NeuroNEXT Network

Standard Operating Procedure (SOP)

Investigational Site Staff Training

Version 4.0

SOP NN PM 504

Originators: NeuroNEXT CCC and DCC Personnel

Reviewed and Approved by

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NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR INVESTIGATIONAL SITE STAFF TRAINING

SOP: NN PM 504 Version No.: 4.0 Issue Date: 01Mar2024 Effective Date: 15Apr2024	INVESTIGATIONAL SITE STAFF TRAINING	Supersedes Document Version : 3.0 Effective Date : 08Apr2023

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11-Mar-2024

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1. POLICY

For all NeuroNEXT Network studies, each participating Clinical Study Site (CSS) will undergo ongoing staff training on:

- aspects of the study protocol;
- scientific rationale for the study;
- management of anticipated adverse events applicable to the Investigational Product;
- adverse event management;
- principles of Good Clinical Practice (GCP); and
- other study-related topics, as determined by the CCC, the DCC, and the PPI (or designee).

Each CSS will undergo re-training as needed throughout the course of a clinical investigation. New site staff members that join study participation after initial CSS training has occurred will be trained before they are permitted to engage in any study-related tasks. The CCC and DCC will maintain records of CSS trainings / certifications.

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 E6(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 NeuroNEXT CCC and DCC are responsible for verifying that each participating CSS site meets all applicable requirements for facilities, personnel, Good Clinical Practices (GCP) compliance, and regulatory compliance prior to initiation of the clinical investigation at that site, and maintaining records of trainings/certifications.

The CCC is responsible for issuing a written notification of CSS activation once all required study start-up training and documentation is completed for a CSS participating in a given study. The CCC is also responsible for forwarding the notification of Single Institutional Review Board (SIRB) approval/activation and approved Informed Consent Forms to the CSS.

The CCC and DCC are responsible for ensuring that all site personnel who will participate in the conduct of the clinical investigation have completed a protocol training session prior to the initiation of that site staff member's participation in the clinical investigation.

The DCC is responsible for ensuring that all site personnel who perform data entry into the electronic data entry system have completed Data Entry Certification prior to the initiation of data entry activities.

The CCC and DCC are responsible for reviewing the qualifications of site personnel who will be performing specified clinical research procedures, and for verifying the training of site personnel in these procedures prior to certification of the CSS and before any staff member begins newly delegated tasks.

The CCC and DCC are responsible for confirming, prior to CSS certification, that any laboratories at participating sites that perform laboratory processing or point-of-care testing for the clinical investigation are compliant with Good Laboratory Practices and institutional guidelines.

The CCC, in collaboration with the DCC and the PPI as needed, is responsible for creating and providing appropriate study materials and checklists to aid in conduct of a clinical investigation to all CSS.

The CCC is responsible for informing the Protocol Principal Investigator (PPI) of any participating CSS investigator who has failed to maintain appropriate licensure or certification requirements, as specified in applicable regulations.

When appropriate (or as requested by the PPI), the CCC and the DCC are responsible for providing CSS training and retraining on the following areas using an appropriate training medium:

- protocol compliance;
- clinical research procedures;
- adherence to GCP; and
- regulatory requirements.

4. APPLICABLE REGULATIONS AND GUIDELINES

ICH E6, 5.5	Trial Management, Data Handling and Record Keeping
ICH E6, 5.15	Record Access
ICH E6, 8.0	Essential Documents for the Conduct of a Clinical Trial

5. REFERENCES TO OTHER APPLICABLE SOPS

NN RA 202	Trial Master File Maintenance
NN RA 203	Site Regulatory File Maintenance
NN SS 402	Site Initiation Visits and Site Training
NN SS 403	Routine Monitoring Visits
NN SS 404	Site Performance Monitoring
NN SS 405	Study Closeout Visits
NN PM 503	Study Materials Development
NN DM 1005	Data Collection and Data Handling

6. ATTACHMENTS AND REFERENCES

NN PM 504 – A	Document History

7. TERMS AND ABBREVIATIONS

The following terms and abbreviations are used in this document:

CAPA	Corrective Action and Preventative Action plan
CCC	Clinical Coordinating Center at Massachusetts General Hospital
CSS	Clinical Study Site
DCC	Data Coordinating Center at The University of Iowa

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FDA	U.S. Food and Drug Administration
GCP	Good Clinical Practice
ICH	International Council for Harmonisation
PPI	Protocol Principal Investigator
SIRB	Single Institutional Review Board

8. SPECIFIC PROCEDURES

A. Site and Personnel Training

#	*Who*	*Task*	*Attachment*	*Related SOP*
1.	CCC, DCC, and PPI or designee	Determine which trainings, certifications, and regulatory requirements are to be met by the participating CSS prior to initiation of the clinical investigation, and throughout the duration of the investigation.		NN RA 202 NN SS 402
2.	CCC	Confirm that the site has completed training in all applicable GCP guidance documents, clinical and laboratory procedures, data entry procedures, and use of study-related equipment or instrumentation.		NN SS 402 NN DM 1005
3.	CCC	Provide a written notice of approval and activation to each CSS that has completed all required training and site activation activities, along with the notification of SIRB approval/activation and the Informed Consent Form(s).		
4.	CCC	Maintain documentation of CSS and personnel trainings / certifications for each CSS in the study Trial Master File.		NN RA 202
5.	CSS	Maintain documentation of CSS and personnel training in the Site Regulatory Binder.		NN RA 203

B. Ongoing Site and Personnel Training

#	*Who*	*Task*	*Attachment*	*Related SOP*
1.	CCC, DCC, and PPI or designee	Develop requirements for scheduling ongoing trainings for participating CSS.		
2.	CCC, DCC	Provide on-site training or web-based training per schedule or ‘for cause’, as warranted.		NN SS 402 NN SS 404

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#	*Who*	*Task*	*Attachment*	*Related SOP*
3.	CCC, DCC Study Monitor	Periodically review any applicable instrumentation maintenance certifications to ensure that they are current.		NN SS 403
4.	CCC	Review certification-related documents for each participating CSS to ensure that they are accurate and complete.		NN SS 403
5.	DCC, CCC	Report lapses in certifications to the PPI, and follow up with the site to ensure that criteria for certification are re-established, or to initiate procedures for re-certification, when necessary.		NN SS 404
6.	DCC, CCC, and PPI or designee	If a site demonstrates a need for retraining, work with site personnel and the PPI to create a Corrective Action and Preventative Action (CAPA) plan to rectify any issues and perform retraining.		NN SS 404

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Attachment NN PM 504 - A. Document History

NeuroNEXT Network Standard Operating Procedure (SOP) Investigational Site Staff Training SOP NN PM 504					
Version	**Description of Modification**	**Reason or Justification for Modification**	**Issue Date**	**Effective Date**	**Reviewer(s)**
1.0	New	N/A	06Apr2012	06May2012	N/A
2.0	Revised to indicate that the CCC is responsible for sending written notification of activation to CSS that have completed all training and site activation requirements, along with the SIRB approval/activation letter and ICFs. The CCC is also responsible for reviewing any certification-related documents for each CSS to ensure that they are accurate and complete. Other minor edits.	Update 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.	Updates for version 3.0	22Feb2023	08Apr2023	Catherine Gladden
4.0	Minor edits for clarity	Periodic review	01Mar2024	15Apr2024	Preeti Paul

NN PM 504 Investigational Site Staff Training v4.0 clean

Final Audit Report 2024-03-11

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Document page count:	7
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