NeuroNEXT Network

Standard Operating Procedure (SOP)

Single Institutional Review Board (SIRB) Reporting

Version 3.0

SOP NN SM 602

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 08:17 CST* 08-Mar-2024
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Name and Title: Merit E. Cudkowicz, MD MSc (CCC Principal Investigator)
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Name and Title: Marianne Chase, BA (CCC Senior Director of Clinical Trials Operations)

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR SIRB REPORTING

SOP: NN SM 602 Version No: 3.0 Issue Date: 01Mar2024 Effective Date: 15Apr2024	SIRB REPORTING	Supersedes Document: Version 2.0 Effective Date: 08Apr2023

Signature and Date: Dixie Ecklund *Electronically signed by: Dixie Ecklund* *Reason: I approve this document* *Date: Feb 24, 2024 17:19 CST* 24-Feb-2024
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Name and Title: Stacey Grabert, Pharm.D, MS, (CCC Director of Quality Assurance)
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Name and Title: Joan Ohayon, RN, MSN, CRNP, MSCN (NINDS, NeuroNEXT Program Official)

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR SIRB REPORTING

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1. POLICY

Employees, professional staff or other agents of institutions participating as a Clinical Study Site (CSS) for a NeuroNEXT Network human research study overseen by the NeuroNEXT Single IRB (SIRB) are required to report unanticipated problems (including adverse events), injuries to participants, protocol deviations/violations, changes initiated without SIRB approval to eliminate apparent immediate hazards to participant/s, complaints, non-compliance and cessation of research activities that are determined, discovered, or learned by them in connection with the conduct of a NeuroNEXT human research study in accordance with the standards, time frames, and procedures specified in this SIRB Reporting SOP, which includes the attached SIRB Reporting Table (section 8: Procedures).

2. SCOPE

This SOP applies to all employees, professional staff or other agents of institutions participating as a Network or Non-Network CSS for a NeuroNEXT Network human research study overseen by the Mass General Brigham Human Research Committee (MGBHRC), formerly known as Partners Human Research Committee (PHRC), the Institutional Review Board (IRB) selected by the National Institute of Neurological Disorders and Stroke (NINDS) to serve as the NeuroNEXT SIRB.

3. ROLES AND RESPONSIBILITIES

A. NeuroNEXT Clinical Study Site Principal Investigator

The NeuroNEXT Clinical Study Site Principal Investigator (CSS PI) or designee is responsible for reporting to the SIRB any unanticipated problems (including adverse events), injuries to participants, protocol deviations/violations, changes initiated without SIRB approval to eliminate apparent immediate hazards to participant/s, complaints, non-compliance, and cessation of research activities that are determined, discovered, or learned by them in connection with the conduct of a NeuroNEXT human research study, in accordance with the standards defined in the SIRB Reporting Table (section 8: Procedures).

Reports are made through the NeuroNEXT Clinical Coordinating Center as follows:

1. The CSS PI or designee completes the appropriate Report Form identified on the SIRB Reporting Table, and submits the completed form to the NeuroNEXT Clinical Coordinating Center IRB Liaison (CCC-SIRB Liaison) or designee via the online data entry system.
2. The CCC-SIRB Liaison is then responsible for submitting the necessary information to the SIRB.
3. CSS and CCC reports are to be made in accordance with the time frames specified in the SIRB Reporting Table.

B. NeuroNEXT Clinical Coordinating Center

The CCC-SIRB Liaison or designee is responsible for submitting reports to the SIRB of unanticipated problems (including adverse events), injuries to participants, protocol deviations/violations, changes initiated without SIRB approval to eliminate apparent immediate hazards to participant/s, complaints, non-compliance and cessation of research activities that they receive from CSSs in connection with the conduct of a NeuroNEXT human research study.

The CCC-SIRB Liaison is responsible for submitting necessary information as detailed in the SIRB Report Form to the SIRB in accordance with the time frames specified in the SIRB Reporting Table.

C. NeuroNEXT Data Coordinating Center

The NeuroNEXT Data Coordinating Center (DCC) is responsible for developing the data entry system for reporting by the CSS PI/designee of unanticipated problems (including adverse events), injuries to participants, protocol deviations/violations, changes initiated without SIRB approval to eliminate apparent immediate hazards to participant/s, complaints, non-compliance and cessation of research activities that are determined, discovered, or learned by them in connection with the conduct of a NeuroNEXT human research study for review by the CCC-SIRB Liaison to determine required reporting to the SIRB and in accordance with the standards defined in the SIRB Reporting Table.

DCC and CCC reports are to be made in accordance with the time frames specified in the SIRB Reporting Table.

D. NeuroNEXT Single Institutional Review Board

The SIRB is responsible for reviewing reports of the unanticipated problems (including adverse events), injuries to participants, protocol deviations/violations, changes initiated without SIRB approval to eliminate apparent immediate hazards to participant/s, complaints, non-compliance and cessation of research activities that they receive from the NeuroNEXT CCC in connection with the conduct of a NeuroNEXT human research study.

When reviewing any of the aforementioned reports, the NeuroNEXT SIRB is responsible for making the determination as to whether the report constitutes an unanticipated problem involving risks to participants or others or serious or continuing noncompliance with applicable laws and regulations or the requirements or determinations of the SIRB and for taking appropriate responsive action, which may include suspension or termination of SIRB approval of the research.

The NeuroNEXT SIRB is responsible for informing the reporting CSS PI/designee through the NeuroNEXT CCC of the findings, determinations, actions taken, and any modifications or remedial action required by the SIRB in response to such reports and, when applicable, informing all NeuroNEXT CSS PIs of any discovery or determination that affects participant safety or the conduct of the trial at all CSSs.

E. External Reporting

Responsibilities regarding any required reporting to sponsors/funding agencies, OHRP, FDA and/or other oversight authorities of any serious or continuing non-compliance, unanticipated problems involving risks to participants or others, and suspension or termination of SIRB approval in connection with a NeuroNEXT human research study will be coordinated as described in the NeuroNEXT Single IRB Reliance Agreement executed by the CSS.

4. APPLICABLE REGULATIONS AND GUIDELINES

Ethical Principles
All parties shall be guided by the *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, generally known as the “Belmont Report.”

45 Code of Federal Regulations 46
21 Code of Federal Regulations 56
21 Code of Federal Regulations 50

5. REFERENCES TO OTHER APPLICABLE SOPs

NN SM 601 SIRB Reliance SOP

SOP: NN SM 602 Version No: 3.0 Issue Date: 01Mar2024 Effective Date: 15Apr2024	SIRB REPORTING	Supersedes Document: Version 2.0 Effective Date: 08Apr2023

6. ATTACHMENTs AND REFERENCES

NN SM 602-A Document History

7. TERMS AND ABBREVIATIONS

The following terms and abbreviations are used in this document:

ADE	Adverse Device Effect
AE	Adverse Event
CCC	NeuroNEXT Clinical Coordinating Center at Massachusetts General Hospital
CCC-SIRB Liaison	NeuroNEXT Clinical Coordinating Center Single Institutional Review Board Liaison
CFR	Code of Federal Regulations
SIRB	NeuroNEXT Single Institutional Review Board
CSS	Clinical Study Site that conducts research for a particular NeuroNEXT protocol
CSS PI	Principal Investigator who is responsible for implementing and conducting a specific NeuroNEXT protocol at a Clinical Study Site
DCC	NeuroNEXT Data Coordinating Center at the University of Iowa
DMC	Data Monitoring Committee
DSMB	Data and Safety Monitoring Board
DSMC	Data and Safety Monitoring Committee
eIRB	Electronic Institutional Review Board (Form)
FDA	US Food and Drug Administration
HIPAA	Health Information Portability and Accountability Act
MGBHRC	Mass General Brigham Human Research Committee
NINDS	National Institute of Neurological Disorders and Stroke
OHRP	Office for Human Research Protections
PPI	Protocol Principal Investigator of a NeuroNEXT protocol
SAE	Serious Adverse Event
SIRB	NeuroNEXT Single Institutional Review Board
UADE	Unanticipated Adverse Device Effect

8. SPECIFIC PROCEDURES

The specific requirements, timeframes, and procedures for making reports to the NeuroNEXT SIRB of unanticipated problems (including adverse events), injuries to participants, protocol deviations/violations, changes initiated without SIRB approval to eliminate apparent immediate hazards to participant/s, complaints, non-compliance and cessation of research activities as required

by this SOP are outlined in the attached SIRB Reporting Table. Note that certain types of events need only be reported at Continuing Review.

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR SIRB REPORTING

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NEURONEXT SIRB REPORTING REQUIREMENTS

Type of Report	Description	Reporting Procedures	Form	Time Frame
Local CSS Adverse Events (AE)	*Adverse event* means any untoward or unfavorable medical occurrence in a human participant, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the participant's participation in the research.	CSS PI/designee reports all Adverse Events to CCC-SIRB Liaison via the online data entry system	NeuroNEXT Adverse Event Form	Report all Adverse Events within 5 working days/7 calendar days of the date the CSS PI first becomes aware of the Adverse Event except Serious Adverse Events as noted below
Serious Adverse Events (SAE)	*Serious adverse event* means any untoward or unfavorable medical occurrence in a human participant which results in death, life-threatening, hospitalization, disability or permanent damage, congenital anomaly/birth defect, or required an intervention to prevent permanent impairment and temporally associated with the participant's participation in the research.	CSS PI/designee reports all Serious Adverse Events to CCC-SIRB Liaison via the online data entry system	NeuroNEXT Adverse Event Form	Report Serious Adverse Events (SAEs) within 24 hours of when CSS PI first becomes aware of the Adverse Event

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NEURONEXT SIRB REPORTING REQUIREMENTS

Type of Report	Description	Reporting Procedures	Form	Time Frame
Unexpected and Possibly Related Adverse Events	*Unexpected* means that the incident, experience, or outcome in terms of nature, severity or frequency is not described in the protocol-related documents, such as the SIRB-approved research protocol and informed consent document or the characteristics of the study population being studied. *Possibly related* means there is a *reasonable possibility* that the adverse event may have been caused by the procedures involved in the research. *Reasonable possibility* means that the event is more likely than not related to participation in the research or, in other words, there is a >50% likelihood that the event is related to the research procedures.	CCC-SIRB Liaison reports all Unexpected Adverse Events that are Possibly Related to the Research to the SIRB via the online data entry system	eIRB Adverse Event Form	Report Unexpected and Possibly Related Adverse Events within 5 working days/7 calendar days) of the date the CSS PI first becomes aware of the Adverse Event
Continuing Review Progress Report - Adverse Events	At continuing review, the SIRB reviews all available information in a summary fashion to prevent unblinding regarding adverse events that have occurred in the trial.	CCC-SIRB Liaison provides updated summary information on Adverse Events	eIRB Continuing Review Form	Continuing Review

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NEURONEXT SIRB REPORTING REQUIREMENTS

Type of Report	Description	Reporting Procedures	Form	Time Frame
Local Adverse Device Effects (ADE)	*Adverse device effect* means any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device.	CSS reports all Adverse Device Effects to CCC-SIRB Liaison via the online data entry system	NeuroNEXT Adverse Device Effect Form	Report all Adverse Events within 5 working days/7 calendar days of the date the CSS PI first becomes aware of the Adverse Device Effect, except Serious Adverse Device Effects as noted below
Serious Adverse Device Effects (SAE)	*Serious adverse device effect* means any untoward or unfavorable medical occurrence in a human participant which results in death, life-threatening, hospitalization, disability or permanent damage, congenital anomaly/birth defect, or required an intervention to prevent permanent impairment and temporally associated with the participant's participation in the research.	CSS PI/designee reports all Serious Adverse Device Effects to CCC-SIRB Liaison via the online data entry system	NeuroNEXT Adverse Device Effect Form	Report Serious Adverse Device Events (SAEs) within 24 hours of when CSS PI first becomes aware of the Adverse Device Effect

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NEURONEXT SIRB REPORTING REQUIREMENTS

Type of Report	Description	Reporting Procedures	Form	Time Frame
Unanticipated Adverse Device Effects (UADE)	*Unanticipated adverse device effect* means any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of participants.	CCC-SIRB Liaison reports all Unanticipated Adverse Device Effects to SIRB	eIRB Adverse Event Form	Report any Unanticipated Adverse Device Effect within 5 working days/7 calendar days) of the date the CSS PI first becomes aware of the Adverse Event
Continuing Review Progress Report - Adverse Device Effects	At continuing review, the SIRB reviews all available information in a summary fashion to prevent unblinding regarding adverse device effects that have occurred in the trial.	CCC-SIRB Liaison provides updated summary information on Adverse Device Effects to SIRB	eIRB Continuing Review Form	Continuing Review

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NEURONEXT SIRB REPORTING REQUIREMENTS

Type of Report	Description	Reporting Procedures	Form	Time Frame
Local CSS Unanticipated Problems Involving Risks to Participants or Others	*Unanticipated problem involving risks to participants or others* means any incident, experience, information, outcome, or other problem that is *unexpected* given the research procedures and that indicates that the research places participants at a greater risk of physical, psychological, economic, legal, or social harm than was previously known or recognized. Unanticipated problems include, but are not limited to: • Medication, procedural or laboratory errors • Breach of confidentiality or HIPAA violation • Complaints that indicate participants' rights, safety or welfare were adversely affected • Change initiated without SIRB approval to eliminate apparent immediate hazards to participant/s	1. CSS PI/designee reports to CCC-SIRB Liaison via the online data entry system 2. CCC-SIRB Liaison reports to SIRB	NeuroNEXT Reportable Event Form eIRB Other Event Form	Report within 5 working days/7 calendar days of the date the CSS PI first becomes aware of the problem
Safety Monitoring Reports	*Safety monitoring report* means any DMC, DSMB, DSMC or sponsor analysis that describes a safety problem	CCC-SIRB Liaison reports to the SIRB	eIRB Other Event Form	Report within 5 working days/7 calendar days of the date the CCC receives the report

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Apparent Serious or Continuing Noncompliance	*Noncompliance* means any failure to comply with any applicable federal, state, or local laws and regulations or the requirements or determinations of the PHRC, including institutional policies related to human participant protection. *Serious noncompliance* means any noncompliance that negatively impacts the rights and welfare of participants or compromises the integrity of the study data. For example, serious noncompliance might include, but is not limited to, the following violations: (1) failure to obtain prospective PHRC approval; (2) failure to obtain informed consent of participant(s); (3) enrollment of participant(s) who do not meet all eligibility criteria; (4) obtaining informed consent using an invalid/outdated research consent form that is missing information that might affect the individual's willingness to participate or continue to participate in the research; (4) failure to perform follow-up as outlined in the protocol where the lack of follow-up places the participant at increased risk of harm; and (5) failure to report a serious unanticipated problem involving risks to participants or others, including adverse events. *Continuing noncompliance* means any noncompliance that occurs repeatedly after appropriate remedial education or corrective action has been instituted taking into consideration all relevant factors, including, for example: (1) whether the	1. CSS PI/designee reports to CCC-SIRB Liaison via the online data entry system 2. CCC-SIRB Liaison reports to SIRB	NeuroNEXT Reportable Event Form eIRB Other Event Form	Report within 5 working days/7 calendar days of the date the CSS PI first becomes aware of the problem Report within 5 working days/7 calendar days of the date the CSS PI first becomes aware of the problem

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Type of Report	Description	Reporting Procedures	Form	Time Frame
	continuing noncompliance was intentional, or (2) whether the investigator collaborated in remedial activity and the continuing noncompliance was not intentional.			
Major Unapproved Protocol Deviations	*Major Unapproved Protocol Deviation* means any alteration/modification to the PHRC-approved research that has the potential to negatively impact participant safety or integrity of study data (ability to draw conclusions from the study data), or affect the participant's willingness to participate in the study.	1. CSS PI/designee reports to CCC-SIRB Liaison via the online data entry system 2. CCC-SIRB Liaison reports to SIRB	NeuroNEXT Deviation Form eIRB Other Event Form	Report within 24 hours of the date the CSS PI first becomes aware of the deviation Report within 5 working days/7 calendar days of the date the CSS PI first becomes aware of the problem
Changes Initiated Without SIRB Approval To Eliminate Apparent Immediate Hazards To Participant/S,	See *Unanticipated Problems*	1. CSS PI/designee reports to CCC-SIRB Liaison via the online data entry system 2. CCC-SIRB Liaison reports to SIRB	NeuroNEXT Deviation Form eIRB Other Event Form	Report within 24 hours of the date the CSS PI first becomes aware of the change initiated without SIRB approval Report within 5 working days/7 calendar days of the date the CSS PI first becomes aware of the problem

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Type of Report	Description	Reporting Procedures	Form	Time Frame
Complaints	Complaints that indicate participants' rights, safety or welfare were adversely affected - See *Unanticipated Problems*	1. CSS PI/designee reports to CCC-SIRB Liaison via the online data entry system 2. CCC-SIRB Liaison reports to SIRB	NeuroNEXT Reportable Event Form eIRB Other Event Form	Report within 5 working days/7 calendar days of the date the CSS PI first becomes aware of the problem
Cessation of Research Activities	Cessation of research activities See also *Unanticipated Problems* when cessation of research is for safety problems	1. CSS PI/designee reports to CCC-SIRB Liaison 2. CCC-SIRB Liaison reports to SIRB	NeuroNEXT Site Close Out Form eIRB Amendment Form	Report within 30 calendar days of the date the CSS ceases research activities
Minor Unapproved Protocol Deviations	*Minor Unapproved Protocol Deviation* means any deviation from the PHRC-approved research that does not have the potential to negatively impact participant safety or integrity of study data (ability to draw conclusions from the study data), or affect participant's willingness to participate in the study.	1. CSS PI/designee reports to CCC-SIRB Liaison 2. CCC-SIRB Liaison reports to SIRB	NeuroNEXT Deviation Form eIRB Continuing Review Form	Continuing Review

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Attachment NN SM 602 - A. Document History

NeuroNEXT Network Standard Operating Procedure (SOP) SIRB Reporting SOP NN SM 602					
Version	**Description of Modification**	**Reason or Justification for Modification**	**Issue Date**	**Effective Date**	**Reviewer(s)**
1.0	New	N/A	06Apr2012	06May2012	N/A
1.0	Reviewed – no changes (2016)	N/A	06Apr2012	06May2012	N/A
2.0	Updated IRB name from Partners to MGB; Updated signature block to accommodate for electronic signatures. Additional minor updates throughout.	Updated for version 2.0	22Feb2023	08Apr2023	Catherine Gladden
3.0	Minor edits for clarity	Periodic review	01Mar2024	15Apr2024	Preeti Paul

NN SM 602 Single Institutional Review Board Reporting v3.0 clean

Final Audit Report 2024-03-11

Created:	2024-02-22
By:	Tania Leeder (tleeder@mgb.org)
Status:	Signed
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Number of Documents:	1
Document page count:	15
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"NN SM 602 Single Institutional Review Board Reporting v3.0 clean" History

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

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2024-02-22 - 7:46:43 PM GMT

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

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2024-02-22 - 7:55:47 PM GMT

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Challenge: The user opened the agreement.

2024-02-22 - 11:11:10 PM GMT

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

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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.

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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.

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2024-03-08 - 9:19:54 AM GMT- IP address: 172.226.137.0

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Signer cscoffey@iowa.uiowa.edu entered name at signing as Christopher S. Coffey
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ohayonj@ninds.nih.gov authenticated with Adobe Acrobat Sign.
Challenge: The user opened the agreement.
2024-03-11 - 3:20:42 PM GMT

Signer ohayonj@ninds.nih.gov entered name at signing as Joan Ohayon
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Document e-signed by Joan Ohayon (ohayonj@ninds.nih.gov)
Signing reason: I approve this document
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Agreement completed.
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