

# NeuroNEXT Network

## Standard Operating Procedure (SOP)


SOP Training

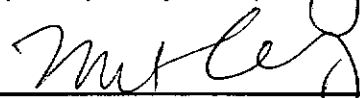
Version 2.0

SOP NN GA 102


Originators: NeuroNEXT CCC and DCC Personnel

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Issue Date

  
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Effective Date (30 calendar days after the Issue Date)

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

SOP: NN GA 102 Version No.: 2.0 Effective Date: 21Oct2016	SOP TRAINING	Supercedes Document: Version 1.0 Effective Date: 21Apr2012
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**1. POLICY**

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 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 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 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.

**2. SCOPE**

This SOP has been developed to be in alignment with federal regulations and Good Clinical Practices (GCP) as set forth in the 1996 ICH E6 Consolidated Guidance. 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
- PPI                    Protocol Principal Investigator
- 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.		
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.		

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

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

<b>NeuroNEXT Network Standard Operating Procedure (SOP)</b> <b>SOP Training</b> <b>SOP NN GA 102</b>				
<b>Version</b>	<b>Description of Modification</b>	<b>Reason or Justification for Modification</b>	<b>Issue Date</b>	<b>Effective Date</b>
1.0	New	N/A	22Mar/2012	21Apr2012
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

Page 6 of 6 is blank – was included in error in approved document.