NeuroNEXT Network

Standard Operating Procedure (SOP)

Data Collection and Data Handling

Version 2.0

SOP NN DM 1005

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NN DM 1005

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR DATA COLLECTION AND DATA HANDLING

SOP: NN DM 1005 Version No.: 2.0 Effective Date: 21Oct2016	DATA COLLECTION AND DATA HANDLING	Supercedes Document: Version 1.0 Effective Date: 29Apr2012

1. POLICY

This SOP provides guidance for NeuroNEXT Data Coordinating Center (DCC) staff regarding proper procedures for electronic data collection and electronic data handling to ensure confidence in the reliability, quality, and integrity of electronic data.

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 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 RESPONSIBILITY

The DCC is responsible for adhering to the procedures outlined in this SOP, and for ensuring that procedures are adhered to by individuals requesting data from the DCC.

4. APPLICABLE REGULATIONS AND GUIDELINES

ICH E6	Good Clinical Practice: Consolidated Guidance, April 1996
21 CFR Part 11	Electronic Records; Electronic Signatures
FDA Guidance	Part 11, Electronic Records; Electronic Signatures – Scope and Application, FDA, August 2003
FDA Guidance	Computerized Systems Used in Clinical Investigations, FDA, May 2007
FDA Guidance	Computerized Systems Used in Clinical Trials, FDA, April 1999
FDA Guidance	General Principles of Software Validation; Final Guidance for Industry and FDA Staff, January 2002
NIH	HIPAA Privacy Rule: Information for Researchers <http://privacyruleandresearch.nih.gov/>

5. REFERENCES TO OTHER APPLICABLE SOPS

NN SS 402	Site Initiation Visits and Site Training
NN SS 403	Routine Monitoring Visits
NN SS 405	Study Close Out Visits
NN PM 503	Study Materials Development
NN PM 504	Investigational Site Staff Training
NN CS 702	Application Development and Validation

NN CS 704	System Security Measures and Website Access
NN CS 705	Data Backup, Recovery, and Contingency Plans
NN CS 706	Retention and Protection of Electronic Records
NN BIO 904	Generation and Validation of Analysis Data Sets
NN DM 1001	Clinical Data Management
NN DM 1002	Data Management Plan Development
NN DM 1003	Case Report Form Development
NN DM 1004	Specifications Development, Testing Plans, and Validation Documentation
NN DM 1006	Adverse Event Coding

6. ATTACHMENTS AND REFERENCES

NN DM 1005 – A	Document History
NN DM 1005 – B	Data Change Request Form Template

7. TERMS AND ABBREVIATIONS

The following terms and abbreviations are used in this document:

CCC	Clinical Coordinating Center at Massachusetts General Hospital
Clinical Study Site (CSS)	Clinical site that conducts research for a NeuroNEXT protocol within or outside the Network
DCC	Data Coordinating Center at The University of Iowa
DM	Data Management Team at the DCC
IT	Information Technology Team at the DCC
Protocol Principal Investigator (PPI)	Principal Investigator of a NeuroNEXT protocol

8. SPECIFIC PROCEDURES

A. Data System Validation and Security

#	*Who*	*Task*	*Attachment/ Reference*	*Related SOP*
1.	DCC DM and IT	Conduct verification testing and validation to help ensure and document that the electronic data capture system is validated for its intended use.		NN CS 702 NN DM 1001 NN DM 1003 NN DM 1004
2.	DCC IT	Ensure that the electronic data system is secured with restricted access.		NN CS 704
3.	DCC IT	Ensure that the electronic data system is appropriately backed-up and/or replicated.		NN CS 705

B. Electronic Data Collection

#	*Who*	*Task*	*Attachment/ Reference*	*Related SOP*
1.	Study Team	Ensure that the clinical protocol, User Guides, and/or Manuals of Operation describe in detail all methods that are to be used for collecting, evaluating, changing, and submitting study data to the DCC.		
2.	DCC DM, IT, Study Team	Ensure that the same fundamental elements of data quality (attributable, legible, contemporaneous, original, and accurate) that are expected of paper records are incorporated into the electronic data system.		NN DM 1001 NN DM 1003 NN DM 1004
3.	DCC DM, IT, Study Team	Identify valid values or ranges, data types, skip-out relationships, and mandatory requirements that are to be checked by automated page validation systems.		NN CS 702
4.	DCC DM, IT, Study Team	Ensure that appropriate logic checks are programmed into the data entry system to help prevent entry of discrepant data.		NN CS 702
5.	DCC DM and Study Monitors	Ensure the accuracy and completeness of the electronic data collected.		
6.	DCC DM and Biostatisticians	Generate reports to identify missing data and to help ensure timely data entry.		
7.	DCC DM and Protocol Coordinators	Train individuals at the DCC and CSS (if applicable) in proper data collection and handling procedures via in-person or webinar training sessions, and document the training.		
8.	DCC DM and Protocol Coordinators	Instruct trainees in proper procedures for entering and/or changing data (if authorized to do so), navigating the study website, and utilizing all applicable modules related to data entry (e.g. Query System).		NN SS 402 NN PM 504 NN DM 1001
9.	DCC DM and Protocol Coordinators	Assign appropriate user roles after training has been completed and documented.		
10.	DCC IT, DM, and Protocol Coordination	Maintain a listing of the individuals who are authorized to enter and/or change data.		NN CS 704

C. Electronic Signatures and User Access

#	*Who*	*Task*	*Attachment/ Reference*	*Related SOP*
1.	DCC Leadership	Certify to the regulatory agency (FDA) that the electronic signatures in the DCC data systems are the legally binding equivalents of traditional handwritten signatures (as required by 21 CFR 11.100(c)). Submit certification (as set forth in 21 CFR 11.100) in paper form signed with a traditional handwritten signature to the Office of Regional Operations	21 CFR Part 11	NN CS 704

#	Who	Task	Attachment/ Reference	Related SOP
		(HFC-100), 5600 Fishers Lane, Rockville, Maryland 20857. Submit certification prior to the use of electronic signatures, or at the time that the use of electronic signatures is initiated. A single certification may cover all electronic signatures used by persons in a given organization.		
2.	DCC IT and Protocol Coordination	Instruct Users that they may only use their own passwords for gaining entry to the data system. Instruct Users that they may not share passwords with others. Instruct Users that they may not log on to the data system in order to provide access to other persons.		NN SS 402 NN PM 504 NN CS 704 NN DM 1001
3.		Instruct Users to log off of the data system when they leave their workstation. Create an automatic log off or other protection for periods of system inactivity to prevent unauthorized data entry.		NN SS 402 NN PM 504 NN CS 704 NN DM 1001

D. Query System

#	Who	Task	Attachment/ Reference	Related SOP
1.	DCC DM	Maintain Query System Specifications, and update as needed.		NN DM 1004
2.	DCC IT, DM and/or Protocol Coordination	Make the module available to authorized users for resolving post submission data inconsistencies. Provide training to the Users.		NN SS 402 NN PM 504 NN CS 704 NN DM 1001
3.	DCC DM, IT, and Protocol Coordination	Create a listing (specifications) of desired error checks (i.e. inter-form and intra-form logic checks).		NN DM 1003 NN DM 1004
4.	DCC DM and/or Protocol Coordination	Modifications to Query System error checks (e.g. additions, deletions, changes) will be documented, and implementation will be managed through FogBugz® cases and procedures.		NN DM 1004
5.		Initiate error checks through the Query System on a regular basis according to the requirements for a study. Release error checks to clinical study sites as needed for resolution.		

E. Manage eCRF Status

#	Who	Task	Attachment/ Reference	Related SOP
1.	DCC DM	Maintain Manage eCRF Status specifications.		NN DM 1004

#	Who	Task	Attachment/ Reference	Related SOP
2.	DCC IT and/or Protocol Coordination	Make this module available to authorized Users in order to manage the status of individual eCRFs and/or to mark entire visits as unobtainable. Provide training to the Users.		NN SS 402 NN PM 504 NN CS 704 NN DM 1001
3.	DCC DM	Indicate in the specifications the possible statuses available for each form (i.e. Not started, Incomplete, Complete, Unobtainable, Deleted) based on the role of the User.		NN DM 1001

F. DCC Centralized Data Entry

#	Who	Task	Attachment/ Reference	Related SOP
1.	DCC and CSS	CSS responsibilities and procedures regarding forms sent to the DCC for data entry will be described in the Manuals of Operations (or similar) for the protocols.		NN PM 503
2.	DCC	DCC responsibilities and procedures regarding centralized data entry at the DCC will be described in the study Data Management Plan or similar protocol manual or document.		
3.	DCC Protocol Coordination	All paper forms received at the DCC for data entry will be date-stamped and logged.		
4.	DCC Protocol Coordination	Perform a QC check of all data against the source documentation		
5.		Completion of data entry (first and/or second data entry) will be logged.		
6.		Second data entry of data for a form, if applicable, may not be completed by the person who entered the first set of data.		
7.		Data items that do not match after first and second entry will be compared, discrepancies will be resolved, and the corrected answer will be chosen.		
8.		The paper forms received by the DCC for data entry are subject to the same retention requirements as are all other data for the protocol.		

G. Electronic Data Transfer

#	Who	Task	Attachment/ Reference	Related SOP
1.	DCC IT, DM	When a study requires that the DCC receive or send electronic data from an outside source, collaborate with the appropriate entity to develop a Data Transfer Agreement. This document specifies how and when the data will be transferred, the expected data format, and the expected filename.		

#	Who	Task	Attachment/ Reference	Related SOP
2.	DCC IT, DM	As part of the Data Transfer Agreement, or in a separate study document, obtain a Data Dictionary that provides a description of the specific data fields that are to be included in the data transfer.		
3.	DCC IT, DM	It is preferable to retrieve data through a secure file transfer protocol (FTP) site or another secure site. Depending on the requirements described in the Data Transfer Agreement, other methods may be used.		
4.	DCC	Archive the data file to the DCC file server.		
5.		Import the data into the appropriate database.		
6.	DCC Protocol Coordination and/or DM	If applicable to a study, maintain a log (e.g. Excel spreadsheet) to track whether expected data have been received, and were received within the required timeframe.		
7.	DCC DM, Protocol Coordination, or Biostatistics	As appropriate to a study, generate and review reports to ensure that all expected data have been received and/or accounted for in the database.		
8.	DCC DM, Protocol Coordination, or Biostatistics	As appropriate to a study, generate and review reports to check the transferred data for discrepancies and for extreme values (if applicable).		

H. Data Change Requests

#	Who	Task	Attachment/ Reference	Related SOP
1.	DCC	If, at any time, a request to change subject data is made by a clinical site, and it is NOT possible to make this change via post-complete change, Query System, or another electronic/automatic system, a Data Change Request form is required.	NN DM 1004-B	
2.		A Data Change Request form for the applicable study is completed, verified by the site, and sent to the DCC.		
3.	DCC DM	The form is reviewed for completeness, logic, and for potential protocol deviations. The database is reviewed to confirm that the change has not already been made, and that it cannot be made through any other mechanism.		
4.		If a study uses paper CRFs as source documents, a copy of the corrected, applicable paper form must accompany the data change request (when possible).		
5.		All Data Change Request forms (and corrected paper forms, if applicable) are stored at the DCC by protocol, center, and subject.		

Attachment NN DM 1005 - A. Document History

NeuroNEXT Network Standard Operating Procedure (SOP) Data Collection and Data Handling SOP NN DM 1005				
Version	**Description of Modification**	**Reason or Justification for Modification**	**Issue Date**	**Effective Date**
1.0	New	N/A	30Mar2012	29Apr2012
2.0	Updated procedures for electronic data system validation and security, electronic data collection, Query System, manage eCRF status, and DCC centralized data entry, and data change requests. Completely revised section 8.G for electronic data transfers to align with current procedures.	Updates for v2.0	21Sep2016	21Oct2016