NeuroNEXT Network

Standard Operating Procedure (SOP)

Study Closeout Visits

Version 4.0

SOP NN SS 405

Originators: NeuroNEXT CCC and DCC Personnel

Reviewed and Approved by:

Signature and Date: Christopher S. Coffey *Electronically signed by: Christopher S. Coffey* *Reason: I approve this document* *Date: Mar 8, 2024 08:23 CST* 08-Mar-2024
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SOP: NN SS 405 Version No: 4.0 Issue Date: 01Mar2024 Effective Date: 15Apr2024	STUDY CLOSEOUT VISITS	Supersedes Document Version : 3.0 Effective Date : 08Apr2023

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Dixie Ecklund

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

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1. POLICY

The study closeout visit is intended to bring the study to a close at a NeuroNEXT clinical study site (CSS). The closeout visit is conducted according to the study monitoring plan and is scheduled after all obtainable visits for study participants at the CSS have been completed and all data have been entered.

The term “study closeout visit” applies to all types of study closeout visits (on-site, regulatory only, remote) and all activities (pre-visit, during the visit, and post-visit) that are conducted by the NeuroNEXT Data Coordinating Center (DCC) and/or the Clinical Coordinating Center (CCC) until the study has been closed out at a CSS and with the Single Institutional Review Board (SIRB) and local site IRBs, as applicable.

Closeout visit activities that are conducted by the CCC and/or the DCC include, but are not limited to:

- reviewing the contents of the Trial Master File, the Site Regulatory Binder, and CSS study files;
- verifying that required regulatory documents and study records are on file, organized, and stored in a secure location;
- verifying that all protocol deviations have been resolved and corrective actions have been implemented;
- reviewing regulatory requirements regarding records retention and SIRB reporting requirements with the investigator;
- reviewing remaining un-monitored clinical data and resolving remaining data issues (e.g. data queries);
- confirming the final disposition of the investigational product/device, if applicable, and any other ancillary items used for the study;
- confirming that all participants laboratory specimens have been forwarded to the appropriate location;
- generating final closeout visit reports, following up on all observations until they are resolved, and transmitting copies of the completed reports to the CSS, the CCC or DCC (as applicable), and the PPI/Sponsor;
- verifying that all monitoring requirements set forth in the study monitoring plan have been completed;
- determining, at the request of the PPI/Sponsor, that the investigator’s obligations have been met and that all applicable study and regulatory requirements have been fulfilled.

The CCC may conduct a remote closeout of regulatory documents via email, teleconference or video conference. Depending on the study, a remote closeout of sites with limited enrollment or no unmonitored data since the last monitoring visit may be conducted by the DCC.

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 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

The NeuroNEXT DCC and the CCC are responsible for conducting closeout visit activities with participating CSS according to the study monitoring plan. Closeout activities may take place after the last participant at a CSS has completed the study and all data entry has been completed.

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

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 Report(s) by Investigator
ICH E6, 5.18	Monitoring
ICH E6, 5.20	Noncompliance
ICH E6, 5.21	Premature Termination or Suspension of a Trial (Sponsor)
ICH E6, 5.22	Clinical Trial/Study Reports

5. REFERENCES TO OTHER APPLICABLE SOPS

NN GA 104	Conflict of Interest and Financial Disclosure Requirements for Clinical Study Sites
NN GA 107	Data Sharing
NN GA 109	Sharing Data with Industry Collaborators
NN RA 201	Regulatory Authority Submissions and Contact
NN RA 202	Trial Master File Maintenance and Auditing
NN RA 203	Site Regulatory File Maintenance
NN RA 205	Adverse Events: Sponsor Responsibilities
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 404	Site Performance Monitoring
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 PM 507	Study Closeout
NN SM 602	Single Institutional Review Board Reporting
NN SM 603	Participant Eligibility and Enrollment
NN DM 1005	Data Collection and Data Handling

6. ATTACHMENTS AND REFERENCES

NN SS 405 - 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 participant at the
sites CSS	Clinical Study Site
CSS PI	Clinical Study Site Principal Investigator
DCC	Data Coordinating Center at The University of Iowa
FDA	U.S. Food and Drug Administration
ICH	International Council for Harmonisation
IRB	Institutional Review Board
PPI	Protocol Principal Investigator
PSC	Protocol Steering Committee
TMF	Trial Master File
SIRB	Single Institutional Review Board

8. SPECIFIC PROCEDURES

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.

A. Preparing for Study Closeout Visits

#	*Who*	*Task*	*Attachment*	*Related SOP*
1.	Study Team	Develop a closeout visit plan that includes steps necessary to complete study closure at all participating CSS, including a timeline.		
2.	DCC PC and/or CCC PM, or designee	Verify that all participant visits and follow-up visits at the CSS are complete.		

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#	*Who*	*Task*	*Attachment*	*Related SOP*
3.	CCC PM, DCC PC, and PPI/Sponsor	Determine whether an onsite or remote closeout of regulatory documents will be conducted at a CSS.		
4.	CCC PM and/or DCC PC, or designee	Review the relevant contents of the project and site files in the TMF, if applicable, prior to the closeout visit or teleconference/video conference. Note that for sites that did not enroll any participants, closeout activities may be conducted via email without teleconference/video conference.		
5.	CCC PM	Review a final report of all regulatory documents that have been uploaded to the study website/TMF for reconciliation.		
6.	DCC PC, CCC PM and PPI/Sponsor	Determine whether an onsite or remote closeout of site files and study data will be conducted at a CSS.		NN SS 403
7.	DCC PC or designee	Review closeout visit monitoring requirements in the study monitoring plan.		NN SS 403
8.	DCC PC, DM, BIO; CCC PM	Determine reports/data listings that are needed for the closeout visit.		NN SS 403
9.	DCC PC or designee	Review previous monitoring reports to assess the scope of study documentation that must be available for review.		NN SS 403
10.	DCC PC or designee	If applicable, review data report and data queries for unmonitored data that are expected per the study monitoring plan since the time of the last monitoring visit.		NN SS 403 NN DM 1005
11.	Study Team	Review data completeness reports to track missing data and incomplete forms until all are accounted for.		
12.	DCC PC and/or CCC PM, or designee	Verify that data entry for the site is complete.		
13.	DCC IT and PC or designee	Track and verify that all Data Change Requests are complete.		NN DM 1005
14.	DCC PC and/or CCC PM, or designee	Verify that all outstanding AEs and SAEs have been resolved according to the requirements described in the safety monitoring plan for the study.		NN RA 206 NN SM 602

#	*Who*	*Task*	*Attachment*	*Related SOP*
15.	CCC PM and/or DCC PC, or designee	Verify that all protocol deviations have been resolved and corrective action plans have been accepted by the PPI/Sponsor or designee (if applicable to a study).		
16.	DCC PC and/or CCC PM, or designee	Contact the CSS PI and the CSS Coordinator to arrange onsite or remote closeout visit(s) within a specified time period after the last participant's participation has concluded (if applicable).		NN PM 501
17.	DCC PC and/or CCC PM, or designee	For remote closeout visits, provide instructions to the CSS for teleconferencing or video conferencing (if necessary).		
18.	DCC PC and/or CCC PM, or designee	Confirm date and logistics of the closeout visit(s) with the CSS PI and the CSS Coordinator in writing.		NN PM 501
19.	DCC PC or designee	Inform the Study Team of the closeout visit date(s).		
20.	DCC PC and/or CCC PM, or designee	Remote closeout will be considered for CSS with limited enrollment or with limited data to be reviewed. If closeout at a CSS is to be conducted remotely by central review, contact the site and request that copies of completed paper CRFs and source documentation for all participants be uploaded to a secure platform for the DCC to review according to the provisions in the study monitoring plan.		NN PM 507
21.	DCC PC and/or CCC PM, or designee	Review the paper CRFs against data listings to ensure that data have been entered correctly, and that there are no missing data.		NN PM 507

B. Conducting a Study Closeout Visit

(For specific procedures related to closeout of regulatory documents, see Section 8.C)

#	*Who*	*Task*	*Attachment*	*Related SOP*
1.	DCC PC and/or CCC PM, or designee	If a CSS has unmonitored data, conduct applicable tasks listed in NN SS 403 *Routine Monitoring Visits*.		NN SS 403
2.	DCC PC and/or CCC PM, or designee	Resolve any outstanding data corrections or issues with missing or incomplete CRFs.		NN PM 507 NN DM 1005

#	*Who*	*Task*	*Attachment*	*Related SOP*
3.	DCC PC and/or CCC PM, or designee	Review the site's source documentation to ensure that it is current and complete.		NN RA 203
4.	DCC PC and/or CCC PM, or designee	If applicable, reconcile and collect all original investigational product accountability records.		NN PM 505
5.	DCC PC and/or CCC PM, or designee	If applicable, make copies of all investigational product accountability records for the study files at the CSS.		NN PM 505
6.	DCC PC and/or CCC PM, or designee	Verify the disposition of the investigational product/device.		NN PM 505
7.	CCC PM and/or DCC PC, or designee	Verify the disposition of study equipment, laboratory kits, and other study supplies (as applicable).		NN PM 505
8.	DCC PC and/or CCC PM, or designee	Verify that any laboratory specimens that remain at the CSS are handled or forwarded to the appropriate location according to the requirements of the study protocol and the informed consent document(s) signed by the study participants.		
9.	DCC PC and/or CCC PM, or designee	Conduct a closeout visit meeting with the CSS PI, CSS Study Coordinator, and any other applicable personnel.		
10.	DCC PC and/or CCC PM, or designee	Discuss with the investigator the requirements for maintaining clinical study documentation in a secure location after study completion for the period of time specified by FDA and/or the PPI/Sponsor.		NN RA 202 NN RA 203 NN CS 706 NN DM 1005
11.	DCC PC and/or CCC PM, or designee	Verify that the Delegation of Responsibility log has been updated with an end date for all personnel who were involved with study activities that will no longer occur.		NN RA 202 NN RA 203
12.	DCC PC and/or CCC PM, or designee	Obtain contact information for an individual at the site who may be contacted with questions if necessary after study closeout.		NN PM 501

#	*Who*	*Task*	*Attachment*	*Related SOP*
13.	DCC PC and/or CCC PM, or designee	Verify that all monitoring requirements described in the study monitoring plan have been completed.		NN SS 403
14.	DCC PC and/or CCC PM, or designee	Document the study closeout visit, and collect the final monitoring log, if conducted on site.		NN SS 402 NN SS 403

C. Conducting a Regulatory Document Closeout Visit

#	*Who*	*Task*	*Attachment*	*Related SOP*
1.	CCC PM and/or DCC PC, or designee	Review the contents of the Site Regulatory Binder with the CSS Coordinator and other CSS personnel, if applicable.		
2.	CCC PM and/or DCC PC, or designee	Confirm the long-term storage location(s) for the regulatory documents with the CSS.		NN RA 203
3.	CCC PM and/or DCC PC, or designee	Verify that the Delegation of Responsibility log has been updated with an end date for all applicable personnel.		NN RA 202 NN RA 203
4.	CCC PM and/or DCC PC, or designee	Verify that the site has completed all required regulatory activities.		
5.	CCC PM and/or DCC PC, or designee	Send a post-review report to the CSS PI, the CSS Coordinator, the PPI/Sponsor, and the DCC. The report details all required corrections to study regulatory documents and identifies any missing documents that must be obtained prior to study closeout.		

D. Post-visit Activities and Study Closeout Visit Report(s)

#	*Who*	*Task*	*Attachment*	*Related SOP*
1.	DCC PC and/or CCC PM, or designee	Instruct the CSS to transmit any required regulatory documents that were identified at the closeout visit to the CCC (as needed).		NN RA 202 NN RA 203 NN PM 501

#	*Who*	*Task*	*Attachment*	*Related SOP*
2.	DCC PC and/or CCC PM, or designee	Complete study closeout report(s) for regulatory documents and site file/study data (as applicable), and transmit the report(s) to the CSS PI, the PPI/Sponsor, and the CCC or DCC (as applicable). • These reports summarize findings from the monitoring visit(s) and include instructions for study records retention. If applicable, include a list of clinical site responsibilities and deliverables prior to study closeout.		NN SS 403
3.	DCC PC and/or CCC PM, or designee	Follow up on any issues discovered during the study closeout visit(s) and detailed in the study closeout visit report(s) until all are resolved.		NN SS 403 NN PM 507
4.	DCC PC	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 PM 507 NN DM 1005
5.	DCC PC and/or CCC PM, or designee	Confirm that the CSS PI and/or the responsible leader of the Study Team at each CSS has reviewed and signed off on all study data that have been submitted for all participants at the close of the study.		NN GA 107 NN GA 109 NN DM 1005
6.	CCC PM and/or DCC PC, or designee	Make the final determination that the investigator's obligations have been met and that all study and regulatory requirements have been fulfilled.		
7.	CCC PM or designee	Verify that the clinical site has updated the Delegation of Responsibility log to reflect the official date of SIRB closure as the end date for all active study personnel, request a copy for the CCC, and file the copy with the site regulatory documents.		
8.	CCC PM and SIRB Liaison	Complete closeout procedures with the SIRB.		
9.	DCC PC and/or CCC PM, or designee	Provide the study PPI/Sponsor with the final monitoring visit report(s).		
10.	CCC PM or designee	File the study closeout visit report(s) with the regulatory documents.		
11.	Study Team	Review and follow procedures described in SOP NN PM 507 *Study Closeout*.		NN PM 507

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Attachment NN SS 405 - A. Document History

NeuroNEXT Network Standard Operating Procedure (SOP) Study Closeout Visits SOP NN SS 405					
Version	**Description of Modification**	**Reason or Justification for Modification**	**Issue Date**	**Effective Date**	**Reviewer**
1.0	New	N/A	06Apr2012	06May2012	N/A
2.0	This SOP was extensively revised, and material pertaining to suspension or early termination of a study or a clinical site was relocated to a new NeuroNEXT SOP. Study closeout visits include all types of visits and activities that are conducted by the CCC and DCC to close out the study. The specific procedures section was modified and expanded to reflect procedures that are conducted before, during, and following study closeout visits, and includes procedures for conducting closeout of regulatory documents.	Updates for v2.0	21Sep2016	21Oct2016	N/A
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 v3.0	22Feb2023	08Apr2023	Catherine Gladden

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4.0	Minor formatting changes and updates throughout	Periodic Review	01Mar2024	15Apr2024	Preeti Paul

NN SS 405 Study Closeout Visits v4.0 clean

Final Audit Report 2024-03-11

Created:	2024-02-22
By:	Tania Leeder (tleeder@mgb.org)
Status:	Signed
Transaction ID:	CBJCHBCAABAAcyOKovHqqUyN3tT7nk9Gru1G5i-iaO_R
Number of Documents:	1
Document page count:	12
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Supporting files page count:	0

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Document emailed to christopher-coffey@uiowa.edu for signature
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2024-03-11 - 3:22:58 PM GMT

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Signature Date: 2024-03-11 - 3:23:13 PM GMT - Time Source: server- IP address: 72.83.187.43

Agreement completed.

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