

NeuroNEXT Network

Standard Operating Procedure (SOP)

SOP Training

Version 4.0

SOP NN GA 102




Originators: NeuroNEXT CCC and DCC Personnel

Reviewed and Approved by:

Signature and Date: <i>Christopher S. Coffey</i> <small>Electronically signed by: Christopher S. Coffey Reason: I approve this document Date: Feb 23, 2024 12:39 CST</small>	23-Feb-2024
Name and Title: Christopher S. Coffey, PhD (DCC Principal Investigator)	
Signature and Date: <i>M</i> <small>Electronically signed by: Merit Cudkowicz Reason: I approve this document Date: Feb 22, 2024 12:50 CST</small>	22-Feb-2024
Name and Title: Merit E. Cudkowicz, MD MSc (CCC Principal Investigator)	
Signature and Date: <i>Marianne Chase</i> <small>Electronically signed by: Marianne Chase Reason: I approve this document Date: Feb 22, 2024 12:55 EST</small>	22-Feb-2024
Name and Title: Marianne Chase, BA (CCC Senior Director of Clinical Trials Operations)	

**NN GA 102
NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR
SOP TRAINING**

SOP: NN GA 102 Version No.: 4.0 Issue Date: 01Mar2024 Effective Date: 15Apr2024	SOP TRAINING	Supersedes Document : Version 3.0 Effective Date : 08Apr2023
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Signature and Date:  Electronically signed by: Dixie Ecklund Reason: I approve this document Date: Feb 23, 2024 11:59 CST <div style="text-align: right;">23-Feb-2024</div>	
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 13:50 EST <div style="text-align: right;">22-Feb-2024</div>	
Name and Title: Stacey Grabert, Pharm.D, MS, (CCC Director of Quality Assurance)	
Signature and Date:  Electronically signed by: Joan Ohayon Reason: I approve this document Date: Mar 4, 2024 13:14 EST <div style="text-align: right;">04-Mar-2024</div>	
Name and Title: Joan Ohayon, RN, MSN, CRNP, MSCN (NINDS, NeuroNEXT Program Official)	

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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 as an attachment a document history form 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.

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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.		

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#	<i>Who</i>	<i>Task</i>	<i>Attachment</i>	<i>Related SOP</i>
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.		
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.		

NN GA 102
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Attachment NN GA 102 - A. Document History

NeuroNEXT Network Standard Operating Procedure (SOP) SOP Training SOP NN GA 102					
Version	Description of Modification	Reason or Justification for Modification	Issue Date	Effective Date	Reviewer(s)
1.0	New	N/A	22Mar/2012	21Apr2012	N/A
2.0	Removed material pertaining to PWIs, added material to the policy section, and extensively revised the specific procedures. All new NeuroNEXT personnel are required to sign into the NeuroNEXT website to acknowledge understanding of assigned SOPs during orientation training and before they are approved to work on study activities. Prior to the effective date of the SOP, applicable established NeuroNEXT personnel are expected to review new or updated SOPs that are assigned for their review.	Formalized, version controlled PWIs will not be developed. Other changes are updates for version 2.0.	21Sep2016	21Oct2016	N/A
3.0	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.	Updated for version 3.0	22Feb2023	08Apr2023	Catherine Gladden
3.0	No Edits to SOP	Periodic Review	01Mar2024	15Apr2024	Preeti Paul










NN GA 102 SOP Training v4.0 clean














Final Audit Report

2024-03-04

Created:	2024-02-22
By:	Tania Leeder (tleeder@mgb.org)
Status:	Signed
Transaction ID:	CBJCHBCAABAA221pa3kKGxSaxG9btCVxaaJNL6lk9fUU
Number of Documents:	1
Document page count:	6
Number of supporting files:	0
Supporting files page count:	0


"NN GA 102 SOP Training v4.0 clean" History

-  Document created by Tania Leeder (tleeder@mgb.org)
2024-02-22 - 5:40:18 PM GMT
-  Document emailed to christopher-coffey@uiowa.edu for signature
2024-02-22 - 5:42:13 PM GMT
-  Document emailed to cudkowicz.merit@mgh.harvard.edu for signature
2024-02-22 - 5:42:14 PM GMT
-  Document emailed to mchase@mgh.harvard.edu for signature
2024-02-22 - 5:42:14 PM GMT
-  Document emailed to dixie-ecklund@uiowa.edu for signature
2024-02-22 - 5:42:14 PM GMT
-  Document emailed to Stacey Grabert (SGrabert@mgh.harvard.edu) for signature
2024-02-22 - 5:42:14 PM GMT
-  Document emailed to ohayonj@ninds.nih.gov for signature
2024-02-22 - 5:42:14 PM GMT
-  Email viewed by dixie-ecklund@uiowa.edu
2024-02-22 - 5:52:36 PM GMT
-  Email viewed by mchase@mgh.harvard.edu
2024-02-22 - 5:54:58 PM GMT

-  mchase@mgh.harvard.edu authenticated with Adobe Acrobat Sign.
Challenge: The user opened the agreement.
2024-02-22 - 5:55:16 PM GMT
-  Signer mchase@mgh.harvard.edu entered name at signing as Marianne Chase
2024-02-22 - 5:55:33 PM GMT
-  Document e-signed by Marianne Chase (mchase@mgh.harvard.edu)
Signing reason: I approve this document
Signature Date: 2024-02-22 - 5:55:35 PM GMT - Time Source: server
-  Email viewed by cudkowicz.merit@mgh.harvard.edu
2024-02-22 - 6:49:20 PM GMT
-  cudkowicz.merit@mgh.harvard.edu authenticated with Adobe Acrobat Sign.
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2024-02-22 - 6:49:50 PM GMT
-  Signer cudkowicz.merit@mgh.harvard.edu entered name at signing as Merit Cudkowicz
2024-02-22 - 6:50:05 PM GMT
-  Document e-signed by Merit Cudkowicz (cudkowicz.merit@mgh.harvard.edu)
Signing reason: I approve this document
Signature Date: 2024-02-22 - 6:50:07 PM GMT - Time Source: server
-  Stacey Grabert (SGrabert@mgh.harvard.edu) authenticated with Adobe Acrobat Sign.
Challenge: The user opened the agreement.
2024-02-22 - 6:50:47 PM GMT
-  Document e-signed by Stacey Grabert (SGrabert@mgh.harvard.edu)
Signing reason: I approve this document
Signature Date: 2024-02-22 - 6:50:59 PM GMT - Time Source: server
-  Email viewed by christopher-coffey@uiowa.edu
2024-02-22 - 7:55:15 PM GMT
-  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 - 5:53:43 PM GMT
-  Document emailed to cscoffey@iowa.uiowa.edu for signature
2024-02-23 - 5:53:44 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 - 5:53:59 PM GMT

 Document emailed to ecklundd@uiowa.edu for signature

2024-02-23 - 5:53:59 PM GMT

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2024-02-23 - 5:57:52 PM GMT

 ecklundd@uiowa.edu authenticated with Adobe Acrobat Sign.

Challenge: The user opened the agreement.

2024-02-23 - 5:58:46 PM GMT

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

2024-02-23 - 5:59:31 PM GMT

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Signing reason: I approve this document

Signature Date: 2024-02-23 - 5:59:34 PM GMT - Time Source: server

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2024-02-23 - 6:17:17 PM GMT


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2024-02-23 - 6:38:33 PM GMT


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

2024-02-23 - 6:38:59 PM GMT

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Signing reason: I approve this document

Signature Date: 2024-02-23 - 6:39:02 PM GMT - Time Source: server

 Email viewed by ohayonj@ninds.nih.gov

2024-03-04 - 6:13:52 PM GMT

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

Challenge: The user opened the agreement.

2024-03-04 - 6:14:02 PM GMT

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

2024-03-04 - 6:14:29 PM GMT

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

Signing reason: I approve this document

Signature Date: 2024-03-04 - 6:14:31 PM GMT - Time Source: server

 Agreement completed.

2024-03-04 - 6:14:31 PM GMT