NeuroNEXT Network

Standard Operating Procedure (SOP)

Site Performance Monitoring

Version 3.0

SOP NN SS 404

Originators: NeuroNEXT CCC and DCC Personnel

Reviewed and Approved by:

Signature and Date: Christopher S. Coffey *Electronically signed by: Christopher S. Coffey Reason: I approve this document Date: Mar 8, 2024 08:22 CST* 08-Mar-2024
Name and Title: Christopher S. Coffey, PhD (DCC Principal Investigator)
Signature and Date: *Electronically signed by: Merit Cudkowicz Reason: I approve this document Date: Feb 22, 2024 12:48 CST* 22-Feb-2024
Name and Title: Merit E. Cudkowicz, MD MSc (CCC Principal Investigator)
Signature and Date: Marianne Chase *Electronically signed by: Marianne Chase Reason: I approve this document Date: Feb 22, 2024 15:16 EST* 22-Feb-2024
Name and Title: Marianne Chase, BA (CCC Senior Director of Clinical Trials Operations)

SOP: NN SS 404 Version No.: 3.0 Issue Date: 01Mar2024 Effective Date: 15Apr2024	SITE PERFORMANCE MONITORING	Supersedes : Document Version 2.0 Effective Date : 08Apr2023

Signature and Date:

Dixie Ecklund

Electronically signed by: Dixie Ecklund
Reason: I approve this document
Date: Feb 24, 2024 17:22 CST

24-Feb-2024

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

Signature and Date:

Electronically signed by: Stacey Grabert
Reason: I approve this document
Date: Feb 22, 2024 13:41 EST

22-Feb-2024

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

Signature and Date:

Joan Ohayon

Electronically signed by: Joan Ohayon
Reason: I approve this document
Date: Mar 11, 2024 11:22 EDT

11-Mar-2024

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

SOP: NN SS 404 Version No.: 3.0 Issue Date: 01Mar2024 Effective Date: 15Apr2024	SITE PERFORMANCE MONITORING	Supersedes : Document Version 2.0 Effective Date : 08Apr2023

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 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 proactively 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, 2.0	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
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 Council for Harmonisation
PC	Protocol Coordinator
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 Support 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		

B. 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		
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

Attachment NN SS 404 - A. Document History

NeuroNEXT Network Standard Operating Procedure (SOP) Site Performance Monitoring SOP NN SS 404					
Version	**Description of Modification**	**Reason or Justification for Modification**	**Issue Date**	**Effective Date**	**Reviewer(s)**
1.0	New	N/A	06Apr2012	06May2012	N/A
1.0	Reviewed – no changes (2016)	N/A	06Apr2012	06May2012	N/A
2.0	Updated “1996 ICH E6 Consolidated Guidance” to “2016 Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)”. Updated signature block to accommodate for electronic signatures. Additional minor updates throughout.	Updates for version 2.0	22Feb2023	08Apr2023	Catherine Gladden
3.0	Minor updates for clarity and formatting changes throughout.	Periodic Review	01Mar2024	15Apr2024	Preeti Paul

NN SS 404 Site Performance Monitoring v3.0 clean

Final Audit Report 2024-03-11

Created:	2024-02-22
By:	Tania Leeder (tleeder@mgb.org)
Status:	Signed
Transaction ID:	CBJCHBCAABAARCzqrJ8pf5tynmLz0AU1o4hssIn527Wv
Number of Documents:	1
Document page count:	6
Number of supporting files:	0
Supporting files page count:	0

"NN SS 404 Site Performance Monitoring v3.0 clean" History

Document created by Tania Leeder (tleeder@mgb.org)
2024-02-22 - 6:33:09 PM GMT

Document emailed to christopher-coffey@uiowa.edu for signature
2024-02-22 - 6:34:36 PM GMT

Document emailed to cudkowicz.merit@mgh.harvard.edu for signature
2024-02-22 - 6:34:37 PM GMT

Document emailed to Marianne Chase (mchase@mgh.harvard.edu) for signature
2024-02-22 - 6:34:37 PM GMT

Document emailed to dixie-ecklund@uiowa.edu for signature
2024-02-22 - 6:34:37 PM GMT

Document emailed to Stacey Grabert (SGrabert@mgh.harvard.edu) for signature
2024-02-22 - 6:34:37 PM GMT

Document emailed to ohayonj@ninds.nih.gov for signature
2024-02-22 - 6:34:37 PM GMT

Stacey Grabert (SGrabert@mgh.harvard.edu) authenticated with Adobe Acrobat Sign.
Challenge: The user opened the agreement.
2024-02-22 - 6:41:21 PM GMT

Document e-signed by Stacey Grabert (SGrabert@mgh.harvard.edu)
Signing reason: I approve this document
Signature Date: 2024-02-22 - 6:41:33 PM GMT - Time Source: server

Email viewed by cudkowicz.merit@mgh.harvard.edu
2024-02-22 - 6:47:33 PM GMT

cudkowicz.merit@mgh.harvard.edu authenticated with Adobe Acrobat Sign.
Challenge: The user opened the agreement.
2024-02-22 - 6:47:59 PM GMT

Signer cudkowicz.merit@mgh.harvard.edu entered name at signing as Merit Cudkowicz
2024-02-22 - 6:48:13 PM GMT

Document e-signed by Merit Cudkowicz (cudkowicz.merit@mgh.harvard.edu)
Signing reason: I approve this document
Signature Date: 2024-02-22 - 6:48:15 PM GMT - Time Source: server

Email viewed by christopher-coffey@uiowa.edu
2024-02-22 - 7:55:47 PM GMT

Marianne Chase (mchase@mgh.harvard.edu) authenticated with Adobe Acrobat Sign.
Challenge: The user opened the agreement.
2024-02-22 - 8:15:55 PM GMT

Document e-signed by Marianne Chase (mchase@mgh.harvard.edu)
Signing reason: I approve this document
Signature Date: 2024-02-22 - 8:16:13 PM GMT - Time Source: server

Tania Leeder (tleeder@mgb.org) added alternate signer cscoffey@iowa.uiowa.edu. The original signer christopher-coffey@uiowa.edu can still sign.
2024-02-23 - 6:50:04 PM GMT

Document emailed to cscoffey@iowa.uiowa.edu for signature
2024-02-23 - 6:50:04 PM GMT

Tania Leeder (tleeder@mgb.org) added alternate signer ecklundd@uiowa.edu. The original signer dixie-ecklund@uiowa.edu can still sign.
2024-02-23 - 6:50:18 PM GMT

Document emailed to ecklundd@uiowa.edu for signature
2024-02-23 - 6:50:18 PM GMT

Email viewed by cscoffey@iowa.uiowa.edu
2024-02-23 - 7:14:11 PM GMT

Email viewed by ecklundd@uiowa.edu

2024-02-24 - 11:21:40 PM GMT

ecklundd@uiowa.edu authenticated with Adobe Acrobat Sign.

Challenge: The user opened the agreement.

2024-02-24 - 11:21:52 PM GMT

Signer ecklundd@uiowa.edu entered name at signing as Dixie Ecklund

2024-02-24 - 11:22:05 PM GMT

Document e-signed by Dixie Ecklund (ecklundd@uiowa.edu)

Signing reason: I approve this document

Signature Date: 2024-02-24 - 11:22:08 PM GMT - Time Source: server

Email viewed by cscoffey@iowa.uiowa.edu

2024-03-08 - 9:19:54 AM GMT- IP address: 172.226.137.0

cscoffey@iowa.uiowa.edu authenticated with Adobe Acrobat Sign.

Challenge: The user opened the agreement.

2024-03-08 - 2:22:22 PM GMT

Signer cscoffey@iowa.uiowa.edu entered name at signing as Christopher S. Cofffey

2024-03-08 - 2:22:40 PM GMT- IP address: 128.255.113.139

Document e-signed by Christopher S. Cofffey (cscoffey@iowa.uiowa.edu)

Signing reason: I approve this document

Signature Date: 2024-03-08 - 2:22:43 PM GMT - Time Source: server- IP address: 128.255.113.139

Email viewed by ohayonj@ninds.nih.gov

2024-03-11 - 3:22:19 PM GMT- IP address: 104.47.64.254

ohayonj@ninds.nih.gov authenticated with Adobe Acrobat Sign.

Challenge: The user opened the agreement.

2024-03-11 - 3:22:28 PM GMT

Signer ohayonj@ninds.nih.gov entered name at signing as Joan Ohayon

2024-03-11 - 3:22:38 PM GMT- IP address: 72.83.187.43

Document e-signed by Joan Ohayon (ohayonj@ninds.nih.gov)

Signing reason: I approve this document

Signature Date: 2024-03-11 - 3:22:40 PM GMT - Time Source: server- IP address: 72.83.187.43

Agreement completed.

2024-03-11 - 3:22:40 PM GMT