NeuroNEXT Network

Standard Operating Procedure (SOP)

Study Closeout

Version 2.0

SOP NN PM 507

Originators: NeuroNEXT CCC and DCC Personnel

Reviewed and Approved by

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NN PM 507

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR STUDY CLOSEOUT

1. POLICY

This SOP describes site-level and study-level activities that are conducted by the NeuroNEXT Data Coordinating Center (DCC) and Clinical Coordinating Center (CCC), in collaboration with clinical study sites (CSS), during the final closeout of a study. Some of these activities are performed concurrently, and the timeframe for study closeout may vary somewhat depending on the study.

Resource requirements for study closeout are considered during the study development phase and many activities that are performed during study closeout (e.g. CSS monitoring, data cleaning, and tracking data completeness) are also ongoing throughout the study. Active planning for study closeout generally begins with the close of enrollment, but planning may begin earlier depending on the nature of the study. Study Team members will collaborate to develop a timeline for closeout activities and to define the roles and responsibilities of team members in the closeout process. As the study progresses, closeout activities will be added to the agendas for Study Team meetings.

Activities associated with study closeout visits to CSS, some of which may be conducted by or in collaboration with the CCC, are described in SOP NN SS 405 *Study Closeout Visits*. If the study or participation of a CSS is being terminated early, follow additional applicable procedures described in SOP NN SS 406 *Suspension or Early Termination of a Study or a Clinical Site*.

The CCC leads activities related to close-out of the Trial Master File and close-out of the Site Regulatory Files at CSS.

The DCC leads activities associated with data cleaning and tracking data completeness. These activities continue until the final study data are locked and ready for analysis. Final study data include data that were submitted to the study database through the electronic data capture (EDC) system and any data that were transferred electronically to the DCC from external vendors (e.g. imaging centers or central laboratories, if applicable to a study).

Reports, trackers, and other tools are developed and reviewed for each study to track progress of study closeout. Detailed checklists may be developed for each study that contain required site- and study-level closeout procedures for data and other study activities.

General closeout activities that are performed at the site and study levels as the study nears completion are described below.

Site-level Closeout

Site-level closeout refers to a period in which activities are performed by the NeuroNEXT DCC and the CCC in conjunction with individual CSS to ensure that the participating sites are ready for study-level closeout.

During this period, the DCC and/or the CCC or Study Team (as applicable) conducts closeout monitoring visits according to the study monitoring plan and SOP NN SS 405, reviews site-level reports and tools to track study closeout progress, resolution of data discrepancies, and data completeness, and ensures that all data are accounted for and any necessary data corrections are complete. After it is verified that the data for a CSS are ready for final study data lock, data entry rights for the site are removed, and no further changes to study data by CSS personnel are permitted.

The CCC leads the review of the Site Regulatory Files that have been uploaded to the Regulatory Document Storage area of the NeuroNEXT study-specific website (or other electronic TMF management system, if appropriate) and verifies with the CSS that all required regulatory documents have been collected, are up-to-date, and have been uploaded to the correct location. The CCC also works with each CSS, as needed, to verify that the regulatory files are accurate and complete.

For additional information and specific procedures related to closeout of study files, data, and regulatory documents at CSS, refer to SOP NN SS 405.

The following activities must be completed for each participating CSS before final study closeout:

- preparing for and conducting onsite or remote study closeout visit(s), and submitting a study closeout monitoring report to the CSS PI, the PPI/Sponsor, and the CCC and/or DCC (if applicable);

- verifying the contents of the Site Regulatory Files, subject binders, and other study files at the CSS and submitting a regulatory closeout report to the CSS PI, the PPI/Sponsor, and the DCC and/or the CCC (if applicable);
- verifying the disposition of the investigational product/device, study supplies and equipment, and laboratory specimens (as applicable);
- collecting the monitoring log, and laboratory specimen tracking and/or investigational product accountability logs (as applicable);
- tracking issues or data discrepancies that are described in the closeout monitoring report(s) until resolved;
- verifying that all data queries are resolved and all data corrections are complete;
- deactivating data entry rights and Query System access at CSS after all closeout procedures are complete and assigning 'View Only' access to applicable site personnel;
- collecting documentation of CSS PI signoff on study data from CSS;
- performing reconciliation of invoices and final payments to the CSS;
- closing out the CSS as a performance site with the SIRB.

Study-level Closeout

Study-level closeout refers to a period in which the NeuroNEXT DCC and/or the CCC or Study Team (as applicable) review(s) study-level reports and tools to track study closeout progress, resolution of data discrepancies, and data and regulatory document completeness across sites. The DCC leads efforts to verify that all data queries and discrepancies have been resolved and confirms that the study database is ready to be locked. After the study database is locked, no further changes to study data are permitted.

After the database has been locked, DCC Biostatisticians perform a final data freeze, create analysis data sets, and conduct statistical analyses as described in the study Statistical Analysis Plan (SAP).

Applicable DCC teams collaborate with the PPI/Sponsor and the Study Team or other NeuroNEXT personnel (as needed) to ensure that study data are appropriately de-identified and ready to be shared.

Study-level closeout activities conducted by the DCC and/or CCC, in collaboration with CSS or external vendors (as applicable), may include:

- developing a timeline for study closeout activities, and defining the roles and responsibilities of Study Team members;
- notifying the Study Team, CSS personnel, the PPI/Sponsor, applicable Committees or review Boards (e.g. Protocol Steering Committee [PSC], NeuroNEXT Data and Safety Monitoring Board [DSMB], study Safety Review Committee), and other applicable personnel (e.g. study Safety Monitor) that study closeout procedures are beginning;
- coordinating closeout activities with the PPI/Sponsor and any third-party vendors for the study (if applicable);
- performing activities associated with closeout of the Trial Master File and fulfilling regulatory requirements, in conjunction with the PPI/Sponsor (as applicable);
- reviewing study-level reports and trackers to ensure that all data closeout activities are complete across all participating CSS;
- verifying that any data that have been sent from external vendors (e.g. imaging or central laboratory data) have been successfully uploaded and reconciled (if applicable to a study);
- locking the study database;
- generating and validating analysis data sets;
- performing, documenting, and validating statistical analyses;
- preparing a final study report; and
- preparing and de-identifying study data for sharing.

Please refer to Section 8 of this SOP for additional details and the general sequence of events that occur during the data closeout period.

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 Data Coordinating Center (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

The NeuroNEXT DCC and/or CCC, in collaboration with the Study Team and vendors (as applicable), are responsible for:

- conducting a closeout visit at a CSS after the last subject has completed the study and all data entry has been completed;
- working with CSS (as applicable) to perform all activities related to cleaning and close-out of study data, locking the study database, and conducting statistical analyses according to the study SAP;
- working with CSS to perform all activities related to close-out of the regulatory files (Trial Master File and Site Regulatory Files) and close-out of the study with the Single Institutional Review Board (SIRB);
- monitoring the progress of study closeout activities by creating and reviewing reports and trackers;
- working with the PPI/Sponsor (if applicable), the Study Team, and the CSS as needed to complete site-level and study-level study closeout procedures described in this SOP.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.56	Review of Ongoing Investigations
21 CFR 312.59	Disposition of Unused Supply of Investigational Drug
21 CFR 312.60	General Responsibilities of Investigators
21 CFR 312.62	Investigator Recordkeeping and Record Retention
21 CFR 312.64	Investigator Reports
21 CFR 312.68	Inspection of Investigator's Records and Reports
ICH E6, 4.12	Premature Termination or Suspension of a Trial
ICH E6, 4.13	Final Reports by Investigator
ICH E6, 5.18	Monitoring
ICH E6, 5.20	Noncompliance
ICH E6, 5.21	Premature Termination of a Trial
ICH E6, 5.22	Clinical Trial/Study Reports

5. REFERENCES TO OTHER APPLICABLE SOPS

NN GA 105	Vendor Selection and Agreements
NN GA 107	Data Sharing
NN GA 109	Sharing Data with Industry Collaborators
NN RA 201	Regulatory Authority Submissions and FDA Contact
NN RA 202	Trial Master File Maintenance
NN RA 203	Site Regulatory File Maintenance

NN RA 206	Medical Monitoring and Safety Monitoring
NN SS 401	Site Selection and Qualification
NN SS 402	Site Initiation Visits and Site Training
NN SS 403	Routine Monitoring Visits
NN SS 405	Study Closeout Visits
NN SS 406	Suspension or Early Termination of a Study or a Clinical Site
NN PM 501	Communication
NN PM 505	Investigational Product Management
NN SM 602	Central Institutional Review Board Reporting
NN CS 704	System Security Measures and Website Access
NN CS 706	Retention and Protection of Electronic Records
NN QA 801	Quality Assurance Audits
NN BIO 904	Generation and Validation of Analysis Data Sets
NN BIO 905	Validating Statistical Programs and Deliverables
NN BIO 906	Presenting Statistical Results for a Final Study Report
NN DM 1001	Clinical Data Management
NN DM 1005	Data Collection and Data Handling

6. ATTACHMENTS AND REFERENCES

NN PM 507 – A	Document History

7. TERMS AND ABBREVIATIONS

The following terms and abbreviations are used in this document:

AE	Adverse Events
CCC	Clinical Coordinating Center at Massachusetts General Hospital
CRF	Case Report Forms that are completed for each study subject at the sites
CSS	Clinical Study Site
DCC	Data Coordinating Center at The University of Iowa
DSMB	Data and Safety Monitoring Board
eCRF	Electronic Case Report Form
EDC	Electronic Data Capture
FDA	U.S. Food and Drug Administration
ICH	International Council for Harmonisation
IRB	Institutional Review Board
PPI	Protocol Principal Investigator
PSC	Protocol Steering Committee
SAP	Statistical Analysis Plan
SIRB	Single Institutional Review Board
TMF	Trial Master File (Regulatory Master File)

8. SPECIFIC PROCEDURES

The specific procedures described in this section are organized by closeout activity, and may represent a combination of site-level and study-level tasks. Additional acronyms used in this section: BIO – DCC Biostatistics team; DM – DCC Data Management team; IT – DCC Information Technology team; PC – DCC Protocol Coordination team; PM – CCC Project Management team; QM – Quality Management team.

A. Communications and Project Management (Study Level)

#	*Who*	*Task*	*Attachment*	*Related SOP*
1.	DCC PC and CCC PM	Inform the Study Team, the CSS, the PPI/Sponsor, applicable Committees or review Boards (e.g. PSC, NeuroNEXT DSMB, study Safety Review Committee), and other applicable personnel (e.g. study Safety Monitor) that the study closeout process is beginning, and provide updates as needed or requested.		NN RA 206 NN PM 501
2.	Study Team	Develop a timeline for study closeout activities and define the roles and responsibilities of Study Team members in the closeout process.		
3.	Study Team	Continue to perform all ongoing data cleaning and quality checks and generate relevant reports throughout the study closeout process and resolve any discrepancies.		
4.	Study Team	Determine the contents of specialized reports (e.g. Study Closeout Report) that are used to track study closeout activities and the frequency of distribution.		
5.	Study Team	Determine which Study Team members will be reviewing all reports that track study closeout activities and who will follow up on unresolved items.		
6.	Study Team	If study participants are to carry over to an extension or ancillary study, develop a plan for transfer of subject information (if applicable) and for separate collection and handling of data and regulatory documents for the new study.		NN RA 202 NN RA 203 NN CS 704 NN DM 1005
7.	Study Team	In the case of early termination of the study (e.g. for unreasonable risks posed by the investigation) or a CSS (e.g. for insufficient enrollment, protocol deviations or other non-compliance, or by request of the site), or by order of the PPI/Sponsor, FDA, the SIRB, or upon recommendation of the NeuroNEXT DSMB, follow procedures described in SOP NN SS 406.		NN SS 406

B. Regulatory Closeout

#	*Who*	*Task*	*Attachment*	*Related SOP*
1.	CCC PM or designee	Review for completeness and accuracy all regulatory documents that have been uploaded		NN SS 405

#	Who	Task	Attachment	Related SOP
		to the Regulatory Document Storage area on the NeuroNEXT Network website, including: • essential clinical study documents; • site-specific certifications and investigator documentation.		
2.	CCC PM or designee	Confirm that all activities are completed for final closeout of the study with the SIRB.		NN RA 602

C. Study Closeout Visit and Final Data Corrections (Site Level)

#	Who	Task	Attachment	Related SOP
1.	DCC PC and/or CCC PM, or designee	Follow up on any issues or missing data that were discovered during the study closeout visit until all are resolved.		NN SS 403 NN SS 405
2.	DCC PC and/or CCC PM, or designee	If a CSS does not complete data corrections or resolve issues after repeated attempts by the DCC and/or CCC (if applicable) to follow up, inform study leadership and escalate the process to involve the PPI/Sponsor or others as needed to complete the closeout for the site.		
3.	DCC PC and/or CCC PM, or designee	Verify that all outstanding corrections to the site data have been implemented through a post-complete change or a Data Change Request to the DCC.		NN SS 405 NN DM 1005
4.	DCC PC or designee	Verify that all Data Change Request forms are signed and filed according to study requirements.		NN DM 1005
5.	DCC PC or designee	Communicate final resolutions of data corrections to the CSS.		
6.	DCC PC or designee	Collect documentation of CSS PI signoff on study data for all applicable CSS, if applicable.		NN SS 405

D. Review of CSS Data (Site Level)

#	*Who*	*Task*	*Attachment*	*Related SOP*
1.	DCC PC, BIO, DM, IT	Review reports and perform data quality and completeness checks. 1. Run database queries and data entry edit checks to verify that all are resolved. 2. Run a program to check that all dates within a visit preceded the date of the subsequent visit, and verify that any discrepancies are resolved. 3. Run a program that checks for possible duplicate eCRFs within and across visits, and verify that any discrepancies are resolved. 4. Run all reports related to study closeout to verify that study data are complete and no outstanding data corrections are needed.		NN DM 1005
2.	DCC PC, BIO, DM, IT	If any new or unresolved data issues are discovered, continue to re-run database queries, data entry edit checks, programs, and reports until all issues have been resolved.		NN DM 1005
3.	Study Team	Review trackers related to study closeout to verify that site data are ready to be locked.		
4.	DCC PC or designee	Inform the DCC IT Lead and the Study Team that site data entry rights are ready to be removed.		NN PM 501

E. Deactivating Data Entry Rights at a CSS (Site Level)

#	*Who*	*Task*	*Attachment*	*Related SOP*
1.	DCC IT	After all necessary data corrections have been made: 1. Remove data entry rights for CSS personnel. 2. Assign 'View Only' rights to applicable personnel at the CSS. 3. Disable the ability of the CSS to use the Query System.		NN CS 704
2.	DCC IT	Inform the Study Team that the site data are locked from further changes by the CSS and are ready for study-level closeout.		NN PM 501

F. Data Transfers (Study Level)

#	*Who*	*Task*	*Attachment*	*Related SOP*
1.	DCC PC, BIO, DM, IT	If applicable to a study, verify that all expected imaging and/or central laboratory data described in the Data Transfer Agreement(s) were: • received; • successfully uploaded; • checked for missing data, discrepancies, and extreme values; and • reconciled and resolved of any issues.		
2.	DCC PC, BIO, DM, IT	Confirm that the final, complete data set was received from the PI and/or the vendor(s).		

G. Locking the Study Database (Study Level)

#	*Who*	*Task*	*Attachment*	*Related SOP*
1.	DCC PC and IT	Inform the Study Team of the impending database lock.		NN PM 501
2.	DCC DM	Run queries, data entry checks, programs, and reports across all participating CSS to verify that there are no further data discrepancies to be addressed.		
3.	DCC PC and Study Team	Review study-level reports, trackers, queries, and data entry edit checks to verify that study closeout activities are complete across all participating CSS.		
4.	DCC PC, DM, BIO, IT	If any new or unresolved data issues are discovered, continue to re-run database queries, data entry edit checks, programs, and reports until all issues have been resolved.		
5.	DCC PC or designee	When all study closeout activities are complete, inform DCC IT, DM, and BIO that the study database is ready to be locked.		
6.	DCC IT and DM	Verify that data entry rights for all CSS have been removed, ‘View Only’ status has been assigned for applicable personnel, and Query System access for the sites has been disabled.		
7.	DCC IT and DM	Ensure that the study data are locked from any further changes.		
8.	DCC IT and DM	Inform DCC BIO that the final study database has been locked.		NN BIO 904

H. Statistical Analyses and Reporting Results (Study Level)

#	*Who*	*Task*	*Attachment*	*Related SOP*
1.	DCC BIO	If required for a study, perform a freeze on a subset of cleaned study data for the purpose of generating a preliminary study report.		NN BIO 906
2.	DCC BIO	After all study data have been cleaned, perform a final data freeze on a copy of the locked final database.		NN BIO 904
3.	DCC PC and BIO	Generate and submit the final safety report to the Safety Monitor for the study.		NN RA 206
4.	DCC BIO	Generate final analysis data sets that are to be used in statistical analyses that have been described in the SAP for the study.		NN BIO 904
5.	DCC BIO	Develop, document, and validate statistical programs for analyses that have been described in the SAP for the study.		NN BIO 905
6.	DCC BIO	Present statistical results from the study in a final study report.		NN BIO 906

I. Data Sharing (Study Level)

#	*Who*	*Task*	*Attachment*	*Related SOP*
1.	Study Team	Refer to SOPs NN GA 107 *Data Sharing* and NN GA 109 *Sharing Data with Industry Partners* for procedures related to sharing final study data with study investigators and the scientific community and sharing de-identified data sets for public use.		NN GA 107 NN GA 109
2.	Study Team	Review and follow PPI/Sponsor requirements and guidance documents for data sharing.		
3.	Study Team	Within 12 months of LPLV, prepare final results for PPI submission to ClinicalTrials.gov.		
4.	Study Team	Determine the timeframe for the submission of data to the PPI/Sponsor and/or a repository.		
5.	DCC	De-identify raw study data and statistical analysis data sets in accordance with HIPAA requirements.		
6.	DCC	Verify that all potentially identifiable information has been removed or de-identified prior to sharing study data.		NN GA 107 NN GA 109
7.	DCC DM	Generate annotated Case Report Forms (CRFs) for sharing.		
8.	DCC BIO, DM, QM	Assemble and submit the required deliverables to the appropriate entities.		NN GA 107 NN GA 109

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DIXIE ECKLUND dixie-ecklund@uiowa.edu Security Level: Email, Account Authentication (Required), Login with SSO	 Signature Adoption: Drawn on Device Signature ID: 7006AF62-2EFC-40B6-A067-A08EC02591B6 Using IP Address: 128.255.112.230 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 2/15/2023 8:38:11 AM Viewed: 2/15/2023 2:53:38 PM Signed: 2/15/2023 2:57:47 PM
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Marianne Chase MCHASE@mgh.harvard.edu Sr Director, Clinical Trial Operations Insight OBO The Massachusetts General Hospital Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: 58FE690F-6BCA-4F23-90E3-DA15BCE3F578 Using IP Address: 73.114.253.109 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 2/15/2023 8:38:11 AM Viewed: 2/15/2023 8:40:10 PM Signed: 2/15/2023 8:41:02 PM
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Merit Cudkowicz cudkowicz.merit@mgh.harvard.edu Chief of Neurology Security Level: Email, Account Authentication (Required), Logged in	 DocuSigned by Merit Cudkowicz I approve this document 17-Feb-2023 | 9:37:27 AM EST 9F8FE4180E504C6AB0A67B835E80C644 Signature Adoption: Pre-selected Style Signature ID: 9F8FE418-0E50-4C6A-B0A6-7B835E80C644 Using IP Address: 68.239.56.73 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 2/15/2023 8:38:12 AM Viewed: 2/17/2023 9:37:17 AM Signed: 2/17/2023 9:37:30 AM
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Intermediary Delivery Events	Status	Timestamp

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Carbon Copy Events	Status	Timestamp

Witness Events	Signature	Timestamp

Notary Events	Signature	Timestamp

Envelope Summary Events	Status	Timestamps
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Certified Delivered	Security Checked	2/22/2023 11:20:50 AM
Signing Complete	Security Checked	2/22/2023 11:21:03 AM
Completed	Security Checked	2/22/2023 11:21:03 AM

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