NeuroNEXT Network

Standard Operating Procedure (SOP)

Site Regulatory File Maintenance

Version 2.0

SOP NN RA 203

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NN RA 203

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR SITE REGULATORY FILE MAINTENANCE

SOP: NN RA 203 Version No.: 2.0 Effective Date: 21Oct2016	SITE REGULATORY FILE MAINTENANCE	Supercedes Document: Version 1.0 Effective Date: 21Apr2012

1. POLICY

The NeuroNEXT Protocol Principal Investigator (PPI), acting as the regulatory Sponsor of a study, shall ensure that each Clinical Study Site (CSS) participating in a trial, maintains an organized, easily accessible, and complete Site Regulatory File (SRF) as required by regulation. The CSS will be informed that the SRF for each trial shall be available for monitoring and audits, whether internal or by a third party, and for FDA inspection.

The SRF shall be stored in a secure manner (under lock and key, accessed by authorized personnel only). All SRF contents will be maintained on site for a minimum of two (2) years after the conclusion of the study or two (2) years after FDA marketing approval. After that, the original files may be archived to a secure location that ensures that the files are available within 24 hours as required by regulatory authorities.

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 regulated by FDA and/or applicable review committees.

3. ROLES AND RESPONSIBILITIES

The Sponsor and all participating CSS investigators are responsible for ensuring that complete and accurate regulatory documents are collected and maintained throughout the course of a clinical investigation.

The Sponsor is responsible for verifying that all CSS files are complete, accurate, and securely maintained by the participating investigators.

The Sponsor is responsible for terminating the participation of, and discontinuing shipments of investigational product to, any participating CSS investigator who has failed to maintain, or make available, required records or reports of the study, as required by applicable regulations.

The responsibility to conduct any or all of these activities may be delegated at the discretion of the Sponsor to the NeuroNEXT CCC and/or DCC, or to their subcontractors. Those individuals and entities take on the responsibility for meeting regulatory requirements on behalf of the Sponsor, but the Sponsor has the ultimate responsibility and must therefore, supervise those delegated activities effectively.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.57	Recordkeeping and Record Retention
21 CFR 312.62	Investigator Recordkeeping and Record Retention
21 CFR 312.68	Inspection of Investigator's Records and Reports
ICH E6, 2.10, 2.11	The Principles of ICH GCP
ICH E6, 4.9	Records and Reports
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 SS 401	Site Selection and Qualification
NN SS 402	Roles and Responsibilities of Site PIs
NN SS 403	Initiation Visit and Site Training
NN SS 404	Routine Monitoring Visits
NN SS 405	Study Closeout Visit
NN SS 406	Suspension or Early Termination of a Study or a Clinical Site

6. ATTACHMENTS AND REFERENCES

NN RA 203-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
CFR	Code of Federal Regulations
CSS	Clinical Study Site
DCC	Data Coordinating Center at The University of Iowa
FDA	U.S. Food and Drug Administration
GCP	Good Clinical Practice
ICH	International Conference on Harmonisation
PPI	Protocol Principal Investigator
SRF	Site Regulatory File

8. SPECIFIC PROCEDURES

A. Creating the SRF

#	*Who*	*Task*	*Attachment/ References*	*Related SOP*
1.	CSS	Establish the SRF as appropriate after project approval is secured and site qualification is completed.		NN SS 401
2.	CSS	Organize project and site regulatory files.		NN SS 402
3.	Sponsor / CCC or DCC designee	Review with the CSS investigator and other key personnel the requirements and procedures to create and maintain the site's regulatory file through the duration of the study and after its completion.[1]		NN SS 403

Note:
[1]During the initiation visit, review site's study file.

B. Maintaining the SRF

#	*Who*	*Task*	*Attachment/ References*	*Related SOP*
1.	CSS	Periodically review file contents to ensure they are being kept up to date.		NN SS 402
2.	Sponsor / CCC or DCC designee	Examine study files at sites during routine monitoring visits.		NN SS 404
3.	Sponsor / CCC or DCC designee	Report gaps, missing items, and discrepancies to CSS investigator.		NN SS 404
4.	Sponsor / CCC or DCC designee	Report records retention noncompliance to the Sponsor.		NN SS 404
5.	Sponsor / CCC or DCC designee	At the study closeout visit, confirm that all required documents and records are in the site's regulatory file.		NN SS 405 NN SS 406
6.	Sponsor / CCC or DCC designee	Arrange for archive storage when appropriate, after written approval from Sponsor.		

Attachment NN RA 203 - A. Document History

NeuroNEXT Network Standard Operating Procedure (SOP) Site Regulatory File Maintenance SOP NN RA 203				
Version	**Description of Modification**	**Reason or Justification for Modification**	**Issue Date**	**Effective Date**
1.0	New	N/A	22Mar2012	21Apr2012
2.0	Minor correction to replace ‘data’ with ‘regulatory documents’ in Section 3, and edits to SOP listing.	Updates for version 2.0	21Sep2016	21Oct2016