

# NeuroNEXT Network

## Standard Operating Procedure (SOP) Retention and Protection of Electronic Records Version 4.0 SOP NN CS 706

Originators: NeuroNEXT CCC and DCC Personnel

Reviewed and Approved by:

<b>Signature and Date:</b> <i>Christopher S. Coffey</i> <small>Electronically signed by: Christopher S. Coffey Reason: I approve this document Date: Feb 23, 2024 13:36 CST</small> 23-Feb-2024	
<b>Name and Title:</b> Christopher S. Coffey, PhD (DCC Principal Investigator)	
<b>Signature and Date:</b> <i>Merit Cudkowicz</i> <small>Electronically signed by: Merit Cudkowicz Reason: I approve this document Date: Feb 22, 2024 17:12 CST</small> 22-Feb-2024	
<b>Name and Title:</b> Merit E. Cudkowicz, MD MSc (CCC Principal Investigator)	
<b>Signature and Date:</b> <i>Marianne Chase</i> <small>Electronically signed by: Marianne Chase Reason: I approve this document Date: Feb 22, 2024 14:46 EST</small> 22-Feb-2024	
<b>Name and Title:</b> Marianne Chase, BA (CCC Senior Director of Clinical Trials Operations)	

## NN CS 706

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

SOP: CS 706 Version No.: 4.0 Issue Date: 01Mar2024 Effective Date: 15Apr2024	Retention and Protection of Electronic Records	Supersedes Document Version : 3.0 Effective Date : 08Apr2023
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**Signature and Date:***Dixie Ecklund*

Electronically signed by: Dixie Ecklund  
Reason: I approve this document  
Date: Feb 23, 2024 17:15 CST

23-Feb-2024

**Name and Title:** Dixie J. Ecklund, RN MSN MBA (DCC Associate Director)**Signature and Date:***Stacey Grabert*

Electronically signed by: Stacey Grabert  
Reason: I approve this document  
Date: Feb 22, 2024 15:14 EST

22-Feb-2024

**Name and Title:** Stacey Grabert, Pharm.D, MS, (CCC Director of Quality Assurance)**Signature and Date:***Joan Ohayon*

Electronically signed by: Joan Ohayon  
Reason: I approve this document  
Date: Mar 11, 2024 09:04 EDT

11-Mar-2024

**Name and Title:** Joan Ohayon, RN, MSN, CRNP, MSCN (NINDS, NeuroNEXT Program Official)

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

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### 1. POLICY

The purpose of this SOP is to provide guidelines to the NeuroNEXT Data Coordinating Center (DCC) Information Technology (IT) Team and UI College of Public Health Office of Information Technology (CPH IT) 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 2016 Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2). 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 (August 2003)
FDA	Guidance for Industry: Computerized Systems Used in Clinical Investigations (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

### 5. REFERENCES TO OTHER APPLICABLE SOPS

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

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## 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

	<i><b>Who</b></i>	<i><b>Task</b></i>	<i><b>Attachment/ Reference</b></i>	<i><b>Related SOP</b></i>
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

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	<i>Who</i>	<i>Task</i>	<i>Attachment/ Reference</i>	<i>Related SOP</i>
2.	DCC IT and CPH 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 and CPH 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 and CPH 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

#	<i>Who</i>	<i>Task</i>	<i>Attachment/ Reference</i>	<i>Related SOP</i>
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.		

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#### 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	Reviewer(s)
1.0	New	N/A	30Mar2012	29Apr2012	N/A
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	/A

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3.0	Updated "1996 ICH E6 Consolidated Guidance" to "2016 Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)". Updated signature block to accommodate for electronic signatures. Additional minor updates throughout.	Updates for version 3.0	22Feb2023	08Apr2023	Catherine Gladden
4.0	Minor edits for clarity	Periodic review	01Mar2024	15Apr2024	Preeti Paul








# NN CS 706 Retention Protection Electronic Records v4.0 clean

Final Audit Report

2024-03-11

Created:	2024-02-22
By:	Tania Leeder (tleeder@mgb.org)
Status:	Signed
Transaction ID:	CBJCHBCAABAAgqRvnOBqQBqUI9Ln-0R6pLkJXIkI4SS4
Number of Documents:	1
Document page count:	7
Number of supporting files:	0
Supporting files page count:	0

## "NN CS 706 Retention Protection Electronic Records v4.0 clean" History

-  Document created by Tania Leeder (tleeder@mgb.org)  
2024-02-22 - 7:37:49 PM GMT
-  Document emailed to christopher-coffey@uiowa.edu for signature  
2024-02-22 - 7:41:56 PM GMT
-  Document emailed to cudkowicz.merit@mgh.harvard.edu for signature  
2024-02-22 - 7:41:56 PM GMT
-  Document emailed to Marianne Chase (mchase@mgh.harvard.edu) for signature  
2024-02-22 - 7:41:56 PM GMT
-  Document emailed to dixie-ecklund@uiowa.edu for signature  
2024-02-22 - 7:41:56 PM GMT
-  Document emailed to Stacey Grabert (SGrabert@mgh.harvard.edu) for signature  
2024-02-22 - 7:41:56 PM GMT
-  Document emailed to ohayonj@ninds.nih.gov for signature  
2024-02-22 - 7:41:57 PM GMT



✓ Marianne Chase (mchase@mgh.harvard.edu) authenticated with Adobe Acrobat Sign.

Challenge: The user opened the agreement.

2024-02-22 - 7:46:05 PM GMT

📄 Document e-signed by Marianne Chase (mchase@mgh.harvard.edu)

Signing reason: I approve this document

Signature Date: 2024-02-22 - 7:46:18 PM GMT - Time Source: server

📧 Email viewed by christopher-coffey@uiowa.edu

2024-02-22 - 7:55:48 PM GMT

✓ Stacey Grabert (SGrabert@mgh.harvard.edu) authenticated with Adobe Acrobat Sign.

Challenge: The user opened the agreement.

2024-02-22 - 8:14:27 PM GMT

📄 Document e-signed by Stacey Grabert (SGrabert@mgh.harvard.edu)

Signing reason: I approve this document

Signature Date: 2024-02-22 - 8:14:43 PM GMT - Time Source: server

📧 Email viewed by cudkowicz.merit@mgh.harvard.edu

2024-02-22 - 11:11:48 PM GMT

✓ cudkowicz.merit@mgh.harvard.edu authenticated with Adobe Acrobat Sign.

Challenge: The user opened the agreement.

2024-02-22 - 11:12:03 PM GMT

📄 Signer cudkowicz.merit@mgh.harvard.edu entered name at signing as Merit Cudkowicz

2024-02-22 - 11:12:14 PM GMT

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📧 Tania Leeder (tleeder@mgb.org) added alternate signer cscoffey@iowa.uiowa.edu. The original signer christopher-coffey@uiowa.edu can still sign.

2024-02-23 - 7:10:54 PM GMT

📧 Document emailed to cscoffey@iowa.uiowa.edu for signature

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📧 Tania Leeder (tleeder@mgb.org) added alternate signer ecklundd@uiowa.edu. The original signer dixie-ecklund@uiowa.edu can still sign.

2024-02-23 - 7:11:11 PM GMT

📧 Document emailed to ecklundd@uiowa.edu for signature

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2024-02-23 - 7:36:24 PM GMT

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2024-02-23 - 7:36:38 PM GMT


 Signer cscoffey@iowa.uiowa.edu entered name at signing as Christopher S. Coffey

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Signing reason: I approve this document

Signature Date: 2024-02-23 - 7:36:58 PM GMT - Time Source: server

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2024-02-23 - 11:14:12 PM GMT

 ecklundd@uiowa.edu authenticated with Adobe Acrobat Sign.

Challenge: The user opened the agreement.

2024-02-23 - 11:15:19 PM GMT


 Signer ecklundd@uiowa.edu entered name at signing as Dixie Ecklund

2024-02-23 - 11:15:35 PM GMT

 Document e-signed by Dixie Ecklund (ecklundd@uiowa.edu)

Signing reason: I approve this document

Signature Date: 2024-02-23 - 11:15:38 PM GMT - Time Source: server

 Email viewed by ohayonj@ninds.nih.gov

2024-03-11 - 1:03:28 PM GMT- IP address: 104.47.64.254


 ohayonj@ninds.nih.gov authenticated with Adobe Acrobat Sign.

Challenge: The user opened the agreement.

2024-03-11 - 1:03:44 PM GMT

 Signer ohayonj@ninds.nih.gov entered name at signing as Joan Ohayon

2024-03-11 - 1:04:08 PM GMT- IP address: 72.83.187.43

 Document e-signed by Joan Ohayon (ohayonj@ninds.nih.gov)

Signing reason: I approve this document

Signature Date: 2024-03-11 - 1:04:10 PM GMT - Time Source: server- IP address: 72.83.187.43

 Agreement completed.

2024-03-11 - 1:04:10 PM GMT