

NeuroNEXT Network

Standard Operating Procedure (SOP)


Quality Assurance Audits


Version 2.0

SOP NN QA 801

Originators: NeuroNEXT CCC and DCC Personnel

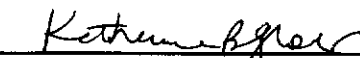
Reviewed and Approved by:


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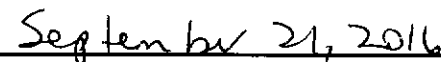

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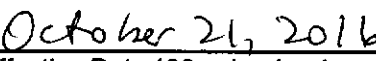

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Issue Date


Effective Date (30 calendar days after the Issue Date)

NN QA 801

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR QUALITY ASSURANCE AUDITS

SOP: NN QA 801 Version No. 2.0 Effective Date: 21Oct2016	QUALITY ASSURANCE AUDITS	Supercedes Document: Version 1.0 Effective Date: 06May2012
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1. POLICY

The Data Coordinating Center (DCC) and/or the Clinical Coordinating Center (CCC) may arrange for periodic audits of ongoing and completed research for the NeuroNEXT Network at Clinical Study Sites (CSS), as required per protocol. These audits may be conducted by the Sponsor, by an external auditor hired by the Sponsor, or by the DCC and/or CCC on behalf of the Sponsor per contract. The DCC and, when applicable, the CCC will act on findings of concern with immediate corrective actions, as well as long-range process improvements.

Audits of CSS will not be performed by personnel responsible for conducting site monitoring visits. Auditors may use procedures outlined in NeuroNEXT SOPs or other mutually agreed-upon procedures, working papers, or tools provided by the auditor to conduct and document the audit.

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 CCC and 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

As required by a NeuroNEXT protocol, the Sponsor, the DCC, and/or the CCC may conduct audit-related activities that include, but are not limited to, the following:

- Determining if audits of the CSS are needed, according to the protocol and in conjunction with the PPI and/or Sponsor
- Identifying a trained and qualified auditor to conduct the program audit; this individual may be either a DCC or CCC employee, or an outside contractor
- Ensuring that the auditor is informed of the requirements for the audit, and his/her responsibilities in performing the audit
- Providing access to all relevant documentation necessary for carrying out a thorough audit, as determined by the PPI and/or Sponsor, DCC and CCC Leadership, as well as the DCC QM Team Lead
- Ensuring that audits are scheduled and completed if appropriate funding is available
- Fully cooperating with QA audits by any authorized third party
- Developing and implementing Corrective Action and Preventative Action (CAPA) plans for any issues identified by an auditor.

As required by a NeuroNEXT protocol, a CSS auditor may be responsible for audit activities that include, but are not limited to, the following:

- Preparing for a CSS audit (as applicable)
- Conducting the audit according to applicable NeuroNEXT SOPs and regulatory requirements

- Reviewing preliminary audit observations with the PPI and the DCC and CCC Leadership
- Documenting observations in an audit report
- Submitting the final audit report to the PPI and/or Sponsor, the DCC PI, the CCC PI, and other applicable entities that may be designated by the DCC PI and the CCC PI.

As required by a NeuroNEXT protocol, the DCC and/or CCC may be responsible for maintaining audit reports, and for maintaining a list of audit dates (to present to an FDA inspector).

The DCC and CCC are responsible for developing and maintaining CAPA plans for any issues that are identified during a CSS audit.

The Study Team is responsible for following up on all corrective actions to ensure resolution.

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

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.54	General Responsibilities of Sponsors
ICH E6, 2.13	The Principles of ICH GCP
ICH E6, 5.1	Quality Assurance and Quality Control
ICH E6, 5.19	Audit
ICH E6, 5.20	Noncompliance
FDA	Compliance Policy Guide 7151.02

5. REFERENCES TO OTHER APPLICABLE SOPS

NN GA 105	Vendor Selection and Agreements
NN RA 202	Trial Master File Maintenance
NN RA 203	Site Regulatory Binder Maintenance
NN SS 402	Site Initiation Visits and Site Training
NN SS 403	Routine Monitoring
NN SS 404	Site Performance Monitoring
NN SS 406	Suspension or Early Termination of a Study or a Clinical Site
NN QA 802	Quality Management

6. ATTACHMENTS AND REFERENCES

NN QA 801 – A	Document History
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7. TERMS AND ABBREVIATIONS

The following terms and abbreviations are used in this document:

CAPA	Corrective and Preventive Action
CCC	Clinical Coordinating Center at Massachusetts General Hospital
Clinical Study Site (CSS)	Clinical site that conducts research for a NeuroNEXT protocol
DCC	Data Coordinating Center at The University of Iowa
FDA	US Food and Drug Administration

PPI	Protocol Principal Investigator
RMF	Regulatory Master File
QA	Quality Assurance
QM	Quality Management

8. SPECIFIC PROCEDURES

A. Auditing a Clinical Study Site (CSS)

#	Who	Task	Attachment/ Reference	Related SOP
1.	Study Team	If it is determined that a CSS audit is necessary, confirm that funding is available prior to scheduling the audit.		
2.	Sponsor	Select an in-house auditor, an external auditor, or delegate responsibility to the CCC and/or DCC per contract to conduct the audit on behalf of the Sponsor.		
3.	CCC and DCC	Work with the auditor and the clinical site to schedule the audit.		
4.	Study Team	If an external auditor is used, and as applicable to the firm, review the firm's SOPs, audit report process, and/or a Scope of Work document to ensure that they are adequate. Alternatively, require the auditor to follow the NeuroNEXT SOP for conducting investigative site audits.		NN GA 105 NN SS 403
5.	DCC / CCC Personnel	Instruct the auditor to meet with the investigator (and staff) to review the purpose and scope of the audit and sign a site monitoring log to document the visit.		
6.	DCC / CCC Personnel	After the audit is complete, request that the auditor provide a report and a completed checklist to the CCC and DCC, and review any significant findings and applicable evidence with the DCC/CCC Leadership and/or other appropriate staff.		
7.	CCC	File the reviewed and approved checklist in the RMF, if applicable.		NN RA 202
8.	Study Team	After reviewing the audit results, determine and document follow-up actions (e.g. no action indicated, data disqualification, study site termination).		NN SS 404 NN SS 406

Attachment NN QA 801 - A. Document History

NeuroNEXT Network Standard Operating Procedure (SOP) Quality Assurance Audits SOP NN QA 801				
Version	Description of Modification	Reason or Justification for Modification	Issue Date	Effective Date
1.0	New	N/A	06Apr2012	06May2012
2.0	Removed procedures for internal audits and references to Project Work Instructions (PWIs). Revised and condensed Roles and Responsibilities section. Clarified that CSS audits may be conducted by the Sponsor, by an external auditor, or by the DCC and/or CCC at the request of the Sponsor per contract. Clarified that the CCC and DCC are responsible for developing and maintaining CAPA plans for any issues that are discovered during audits of CSS, and that the Study Team is responsible for following up on corrective actions to ensure resolution. Condensed and revised the procedures for CSS audits.	Updates for Version 2.0	21Sep2016	21Oct2016