NeuroNEXT Network

Standard Operating Procedure (SOP)

Participant Eligibility and Enrollment

Version 3.0

SOP NN SM 603

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 08:18 CST* 08-Mar-2024
Name and Title: Christopher S. Coffey, PhD (DCC Principal Investigator)
Signature and Date: Merit Cudkowicz *Electronically signed by: Merit Cudkowicz* *Reason: I approve this document* *Date: Feb 22, 2024 17:10 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 14:42 EST* 22-Feb-2024
Name and Title: Marianne Chase, BA (CCC Senior Director of Clinical Trials Operations)

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR PARTICIPANT ELIGIBILITY AND ENROLLMENT

SOP: NN SM 603 Version No: 3.0 Issue Date: 01Mar2024 Effective Date: 15Apr2024	PARTICIPANT ELIGIBILITY AND ENROLLMENT	Supersedes Document : Version 2.0 Effective Date : 08Apr2024

Signature and Date:

Dixie Ecklund

Electronically signed by: Dixie Ecklund
Reason: I approve this document
Date: Feb 24, 2024 17:19 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 15:15 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 09:15 EDT

11-Mar-2024

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

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR PARTICIPANT ELIGIBILITY AND ENROLLMENT

SOP: NN SM 603 Version No: 3.0 Issue Date: 01Mar2024 Effective Date: 15Apr2024	PARTICIPANT ELIGIBILITY AND ENROLLMENT	Supersedes Document : Version 2.0 Effective Date : 08Apr2024

1. POLICY

It is the policy of the NeuroNEXT Network that only those participants who meet the eligibility criteria for a given NeuroNEXT study may be enrolled in that study. Documentation stating that each participant meets the inclusion/exclusion criteria must be available in his/her study participant file and/or in the source documentation, so that the eligibility of each participant can be ascertained.

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 Clinical Coordinating Center (CCC) and Data Coordinating Center (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 participating Site Principal Investigator (PI) is responsible for ensuring written confirmation of a participant's eligibility to be enrolled in a clinical study prior to his/her enrollment in the study.

Study Site PIs are responsible for reviewing and personally documenting and dating review of all Participant Eligibility Forms prior to enrolling a participant. If the task of reviewing participant eligibility is delegated to any site staff member, this must be clearly documented, and delegation of this task must be in compliance with the study protocol, Single Institutional Review Board (CIRB) policies, local institutional policies, and state and federal laws.

Appropriate Participant Eligibility Forms, containing all necessary elements for complete documentation of the participant eligibility review process required by each NeuroNEXT protocol, will be created by the Protocol Principal Investigator (PPI) in collaboration with the DCC and CCC. Screening and Enrollment Logs, and/or other tools, may be developed and implemented on a per protocol basis at the discretion of the PPI, DCC, CCC or study monitors to ensure proper tracking of eligibility and enrollment activities at study sites. Participant Eligibility Forms and other logs or tools will be distributed to each site by the study monitor at the Site Initiation Visit, or during trial participation.

Completed Participant Eligibility Forms must be filed in the participant's file. Study monitors will review participant eligibility and enrollment documents during on-site monitoring visits, and remotely in the interim as necessary.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.60	General Responsibilities of Investigators
ICH E6, 4.5	Compliance with Protocol
ICH E6, 4.7	Randomization Procedures and Unblinding
ICH E6, 5.5	Trial Management, Data Handling and Record Keeping

5. REFERENCES TO OTHER APPLICABLE SOPS

NN GA 103	Document Development and Change Control
NN SS 402	Site Initiation Visits and Site Training

SOP: NN SM 603 Version No: 3.0 Issue Date: 01Mar2024 Effective Date: 15Apr2024	PARTICIPANT ELIGIBILITY AND ENROLLMENT	Supersedes Document : Version 2.0 Effective Date : 08Apr2024

NN SS 403	Routine Monitoring Visits
NN SS 405	Study Close Out Visits

6. ATTACHMENTS AND REFERENCES

NN SM 603 - 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
CSS	Clinical Study Site
DCC	Data Coordinating Center at The University of Iowa
GCP	Good Clinical Practices
ICH	International Council for Harmonisation
PPI	Protocol Principal Investigator
Site PI	Site Principal Investigator

8. SPECIFIC PROCEDURES

A. Participant Eligibility Documentation

#	*Who*	*Task*	*Attachment/ Reference*	*Related SOP*
1.	CCC, DCC, PPI or their designee	Prepare a Participant Eligibility Form to include all inclusion/exclusion criteria listed in the protocol.		NN GA 103
2.	CCC, DCC, PPI or their designee	Prepare, as needed, a Screening and Enrollment Log for use at each study site.		NN GA 103
3.	CCC. DCC, PPI or their designee	Provide these forms to site study personnel prior to site initiation.		NN SS 402

SOP: NN SM 603 Version No: 3.0 Issue Date: 01Mar2024 Effective Date: 15Apr2024	PARTICIPANT ELIGIBILITY AND ENROLLMENT	Supersedes Document : Version 2.0 Effective Date : 08Apr2024

B. Conduct of Screening Activities at the Site

#	*Who*	*Task*	*Attachment*	*Related SOP*
1.	CCC Project Manager, DCC Study Monitor or designee	Instruct investigators, as appropriate per protocol, to use the Screening and Enrollment Log as a running list of all potentially eligible participants screened for the study and to track each participant's informed consent status if enrolled. Instruct investigators that logs submitted to the CCC or DCC should not contain personal identifying information.		
2.	CCC Project Manager, DCC Study Monitor or designee	Instruct investigators to complete a Participant Eligibility Form for each potential participant, based on discussions with the participant and a review of his/her medical records.		
3.	DCC Study Monitor or designee	Verify that logs and checklists and originals or copies of appropriate supporting documentation are held in each site's study file or specific participant file, as appropriate.		NN SS 403 NN SS 405

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR PARTICIPANT ELIGIBILITY AND ENROLLMENT

SOP: NN SM 603 Version No: 3.0 Issue Date: 01Mar2024 Effective Date: 15Apr2024	PARTICIPANT ELIGIBILITY AND ENROLLMENT	Supersedes Document : Version 2.0 Effective Date : 08Apr2024

Attachment NN SM 603 - A. Document History

NeuroNEXT Network Standard Operating Procedure (SOP) Participant Eligibility and Enrollment SOP NN SM 603					
Version	**Description of Modification**	**Reason or Justification for Modification**	**Issue Date**	**Effective Date**	**Reviewer(s)**
1.0	New	N/A	13Apr2012	13May2012	N/A
1.0	Reviewed – no changes (2016)	N/A	13Apr2012	13May2012	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 v2.0	22Feb2023	08Apr2024	Catherine Gladden
3.0	Minor edits for clarity	Periodic review	01Mar2024	15Apr2024	Preeti Paul

NN SM 603 Participant Eligibility and Enrollment v3.0 clean

Final Audit Report 2024-03-11

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

"NN SM 603 Participant Eligibility and Enrollment v3.0 clean" History

Document created by Tania Leeder (tleeder@mgb.org)
2024-02-22 - 7:03:34 PM GMT

Document emailed to christopher-coffey@uiowa.edu for signature
2024-02-22 - 7:06:19 PM GMT

Document emailed to cudkowicz.merit@mgh.harvard.edu for signature
2024-02-22 - 7:06:19 PM GMT

Document emailed to Marianne Chase (mchase@mgh.harvard.edu) for signature
2024-02-22 - 7:06:20 PM GMT

Document emailed to dixie-ecklund@uiowa.edu for signature
2024-02-22 - 7:06:20 PM GMT

Document emailed to Stacey Grabert (SGrabert@mgh.harvard.edu) for signature
2024-02-22 - 7:06:20 PM GMT

Document emailed to ohayonj@ninds.nih.gov for signature
2024-02-22 - 7:06:20 PM GMT

Marianne Chase (mchase@mgh.harvard.edu) authenticated with Adobe Acrobat Sign.

Challenge: The user opened the agreement.

2024-02-22 - 7:41:49 PM GMT

Document e-signed by Marianne Chase (mchase@mgh.harvard.edu)

Signing reason: I approve this document

Signature Date: 2024-02-22 - 7:42:10 PM GMT - Time Source: server

Email viewed by christopher-coffey@uiowa.edu

2024-02-22 - 7:55:47 PM GMT

Stacey Grabert (SGrabert@mgh.harvard.edu) authenticated with Adobe Acrobat Sign.

Challenge: The user opened the agreement.

2024-02-22 - 8:15:16 PM GMT

Document e-signed by Stacey Grabert (SGrabert@mgh.harvard.edu)

Signing reason: I approve this document

Signature Date: 2024-02-22 - 8:15:27 PM GMT - Time Source: server

Email viewed by cudkowicz.merit@mgh.harvard.edu

2024-02-22 - 11:09:55 PM GMT

cudkowicz.merit@mgh.harvard.edu authenticated with Adobe Acrobat Sign.

Challenge: The user opened the agreement.

2024-02-22 - 11:10:13 PM GMT

Signer cudkowicz.merit@mgh.harvard.edu entered name at signing as Merit Cudkowicz

2024-02-22 - 11:10:34 PM GMT

Document e-signed by Merit Cudkowicz (cudkowicz.merit@mgh.harvard.edu)

Signing reason: I approve this document

Signature Date: 2024-02-22 - 11:10:36 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 - 6:53:01 PM GMT

Document emailed to cscoffey@iowa.uiowa.edu for signature

2024-02-23 - 6:53:02 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 - 6:53:15 PM GMT

Document emailed to ecklundd@uiowa.edu for signature

2024-02-23 - 6:53:15 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 - 11:19:30 PM GMT

ecklundd@uiowa.edu authenticated with Adobe Acrobat Sign.
Challenge: The user opened the agreement.
2024-02-24 - 11:19:41 PM GMT

Signer ecklundd@uiowa.edu entered name at signing as Dixie Ecklund
2024-02-24 - 11:19:53 PM GMT

Document e-signed by Dixie Ecklund (ecklundd@uiowa.edu)
Signing reason: I approve this document
Signature Date: 2024-02-24 - 11:19:56 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 - 2:18:03 PM GMT

Signer cscoffey@iowa.uiowa.edu entered name at signing as Christopher S.Coffey
2024-03-08 - 2:18:19 PM GMT- IP address: 128.255.113.139

Document e-signed by Christopher S.Coffey (cscoffey@iowa.uiowa.edu)
Signing reason: I approve this document
Signature Date: 2024-03-08 - 2:18:22 PM GMT - Time Source: server- IP address: 128.255.113.139

Email viewed by ohayonj@ninds.nih.gov
2024-03-11 - 1:15:21 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 - 1:15:31 PM GMT

Signer ohayonj@ninds.nih.gov entered name at signing as Joan Ohayon
2024-03-11 - 1:15:42 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 - 1:15:44 PM GMT - Time Source: server- IP address: 72.83.187.43

Agreement completed.
2024-03-11 - 1:15:44 PM GMT