

NeuroNEXT Network

Standard Operating Procedure (SOP)


Trial Master File Maintenance

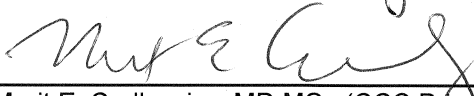
Version 1.0

SOP NN RA 202

Originators: NeuroNEXT CCC and DCC Personnel

Reviewed and Approved by:


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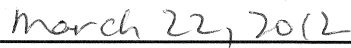

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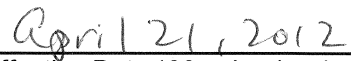

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Issue Date


Effective Date (30 calendar days after the Issue Date)

NN RA 202
NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR
TRIAL MASTER FILE MAINTENANCE

SOP: NN RA 202 Version No.: 1.0 Effective Date:	TRIAL MASTER FILE MAINTENANCE	Supersedes Document: N/A Effective Date: N/A
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1. POLICY

The NeuroNEXT Protocol Principal Investigator (PPI), acting as the regulatory Sponsor of a study, shall maintain an organized, easily accessible, and complete Trial Master File (TMF) as required by regulation. The TMF shall be available for audits, whether internal or by a third party, and for FDA inspection.

The TMF shall be stored in a secure manner (under lock and key, accessed by authorized personnel only). All TMF 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.

These procedures define the organization of the TMF for the overall project, as well as each individual Clinical Study Site (CSS) and the retention policies for these documents and records.

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 and non-NeuroNEXT Clinical Study Site (CSS) 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 Clinical Study Sites (CSS) investigators are responsible for ensuring that complete and accurate data are collected, documented, 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 CSS 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 312.58	Inspection of Sponsor'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	Records Access
ICH E6, 8.0	Essential Documents for the Conduct of a Clinical Trial

5. REFERENCES TO OTHER APPLICABLE SOPS

NN RA 201:	Regulatory Authority Submissions and FDA Contact
NN RA 203:	Site Regulatory File Maintenance
NN SS 401:	Site Selection and Qualification
NN SS 404:	Routine Monitoring Visits
NN SS 406:	Study Close Out Visits

6. ATTACHMENTS AND REFERENCES

NN RA 202-A	Document History
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7. TERMS AND ABBREVIATIONS

The following terms and abbreviations are used in this document:

CCC	Clinical Coordinating Center at Massachusetts General Hospital
CSS	Clinical Study Site
DCC	Data Coordinating Center at The University of Iowa
FDA	US Food and Drug Administration
GCP	Good Clinical Practice
ICH	International Conference on Harmonisation
PPI	Protocol Principal Investigator
TMF	Trial Master File

8. SPECIFIC PROCEDURES

A. Creating the TMF

#	Who	Task	Attachment/ References	Related SOP
1.	Sponsor / CCC or DCC designee	Establish the TMF as appropriate after project funding and/or regulatory approval is secured (as needed) and site qualification is completed. ¹		NN RA 201 SS NN 401
2.	Sponsor / CCC or DCC designee	Organize project and site regulatory files. ¹		NN RA 203
3.	Sponsor / CCC or DCC designee	Arrange for secure storage of all study-related files.		
4.	Sponsor / CCC or DCC designee	Identify personnel with authorized access to the TMF.		

Note:

¹As an investigative site is qualified, establish a separate Site Regulatory File for each participating site.

²During the initiation visit, establish a site's regulatory file.

B. Maintaining the TMF

#	Who	Task	Attachment/ References	Related SOP
1.	Sponsor / CCC or DCC designee	Periodically review TMF contents to ensure they are being kept up to date.		NN SS 404
2.	Sponsor / CCC or DCC designee	Add to the TMF as documents and records become available.		
3.	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 406 NN RA 203
4.	Sponsor / CCC or DCC designee	Arrange for archive storage of TMF and site regulatory files when appropriate.		NN RA 203