

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: <small>DocuSigned by Christopher Coffey</small>  I approve this document 14-Feb-2023 12:48:26 PM PST <small>C68AC8DD80334CF982AED1200765F147</small> 14-Feb-2023
Name and Title: Christopher S. Coffey, PhD (DCC Principal Investigator)
Signature and Date: <small>DocuSigned by Merit Cudkowicz</small>  I approve this document 13-Feb-2023 8:11:41 AM EST <small>9F8FE4180E504C6AB0A67B835E80C644</small> 13-Feb-2023
Name and Title: Merit E. Cudkowicz, MD MSc (CCC Principal Investigator)
Signature and Date: <small>DocuSigned by Marianne Chase</small>  I approve this document 13-Feb-2023 8:52:53 AM EST <small>58FE690F6BCA4F2390E3DA15BCE3F578</small> 13-Feb-2023
Name and Title: Marianne Chase, BA (CCC Senior Director of Clinical Trials Operations)

Signature and Date:

DocuSigned by DIXIE ECKLUND
 | I approve this document
13-Feb-2023 | 10:02:08 AM PST
7006AF622EFC40B6A067A08EC02591B6

13-Feb-2023

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

Signature and Date:

DocuSigned by Stacey Grabert
 | I approve this document
22-Feb-2023 | 11:38:02 AM EST
60CC52B0747A44E6B2208D8D880698C0

22-Feb-2023

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

Signature and Date:

DocuSigned by Joan Ohayon
 | I approve this document
13-Feb-2023 | 11:15:13 AM PST
72C6AAFD8CC4485582ACA0700072901A

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.		

Certificate Of Completion

Envelope Id: B52739AD2EBD428A89A033108F952160 Status: Completed
Subject: Complete with DocuSign: NN GA 102 SOP Training v3.0.docx
Source Envelope:
Document Pages: 5 Signatures: 6 Envelope Originator:
Certificate Pages: 6 Initials: 0 Tania Leeder
AutoNav: Enabled TLEEDER@PARTNERS.ORG
Enveloped Stamping: Disabled IP Address: 73.159.130.82
Time Zone: (UTC-05:00) Eastern Time (US & Canada)

Record Tracking

Status: Original Holder: Tania Leeder Location: DocuSign
2/13/2023 8:04:25 AM TLEEDER@PARTNERS.ORG

Signer Events

Christopher Coffey
christopher-coffey@uiowa.edu
Security Level: Email, Account Authentication
(Required), Login with SSO

Signature

Christopher Coffey

Timestamp

Sent: 2/13/2023 8:07:48 AM
Viewed: 2/14/2023 3:48:17 PM
Signed: 2/14/2023 3:48:29 PM

Signature Adoption: Pre-selected Style
Signature ID:
C68AC8DD-8033-4CF9-82AE-D1200765F147
Using IP Address: 128.255.113.139

With Signing Authentication via DocuSign password
With Signing Reasons (on each tab):
I approve this document

Electronic Record and Signature Disclosure:
Accepted: 2/14/2023 3:48:17 PM
ID: c84c8705-a619-4f5e-88e0-002305b88444

DIXIE ECKLUND
dixie-ecklund@uiowa.edu
Security Level: Email, Account Authentication
(Required), Login with SSO

DocuSigned by DIXIE ECKLUND
I approve this document
13-Feb-2023 | 10:02:08 AM PST
7006AF622EFC40B6A067A08EC02591B6

Sent: 2/13/2023 8:07:49 AM
Viewed: 2/13/2023 1:00:40 PM
Signed: 2/13/2023 1:02:11 PM

Signature Adoption: Drawn on Device
Signature ID:
7006AF62-2EFC-40B6-A067-A08EC02591B6
Using IP Address: 128.255.112.230

With Signing Authentication via DocuSign password
With Signing Reasons (on each tab):
I approve this document

Electronic Record and Signature Disclosure:
Accepted: 2/13/2023 1:00:40 PM
ID: 5753d693-da67-4411-b9a3-50b125ddb334

Signer Events	Signature	Timestamp
---------------	-----------	-----------

Joan Ohayon
ohayonj@ninds.nih.gov
Security Level: Email, Account Authentication
(Required)

Joan Ohayon

Sent: 2/13/2023 8:07:49 AM
Viewed: 2/13/2023 2:14:46 PM
Signed: 2/13/2023 2:15:17 PM

Signature Adoption: Pre-selected Style
Signature ID:
72C6AAFD-8CC4-4855-82AC-A0700072901A
Using IP Address: 71.178.185.120

With Signing Authentication via DocuSign password
With Signing Reasons (on each tab):
I approve this document

Electronic Record and Signature Disclosure:
Accepted: 2/13/2023 2:03:22 PM
ID: 385a0a53-0f0c-4395-88f6-d5700c36e050

Marianne Chase
MCHASE@mgh.harvard.edu
Sr Director, Clinical Trial Operations
Insight OBO The Massachusetts General Hospital
Security Level: Email, Account Authentication
(Required)

Marianne Chase


Sent: 2/13/2023 8:07:49 AM
Viewed: 2/13/2023 8:52:30 AM
Signed: 2/13/2023 8:52:57 AM

Signature Adoption: Pre-selected Style
Signature ID:
58FE690F-6BCA-4F23-90E3-DA15BCE3F578
Using IP Address: 73.114.253.109

With Signing Authentication via DocuSign password
With Signing Reasons (on each tab):
I approve this document

Electronic Record and Signature Disclosure:
Not Offered via DocuSign

Merit Cudkowicz
cudkowicz.merit@mgh.harvard.edu
Chief of Neurology
Security Level: Email, Account Authentication
(Required)

DocuSigned by Merit Cudkowicz

I approve this document
13-Feb-2023 | 8:11:41 AM EST
9F8FE4180E504C6AB0A67B835E80C644


Sent: 2/13/2023 8:07:50 AM
Viewed: 2/13/2023 8:11:29 AM
Signed: 2/13/2023 8:11:43 AM

Signature Adoption: Pre-selected Style
Signature ID:
9F8FE418-0E50-4C6A-B0A6-7B835E80C644
Using IP Address: 68.239.56.73

With Signing Authentication via DocuSign password
With Signing Reasons (on each tab):
I approve this document

Electronic Record and Signature Disclosure:
Accepted: 2/13/2023 8:11:29 AM
ID: 553344af-693f-47b1-a6db-f2d89b76e905

Signer Events	Signature	Timestamp
---------------	-----------	-----------

Stacey Grabert sgrabert@mgh.harvard.edu Director QA Stacey Grabert Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: 60CC52B0-747A-44E6-B220-8D8D880698C0 Using IP Address: 132.183.56.49 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 2/13/2023 8:07:50 AM Viewed: 2/22/2023 11:37:52 AM Signed: 2/22/2023 11:38:05 AM
---	--	--

Electronic Record and Signature Disclosure:
 Accepted: 7/20/2020 8:50:14 AM
 ID: 5ebadf74-e399-40fd-be82-9c7ca902061b

In Person Signer Events	Signature	Timestamp
-------------------------	-----------	-----------

Editor Delivery Events	Status	Timestamp
------------------------	--------	-----------

Agent Delivery Events	Status	Timestamp
-----------------------	--------	-----------

Intermediary Delivery Events	Status	Timestamp
------------------------------	--------	-----------

Certified Delivery Events	Status	Timestamp
---------------------------	--------	-----------

Carbon Copy Events	Status	Timestamp
--------------------	--------	-----------

Witness Events	Signature	Timestamp
----------------	-----------	-----------

Notary Events	Signature	Timestamp
---------------	-----------	-----------

Envelope Summary Events	Status	Timestamps
-------------------------	--------	------------

Envelope Sent	Hashed/Encrypted	2/13/2023 8:07:50 AM
Certified Delivered	Security Checked	2/22/2023 11:37:52 AM
Signing Complete	Security Checked	2/22/2023 11:38:05 AM
Completed	Security Checked	2/22/2023 11:38:05 AM

Payment Events	Status	Timestamps
----------------	--------	------------

Electronic Record and Signature Disclosure
--

ELECTRONIC RECORD AND SIGNATURE DISCLOSURE

From time to time, Insight OBO The Massachusetts General Hospital (we, us or Company) may be required by law to provide to you certain written notices or disclosures. Described below are the terms and conditions for providing to you such notices and disclosures electronically through the DocuSign system. Please read the information below carefully and thoroughly, and if you can access this information electronically to your satisfaction and agree to this Electronic Record and Signature Disclosure (ERSD), please confirm your agreement by selecting the check-box next to 'I agree to use electronic records and signatures' before clicking 'CONTINUE' within the DocuSign system.

Getting paper copies

At any time, you may request from us a paper copy of any record provided or made available electronically to you by us. You will have the ability to download and print documents we send to you through the DocuSign system during and immediately after the signing session and, if you elect to create a DocuSign account, you may access the documents for a limited period of time (usually 30 days) after such documents are first sent to you. After such time, if you wish for us to send you paper copies of any such documents from our office to you, you will be charged a \$0.00 per-page fee. You may request delivery of such paper copies from us by following the procedure described below.

Withdrawing your consent

If you decide to receive notices and disclosures from us electronically, you may at any time change your mind and tell us that thereafter you want to receive required notices and disclosures only in paper format. How you must inform us of your decision to receive future notices and disclosure in paper format and withdraw your consent to receive notices and disclosures electronically is described below.

Consequences of changing your mind

If you elect to receive required notices and disclosures only in paper format, it will slow the speed at which we can complete certain steps in transactions with you and delivering services to you because we will need first to send the required notices or disclosures to you in paper format, and then wait until we receive back from you your acknowledgment of your receipt of such paper notices or disclosures. Further, you will no longer be able to use the DocuSign system to receive required notices and consents electronically from us or to sign electronically documents from us.

All notices and disclosures will be sent to you electronically

Unless you tell us otherwise in accordance with the procedures described herein, we will provide electronically to you through the DocuSign system all required notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you during the course of our relationship with you. To reduce the chance of you inadvertently not receiving any notice or disclosure, we prefer to provide all of the required notices and disclosures to you by the same method and to the same address that you have given us. Thus, you can receive all the disclosures and notices electronically or in paper format through the paper mail delivery system. If you do not agree with this process, please let us know as described below. Please also see the paragraph immediately above that describes the consequences of your electing not to receive delivery of the notices and disclosures electronically from us.

How to contact Insight OBO The Massachusetts General Hospital:

You may contact us to let us know of your changes as to how we may contact you electronically, to request paper copies of certain information from us, and to withdraw your prior consent to receive notices and disclosures electronically as follows:

To contact us by email send messages to: jhenrique@mgh.harvard.edu

To advise Insight OBO The Massachusetts General Hospital of your new email address

To let us know of a change in your email address where we should send notices and disclosures electronically to you, you must send an email message to us at jhenrique@mgh.harvard.edu and in the body of such request you must state: your previous email address, your new email address. We do not require any other information from you to change your email address.

If you created a DocuSign account, you may update it with your new email address through your account preferences.

To request paper copies from Insight OBO The Massachusetts General Hospital

To request delivery from us of paper copies of the notices and disclosures previously provided by us to you electronically, you must send us an email to jhenrique@mgh.harvard.edu and in the body of such request you must state your email address, full name, mailing address, and telephone number. We will bill you for any fees at that time, if any.

To withdraw your consent with Insight OBO The Massachusetts General Hospital

To inform us that you no longer wish to receive future notices and disclosures in electronic format you may:

- i. decline to sign a document from within your signing session, and on the subsequent page, select the check-box indicating you wish to withdraw your consent, or you may;
- ii. send us an email to jhenrique@mgh.harvard.edu and in the body of such request you must state your email, full name, mailing address, and telephone number. We do not need any other information from you to withdraw consent.. The consequences of your withdrawing consent for online documents will be that transactions may take a longer time to process..

Required hardware and software

The minimum system requirements for using the DocuSign system may change over time. The current system requirements are found here: <https://support.docusign.com/guides/signer-guide-signing-system-requirements>.

Acknowledging your access and consent to receive and sign documents electronically

To confirm to us that you can access this information electronically, which will be similar to other electronic notices and disclosures that we will provide to you, please confirm that you have read this ERSD, and (i) that you are able to print on paper or electronically save this ERSD for your future reference and access; or (ii) that you are able to email this ERSD to an email address where you will be able to print on paper or save it for your future reference and access. Further, if you consent to receiving notices and disclosures exclusively in electronic format as described herein, then select the check-box next to ‘I agree to use electronic records and signatures’ before clicking ‘CONTINUE’ within the DocuSign system.

By selecting the check-box next to ‘I agree to use electronic records and signatures’, you confirm that:

- You can access and read this Electronic Record and Signature Disclosure; and
- You can print on paper this Electronic Record and Signature Disclosure, or save or send this Electronic Record and Disclosure to a location where you can print it, for future reference and access; and
- Until or unless you notify Insight OBO The Massachusetts General Hospital as described above, you consent to receive exclusively through electronic means all notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you by Insight OBO The Massachusetts General Hospital during the course of your relationship with Insight OBO The Massachusetts General Hospital.