NeuroNEXT Network

Standard Operating Procedure (SOP)

Suspension or Early Termination of a Study or a Clinical Site

Version 2.0

SOP NN SS 406

Originators: NeuroNEXT CCC and DCC Personnel

Reviewed and Approved by:

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NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR SUSPENSION OR EARLY TERMINATION OF A STUDY OR A CLINICAL SITE

1. POLICY

This SOP describes policies and procedures for the suspension or early termination of a study or a clinical study site (CSS) that may be necessary under scenarios that include, but are not limited to, the following:

- enrollment at a CSS has not met expectations, and the Data Coordinating Center (DCC) (in consultation with the Protocol Principal Investigator [PPI], the Clinical Coordinating Center [CCC], and/or the NeuroNEXT Protocol Steering Committee [PSC], as applicable) has determined that participation of the CSS in the study should be terminated;
- protocol violations have occurred that may result in study subjects being put at risk of serious injury or that render the study data untrustworthy or invalid;
- monitoring at the CSS has shown continuing or other unacceptable noncompliance (violations) with the protocol, and the DCC (in consultation with the PPI, the CCC, and the NeuroNEXT PSC) has determined that the CSS must be terminated from participation;
- unreasonable risks posed by the investigation (e.g., serious adverse events) that warrant study termination have become evident;
- by order of the Sponsor, FDA, the single Institutional Review Board (SIRB), the local IRB (if applicable), or upon recommendations from the NeuroNEXT Data and Safety Monitoring Board (DSMB); or
- by request of the CSS.

For any early termination of study participation at a CSS, subject enrollment is discontinued at the terminated CSS, but enrolled study subjects will typically complete their specified follow-up visits, depending upon the reason(s) for termination.

For cases in which termination is due to protocol violations that may result in study subjects being put at risk or that may render the study data untrustworthy or invalid, the CSS investigator must cease enrolling subjects immediately and report the termination of the study (and reasons) to the SIRB via the CCC, the local IRB, and other appropriate regulatory authorities.

A study closeout visit will be conducted at a terminated CSS according to procedures described in SOP NN SS 405 *Study Closeout Visits*. The closeout visit will not occur until all obtainable enrollment and follow-up visits for study subjects at the terminated CSS have been completed. Closeout of study data for that CSS will be implemented according to procedures described in SOP NN PM 507 *Study Closeout*.

In the event that the entire study is terminated early based on recommendations from the NeuroNEXT DSMB or directives from the FDA, the SIRB, or the Sponsor, the procedures described in this SOP and study closeout procedures described in SOPs NN SS 405 and NN PM 507 will be implemented at all CSS.

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 Study Team is responsible for following procedures described in this SOP, including:

- monitoring study enrollment at CSS, and identifying sites that are lagging in enrollment;

- ascertaining and implementing measures to improve enrollment at lagging CSS;
- determining if significant protocol violations are occurring that justify terminating participation of a CSS for serious or ongoing noncompliance;
- escalating any significant findings to the Site Support Team in compliance with the NeuroNEXT Site Intervention and Escalation Plan;
- conducting study closeout visits per SOP NN SS 405 at a CSS that has been terminated from further participation in the study, or at all CSS if the study has been terminated early.

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 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 RA 201	Regulatory Authority Submissions and FDA Contact
NN RA 202	Trial Master File Maintenance
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 405	Study Closeout Visits
NN PM 501	Communication
NN PM 505	Investigational Product Management
NN PM 507	Study Closeout
NN RA 602	Single Institutional Review Board Reporting
NN CS 704	System Security Measures and Website Access
NN CS 706	Retention and Protection of Electronic Records

NN DM 1001	Clinical Data Management
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 subject at the CSS
CSS	Clinical Study Site
DCC	Data Coordinating Center at The University of Iowa
DSMB	Data and Safety Monitoring Board
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
RMF	Regulatory Master File
SIRB	Single Institutional Review Board

8. SPECIFIC PROCEDURES

Additional acronyms used in this section: DM – Data Management team; IT – Information Technology team; PC – Protocol Coordination team; PM – Project Management team.

A. Early Termination of a CSS for Inadequate Enrollment

#	*Who*	*Task*	*Attachment/ Reference*	*Related SOP*
1.	DCC IT	After receiving notice that participation of a CSS has been terminated for inadequate enrollment, remove the ability for that CSS to enroll additional subjects.	NN Site Intervention and Escalation Plan	NN PM 507 NN CS 704
2.	DCC PC	Establish a schedule for conducting a closeout visit when all follow-up on currently-enrolled subjects has been completed, if applicable.		NN SS 405
3.	DCC PC	Conduct the closeout visit per SOP NN SS 405.		NN SS 405

#	Who	Task	Attachment/ Reference	Related SOP
4.	DCC PC	Advise the investigator to report the termination of CSS participation in the study to the local IRB and other appropriate regulatory authorities as required, and to submit a copy to the CCC.		NN RA 201 NN PM 501

B. Suspension of a Study by FDA, the SIRB, the Sponsor, or upon Recommendations from the NeuroNEXT DSMB

#	Who	Task	Attachment	Related SOP
1.	DCC IT	After receiving notice that a study is suspended, remove the ability for all CSS to enroll additional subjects through the EDC system.	NN Site Intervention and Escalation Plan	NN CS 704
2.	Study Team, Sponsor	Provide written communication of the decision to suspend the study to the applicable CSS for submission to the SIRB and/or to local IRB(s) (if applicable).		NN PM 501
3.	DCC PC and CCC PM	Develop and implement an ongoing communication plan with CSS. The plan should include provisions for formal written communications and teleconferences with CSS staff.		
4.	Study Team, Sponsor	Develop and implement a plan for informing any applicable vendors or central facilities (e.g. imaging facility, central pharmacy, or laboratory) that the study has been suspended.		NN GA 105 NN PM 501
5.	PPI and Study Team	If the study was suspended due to concern about the study design, the investigational product, serious AEs, or other study-related concerns, determine whether a modification to the study protocol is required. If a modification is required, follow applicable NeuroNEXT procedures to amend the study protocol.		NN RA 201 NN SM 602
6.	Study Team	After FDA and/or SIRB (as applicable) approval of an amendment, notify investigator(s) and advise them to notify their local IRB(s) that the study has been amended following the suspension.		NN RA 201
7.	DCC IT	If the suspension of the study is lifted, and upon direction from the PPI or designee, restore the ability for all CSS to enroll subjects through the EDC system, and implement the modifications to the protocol (if applicable).		NN CS 704

C. Early Termination of a Study or a CSS by FDA, an IRB, the Sponsor, or upon Recommendations from the NeuroNEXT DSMB

#	Who	Task	Attachment/ Reference	Related SOP
1.	DCC IT	After receiving notice that a study is terminated at the direction of the Sponsor, FDA, the SIRB, or upon recommendations from the NeuroNEXT DSMB, remove the ability for all CSS to enroll additional subjects through the EDC system.	NN Site Intervention and Escalation Plan	

#	*Who*	*Task*	*Attachment/ Reference*	*Related SOP*
2.	DCC IT	After receiving notice that participation of a CSS in the study is terminated, remove the ability for that CSS to enroll additional subjects through the EDC system.		
3.	DCC Lead Coordinator and CCC (if applicable)	After the study or a CSS is terminated: • obtain documentation of the reason for termination in the form of an FDA notification, a Sponsor memo, minutes from the meeting of the NeuroNEXT DSMB or the applicable IRB, or a summary report from the oversight Board; • follow up with the Sponsor to ensure that the FDA has been notified, if applicable; and • contact the appropriate investigators to ensure that the study is terminated at the CSS, and that the applicable IRB has been notified.		NN RA 201 NN RA 206
4.	DCC PC and CCC (if applicable)	Develop and implement an ongoing communication plan with the CSS to ensure that all study closeout procedures are implemented and any required regulatory documents are filed. The plan should include provisions for formal written communications and teleconferences with CSS staff.		NN RA 201 NN RA 202 NN RA 203 NN SS 405 NN PM 501 NN PM 505 NN PM 507
5.	Study Team, Sponsor	Develop and implement a plan for informing any applicable vendors or central facilities (e.g. imaging facility central pharmacy or laboratory) of termination of the study or CSS.		NN GA 105 NN PM 501
6.	Study Team, Sponsor	If it is deemed necessary, discuss with FDA, the Sponsor, the NeuroNEXT DSMB, and/or the SIRB the consequences of termination for current subjects. If it is decided that subjects may be placed at risk by termination of the study, determine the steps that are to be taken to provide the study product, if applicable, to current subjects and to monitor their safety.		NN RA 201 NN RA 205 NN RA 206 NN PM 501 NN SM 602
7.	Study Team, Sponsor	If, in consultation with FDA, steps are being considered or have been taken to provide current subjects access to the investigational product, advise investigator(s) to notify the SIRB and provide updates as needed.		NN RA 201 NN PM 501 NN SM 602

#	Who	Task	Attachment/ Reference	Related SOP
8.	PPI or designee PPI and/or Sponsor Study Team	If the study was terminated at a CSS due to investigator noncompliance: • advise the CSS PI to notify the local IRB; • advise the NeuroNEXT DSMB of the termination during the next scheduled meeting, or sooner if necessary to ensure subject safety or confidentiality; • follow up to ensure that the appropriate regulatory authorities have been notified. and follow steps 6 and/or 7 above (if applicable); • follow procedures described in SOPs NN SS 405 and NN PM 507 to close out the study at the CSS; • if the CSS will be replaced, follow procedures described in SOPs NN SS 401, NN SS 402, and NN RA 201 to initiate the study at a new CSS.		NN RA 201 NN SS 401 NN SS 402 NN SS 403 NN SS 405 NN PM 501 NN PM 507

D. Communications with Study Subjects

#	Who	Task	Attachment	Related SOP
1.	Study Team	If applicable to a study, provide guidance and work with the Sponsor to develop a plan for communicating information about study results, treatment assignments, and other information thought to be relevant to study subjects.		NN PM 501

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Joan Ohayon ohayonj@ninds.nih.gov Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: 72C6AAFD-8CC4-4855-82AC-A0700072901A Using IP Address: 156.40.137.188 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 2/15/2023 8:23:04 AM Viewed: 2/15/2023 12:04:26 PM Signed: 2/15/2023 12:04:42 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 8:23:03 AM Viewed: 2/15/2023 8:50:08 PM Signed: 2/15/2023 8:51:07 PM
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