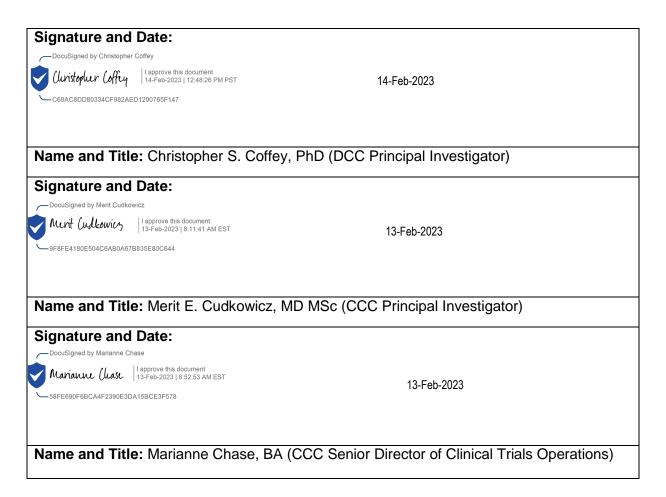
## **NeuroNEXT Network**

## **Standard Operating Procedure (SOP)**

SOP Training
Version 3.0
SOP NN GA 102

Originators: NeuroNEXT CCC and DCC Personnel

Reviewed and Approved by:



#### Signature and Date:

DocuSigned by DIXIE ECKLUND



13-Feb-2023

-7006AF622EFC40B6A067A08EC02591B6

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

#### Signature and Date:

DocuSigned by Stacey Grabert



22-Feb-2023

-60CC52B0747A44E6B2208D8D880698C0

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

#### Signature and Date:

DocuSigned by Joan Ohayon



Joan Olayon | I approve this document | 13-Feb-2023 | 11:15:13 AM PST

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13-Feb-2023

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

#### **NN GA 102**

## NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR SOP TRAINING

#### 1. POLICY

#### SOP Training for New and Established NeuroNEXT Personnel

The NeuroNEXT Clinical Coordinating Center (CCC) and Data Coordinating Center (DCC) will ensure that all CCC, DCC, or other personnel who participate in NeuroNEXT Network activities are trained on Standard Operating Procedures (SOPs) that are appropriate to their roles and responsibilities in the NeuroNEXT Network. NeuroNEXT SOPs are developed and approved according to procedures described in SOP NN GA 101 *Development and Maintenance of SOPs*.

All NeuroNEXT personnel are expected to review SOPs that are applicable to their role in the NeuroNEXT Network. This review/self-training process satisfies the Network requirement for personnel training on the SOPs.

Currently approved SOPs are posted on the secure area of the NeuroNEXT website, and are accessible to all NeuroNEXT Network users. New personnel are required to sign into the website to review and acknowledge understanding of their assigned SOPs as part of their orientation training.

As part of ongoing training, established personnel will be prompted to review any new or substantively revised SOPs relevant to their role in the NeuroNEXT Network that have been issued since their last SOP review.

When new or updated SOPs are issued, or as part of their ongoing training, the DCC Lead Coordinator or a designee will circulate an email notification to all applicable NeuroNEXT Network personnel to inform them that SOPs are available for review. Each revised SOP will have a document history form available that summarizes the modifications that have been made since the previous version. Personnel are expected to complete their review prior to the new effective date of an SOP.

As part of ongoing training, additional collective training for applicable NeuroNEXT Network personnel may be conducted at NeuroNEXT study team meetings or through other methods.

#### 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 within the Network regulated by FDA and/or applicable review committees.

#### 3. ROLES AND RESPONSIBILITIES

All NeuroNEXT CCC and DCC personnel are responsible for reviewing and acknowledging that they understand and will follow all Network SOPs that are applicable to their role in the NeuroNEXT Network, and for performing self-training on new and revised SOPs during the allotted timeframe.

All new NeuroNEXT personnel will be required to review and acknowledge understanding of each SOP that is applicable to their role in the Network before they are approved to perform work on a NeuroNEXT study and are granted data entry rights or permissions to view subject data.

#### 4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.50	General Responsibilities of Sponsors
21 CFR 312.57	Recordkeeping and Record Retention
ICH E6, 2.13	The Principles of ICH GCP
ICH E6, 5.1	Quality Assurance and Quality Control
ICH E6, 5.5	Trial Management, Data Handling and Recordkeeping

#### 5. REFERENCES TO OTHER APPLICABLE SOPS

NN GA 101	Development and Maintenance of SOPs
NN SS 402	Site Initiation Visits and Site Training
NN PM 501	Communication
NN PM 504	Investigative Site Staff Training
NN QA 802	Quality Management

#### 6. ATTACHMENTS AND REFERENCES

NN GA 102 – 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
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
SOP	Standard Operating Procedure

#### 8. SPECIFIC PROCEDURES

### A. SOP TRAINING

#	Who	Task	Attachment	Related SOP
1.	DCC Lead Coordinator or designee	After signature approval, upload new and/or revised SOPs to the secure area of the NeuroNEXT website.		
2.	DCC Lead Coordinator or designee	Send an email notification to all new personnel indicating that SOPs are available for review, and that training (i.e. review and acknowledgement) on their assigned SOPs must occur before they are approved to perform work on a NeuroNEXT study and are granted data entry rights or permissions to view subject data.		
3.	New NeuroNEXT Network personnel	Sign into the secure area of the NeuroNEXT website to review and acknowledge understanding of assigned SOPs as part of orientation training. Self-review of SOPs satisfies the Network requirement for SOP training.		

#	Who	Task	Attachment	Related SOP
4.	DCC Lead Coordinator or designee	If an SOP has been substantively revised or a new SOP has been developed, send an email notification to applicable Network personnel indicating that SOPs are available for review.		
5.	Applicable NeuroNEXT Network personnel	Prior to the effective date, review new or substantively revised SOPs that have been issued and assigned for your review.		

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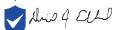
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