR SITE PERFORMANCE MONITORING

1. POLICY

The NeuroNEXT Clinical Coordinating Center (CCC) will work with the Data Coordinating Center (DCC) and Protocol Principal Investigator (PPI)/ Sponsor to monitor site performance at all Clinical Study Sites (CSS) participating in Network studies. The CCC will work with the DCC and PPI to create site performance goals and metrics for each Network study, and will ensure that these goals and metrics are communicated to each participating CSS. In instances where a CSS is not meeting performance goals or metrics, the CCC (in collaboration with the DCC and PPI) will assist the CSS in identifying root causes for performance issues. The CCC will work with the CSS to develop individual Corrective Action and Preventative Action (CAPA) plans and design more effective procedures to prevent similar issues in the future.

The CCC, DCC, and PPI will determine study-specific criteria for suspension and/or termination of CSS participation in a study for inadequate enrollment, non-compliance with the study protocol or Good Clinical Practice (GCP) principles, or other serious issues related to site performance.

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 designee), will develop site performance metrics for each Network study

The CCC Project Manager (PM), and DCC Protocol Coordinator (PC) and monitors (or designee), are responsible for pro-actively identifying potential issues at each CSS. If issues are identified, the study team is responsible for working with the CSS to analyze the root cause of the issue and to develop a CAPA plan. The study team will notify the site support team as needed.

The CCC PM, in collaboration with the DCC PC and monitors and site support team, if needed are responsible for assisting each CSS with implementation of CAPA plans.

The CCC, DCC and PPI (or designee) are responsible for determining criteria for suspension and/or termination of CSS participation in a study.

The PPI or his/her designee, under the direction of/advice from the Protocol Steering Committee (PSC), is responsible for communicating any issues related to suspension or termination of CSS participation in a study, and for communicating any decisions regarding these matters to the CCC, the Single Institutional Review Board (SIRB), the DCC, the protocol study team, and the CSS.

The PSC is responsible for advising the PPI or his/her designee on issues related to suspension or termination of CSS participation in a study.

The DCC is responsible for performing study close-out visits, as needed.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.50	General Responsibilities of Sponsors
21 CFR 312.53	Selecting Investigators and Monitors
ICH E6, 2.7	The Principles of ICH GCP
ICH E6, 5.1	Quality Assurance and Quality Control

5. REFERENCES TO OTHER APPLICABLE SOPS

NN SS 405	Study Close Out Visits
NN PM 501	Communication
NN SM 602	Single Institutional Review Board Reporting

6. ATTACHMENTS AND REFERENCES

NN SS 404 – A	Document History

7. TERMS AND ABBREVIATIONS

The following terms and abbreviations are used in this document:

CAPA	Corrective Action and Preventative Action plan
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
GCP	Good Clinical Practice
ICH	International Conference on Harmonisation
PM	Project Manager
PPI	Protocol Principal Investigator
PSC	Protocol Steering Committee
SIRB	Single Institutional Review Board

8. SPECIFIC PROCEDURES

A. Site Performance Monitoring

#	*Who*	*Task*	*Attachment / References*	*Related SOP*
1.	CCC, DCC, and PPI or designee	Develop site performance metrics for each study		
2.	CCC, DCC	Proactively identify site performance issues.		
3.	CCC, DCC, and PPI or designee	Perform root cause analysis and develop CAPA plans		
4.	CCC, DCC, and Site intervention team,	Work with CSS to implement CAPA plans		
5.	CCC, DCC, and PPI or designee	Determine criteria for suspension and/or termination of CSS participation in study		

A. Closing a Site For Cause

#	*Who*	*Task*	*Attachment / References*	*Related SOP*
1	PPI or designee	Discuss potential suspension and/or termination of CSS participation in study with PSC		

#	*Who*	*Task*	*Attachment / References*	*Related SOP*
2	PSC	Advise PPI on issues related to CSS suspension and or termination from participation in study		
3	PPI or designee	Communicate with CCC, SIRB, DCC and Protocol Study Team members regarding CSS suspension or termination from participation in study		NN PM 501 NN SM 602
4	PPI or designee	Communicate with CSS any decisions related to suspension or termination from participation in study		NN PM 501
5	DCC Monitors	Perform study close out visits, as needed		NN SS 405

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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)	 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 8:18:53 AM Viewed: 2/15/2023 8:54:06 PM Signed: 2/15/2023 8:55:20 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 | 1:52:32 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 8:18:53 AM Viewed: 2/17/2023 1:52:20 AM Signed: 2/17/2023 1:52:34 AM
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