# NeuroNEXT Network

## Standard Operating Procedure (SOP)

Subject Eligibility and Enrollment

Version 2.0

SOP NN SM 603

Originators: NeuroNEXT CCC and DCC Personnel

Reviewed and Approved by:

| |
|---|
| **Signature and Date:**<br>DocuSigned by Christopher Coffey<br>Christopher Coffey \| I approve this document 16-Feb-2023 \| 11:06:24 AM PST<br>C68AC8DD80334CF982AED1200765F147<br>16-Feb-2023 |
| **Name and Title:** Christopher S. Coffey, PhD (DCC Principal Investigator) |
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**Signature and Date:**

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21-Feb-2023 | 6:51:54 AM PST
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21-Feb-2023

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

**NN SM 603**

# NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR SUBJECT ELIGIBILITY AND ENROLLMENT

## 1. POLICY

It is the policy of the NeuroNEXT Network that only those subjects who meet the eligibility criteria for a given NeuroNEXT study may be enrolled in that study. Documentation stating that each subject meets the inclusion/exclusion criteria must be available in his/her study subject file and/or in the source documentation, so that the eligibility of each subject 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 subject'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 Subject Eligibility Forms prior to enrolling a subject. If the task of reviewing subject 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 (SIRB) policies, local institutional policies, and state and federal laws.

Appropriate Subject Eligibility Forms, containing all necessary elements for complete documentation of the subject 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. Subject 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 Subject Eligibility Forms must be filed in the subject's file. Study monitors will review subject 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 |
| 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 Conference on Harmonisation |
| PPI | Protocol Principal Investigator |
| Site PI | Site Principal Investigator |

## 8. SPECIFIC PROCEDURES

### A. Subject Eligibility Documentation

| *#* | *Who* | *Task* | *Attachment/ Reference* | *Related SOP* |
|---|---|---|---|---|
| 1. | CCC, DCC, PPI or their designee | Prepare a Subject 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 |

### 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 subjects screened for the study and to track each subject'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 Subject Eligibility Form for each potential subject, based on discussions with the subject 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 subject file, as appropriate. | | NN SS 403<br>NN SS 405 |

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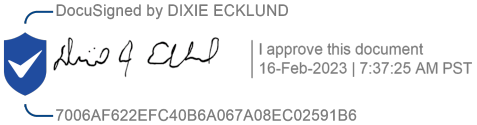
| DIXIE ECKLUND<br>dixie-ecklund@uiowa.edu<br>Security Level: Email, Account Authentication (Required), Login with SSO |  <br><br>Signature Adoption: Drawn on Device<br>Signature ID:<br>7006AF62-2EFC-40B6-A067-A08EC02591B6<br>Using IP Address: 173.19.231.252<br><br>With Signing Authentication via DocuSign password<br>With Signing Reasons (on each tab):<br>I approve this document | Sent: 2/16/2023 8:40:53 AM<br>Viewed: 2/16/2023 10:33:21 AM<br>Signed: 2/16/2023 10:37:28 AM |
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| Marianne Chase<br>MCHASE@mgh.harvard.edu<br>Sr Director, Clinical Trial Operations<br>Insight OBO The Massachusetts General Hospital<br>Security Level: Email, Account Authentication (Required), Logged in |  <br>Signature Adoption: Pre-selected Style<br>Signature ID:<br>58FE690F-6BCA-4F23-90E3-DA15BCE3F578<br>Using IP Address: 73.114.253.109<br><br>With Signing Authentication via DocuSign password<br>With Signing Reasons (on each tab):<br>I approve this document | Sent: 2/16/2023 8:40:54 AM<br>Viewed: 2/17/2023 1:43:40 PM<br>Signed: 2/17/2023 1:44:04 PM |
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