NeuroNEXT Network

Standard Operating Procedure (SOP)
Retention and Protection of Electronic Records
Version 2.0
SOP NN CS 706

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NN CS 706

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR RETENTION AND PROTECTION OF ELECTRONIC RECORDS

SOP: NN CS 706 Version No. 2.0 Effective Date: 21Oct2016	RETENTION AND PROTECTION OF ELECTRONIC RECORDS	Supercedes Document: Version 1.0 Effective Date: 29Apr2012

1. POLICY

The purpose of this SOP is to provide guidelines to the NeuroNEXT Data Coordinating Center (DCC) Information Technology (IT) Team regarding the retention of electronic records after completion of a NeuroNEXT study. Electronic record retention applies to records that have been stored electronically in a secure location to prevent modifications.

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. This SOP is in alignment with Information Technology policies set forth by Information Technology Services at The University of Iowa and the UI College of Public Health Office of Information Technology (UI CPH IT).

3. ROLES AND RESPONSIBILITIES

The NeuroNEXT DCC IT Team is responsible for adhering to the procedures outlined in this SOP, and for ensuring that these procedures are adhered to by other DCC staff or authorized individuals at The University of Iowa who may participate in the protection, retention, or authorized destruction of electronic data or records for NeuroNEXT studies.

4. APPLICABLE REGULATIONS AND GUIDELINES

ICH E6 5.5	Trial Management, Data Handling, Recordkeeping, and Independent Data Monitoring Committee
21 CFR Part 11	Electronic Records; Electronic Signatures
21 CFR 312.57	Recordkeeping and Record Retention
21 CFR 312.62	Investigator Recordkeeping and Record Retention
21 CFR 812.140	Records and Reports
FDA	Guidance for Industry: Part 11, Electronic Records; Electronic Signatures – Scope and Application, FDA, August 2003
FDA	Guidance for Industry: Computerized Systems Used in Clinical Investigations, FDA, May 2007
FDA	Guidance for Industry: Computerized Systems Used in Clinical Trials, April 1999
FDA	Guidance for Industry: Electronic Source Data in Clinical Investigations, September 2013
NIH	HIPAA Privacy Rule: Information for Researchers <http://privacyruleandresearch.nih.gov/>

5. REFERENCES TO OTHER APPLICABLE SOPS

NN SS 405	Study Close-out Visits
NN CS 704	System Security Measures and Website Access

6. ATTACHMENTS AND REFERENCES

NN CS 706 – 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
CPH IT	College of Public Health Office of Information Technology
DCC	Data Coordinating Center at The University of Iowa
FDA	US Food and Drug Administration
UI	The University of Iowa

8. SPECIFIC PROCEDURES

After the completion of a study, the DCC is responsible for archiving study-related data for a specified amount of time as designated by the Sponsor, the FDA, or as required by the study protocol. These policies will be developed in collaboration with the NeuroNEXT Network. Archived data are stored in a secured location to prevent unauthorized access or changes to study data. Electronic records are retained and are accessible for as long as the records retention schedule mandates. Data are stored in a format that allows the data to be retrieved and used at a later time. If it becomes required, by the Sponsor or through internal review, that archived data be retained in a new medium, the DCC will convert all archived data to the new format and confirm that data were not modified in the conversion process.

At the end of the specified retention period, electronic records that contain identifiable information must be disposed of or destroyed using methods that protect confidentiality.

- Data storage media, including CDs and DVDs, will be physically destroyed. Reformatting, deleting, or erasing files stored on disks does not ensure complete destruction of the information. The DCC does not consider these methods to be acceptable for the destruction of data storage media containing identifiable information.
- Hard drives containing identifiable information will be demagnetized and/or physically destroyed so that the information is unrecoverable from the medium.

A. Electronic Records Retention

#	*Who*	*Task*	*Attachment/ Reference*	*Related SOP*
1.	Sponsor or designee	Determine the length of time electronic records must be retained according to sponsor policy, protocol, institutional policy, or FDA regulations.		NN SS 405

#	Who	Task	Attachment/ Reference	Related SOP
2.	DCC IT	Archive electronic data records in a secure location to prevent modification. Control access to archived data to ensure that only authorized individuals can access archived electronic data.		NN CS 704
3.	DCC IT	Periodically review the media used to store archived electronic data records to ensure that data can be retrieved utilizing current technology.		
4.	DCC IT	When technology changes, convert archived electronic data records to the new standard and verify that the conversion has been complete and valid.		
5.	Study Team	Inform the investigator(s)/institution(s) of the need for record retention, and notify the investigator(s)/institution(s) when the trial-related records are no longer needed.		
6.	Clinical Investigators	Retain records that serve as electronic source data (i.e. completed and signed eCRF or certified copy of the eCRF) for the specified period.	FDA Guidance for Industry: Electronic Source Data in Clinical Investigations	

B. Final Disposition

#	Who	Task	Attachment/ Reference	Related SOP
1.	DCC, Study Team, and/or CCC (if applicable)	If applicable, verify with the Sponsor in writing that the DCC is no longer required to maintain study data before any media containing study data are destroyed.		
2.	DCC IT	At the end of the retention period, physically destroy all data storage media for trial-related records, including CDs and DVDs.		
3.	DCC IT	Demagnetize or physically destroy all hard drives used to store electronic data records.		

Attachment NN CS 706 - A. Document History

NeuroNEXT Network Standard Operating Procedure (SOP) Retention and Protection of Electronic Records SOP NN CS 706				
Version	**Description of Modification**	**Reason or Justification for Modification**	**Issue Date**	**Effective Date**
1.0	New	N/A	30Mar2012	29Apr2012
2.0	Updated to include references to The University of Iowa College of Public Health Office of Information Technology (UI CPH IT) and additional applicable regulations and guidelines. Incorporated recent modifications to DCC SOPs, including clarifications of specific procedures for retention of records that serve as electronic source data and the final disposition of study data.	Updated for version 2.0	21Sep2016	21Oct2016