NeuroNEXT Network

Standard Operating Procedure (SOP)

Single Institutional Review Board (SIRB) Reliance Process

Version 2.0

SOP NN SM 601

Originators: NeuroNEXT CCC and DCC Personnel

Reviewed and Approved by:

Signature and Date: DocuSigned by Christopher Coffey Christopher Coffey | I approve this document 15-Feb-2023 | 8:15:21 AM PST C68AC8DD80334CF982AED1200765F147 15-Feb-2023
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15-Feb-2023 | 12:26:35 PM PST

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22-Feb-2023 | 11:19:46 AM EST

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15-Feb-2023 | 8:58:59 AM PST

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15-Feb-2023

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NN SM 601

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR SIRB RELIANCE PROCESS

1. POLICY

A. Purpose and Applicability

This SOP applies to all Network and Non-Network Clinical Study Sites (CSS) that have executed a Reliance Agreement (or RA) to rely on the Mass General Brigham Human Research Committee (MGBHRC), formerly known as Partners Human Research Committee (PHRC), for review of one or more NeuroNEXT clinical trials.

The MGBHRC is comprised of the IRBs of Massachusetts General Hospital and Brigham and Women's Hospital and is the Single IRB (SIRB) for NeuroNEXT. All NeuroNEXT clinical trials will be reviewed by the SIRB. The general eligibility requirements for a CSS to rely on the SIRB are addressed in the Reliance Agreement. These requirements pertain to overall qualifications of the CSS and include completion by the CSS of a satisfactory NeuroNEXT Clinical Study Site IRB Information Sheet. CSSs with an executed RA have been determined by the NeuroNEXT Clinical Coordinating Center (CCC) and SIRB to meet the general requirements.

The purpose of this SOP is to set forth the process for a CSS to cede review to the SIRB of specific/individual NeuroNEXT clinical trial(s) as contemplated under its RA. The SOP describes the flow of protocol-specific information to and from the CSS to the CCC/SIRB and the information, timelines and documentation required for the initial protocol review. It also sets forth the process and requirements for other review decisions for the life of the protocol.

B. Process for Ceding Review of a Trial

a. Initial Protocol Review

i. The Protocol Principal Investigator (PPI) of a NeuroNEXT clinical trial will submit the draft protocol for the trial to the SIRB via the NeuroNEXT CCC-SIRB Liaison. This protocol will be designated by the SIRB as the 'parent' protocol.

ii. The SIRB will perform an initial assessment of the protocol to determine "IRB-readiness" (e.g., completeness of all parts of the submission) and will work with the PPI via the CCC-SIRB Liaison as necessary to address any preliminary issues.

iii. The SIRB via the CCC-SIRB Liaison will send the IRB-ready protocol to the study Project Manager who will provide to all participating CSSs via the CSS designee(s). The CSS designee(s) will initiate an analysis of the protocol at the CSS to identify and inform the SIRB of 1) substantive issues (if any) and 2) local research context issues raised by the protocol. The CSS designee(s) must either be an individual(s) who has knowledge of and experience with the CSS's local research context or involve such individuals at the CSS in the referenced analysis and determinations. Without limiting what is provided by the CSS, the CSS must, at minimum, provide complete information necessary to inform the SIRB of the CSS's local research context as relevant to the protocol. This information shall include:

1. Specific requirements of state or local laws, regulations, policies, standards or other factors applicable to the CSS or the trial that would affect the CSS's conduct of the specific trial including, as applicable;

    a. Identification of legally authorized representatives who can provide consent for individuals to participate in research;

    b. Requirements for enrollment of adults with impaired decision-making capacity;

    c. Age of majority in the state;

    d. Circumstances under which children may consent to their own participation in research (emancipated minors, mature minors, etc.);

    e. Requirements for wards of the state or other special populations (child or adult) to participate in research;

    f. Requirements for obtaining assent of children to participate in research;

g. Processes or requirements for enrollment of non-English-speaking participants;

h. Other information about the local consent process, including practices regarding recruitment and compensation of participants;

i. Requirements of confidentiality of specific types of health information;

j. Special characteristics of the CSS or the community; and

k. Other requirements or factors as applicable.

The SIRB via the CCC-SIRB Liaison may provide a questionnaire form for the CSS to complete to facilitate the provision of the above information in the form of a 'Site Review Sheet'.

2. Based on the CSS's conduct of an investigator conflicts of interest analysis under the applicable policy as described in the NeuroNEXT Conflict of Interest and Financial Disclosure Requirements SOP (COI SOP 104):

   a. A copy of any report of investigator financial conflicts of interest (FCOI Report) made by the CSS to NINDS/the CSS of the PPI/other institution (as applicable under the COI SOP 104) pursuant to the Public Health Service regulations on Promoting Objectivity in Research, 42 CFR Part 50, Subpart F (Public Health Service Regulations);

   b. The specific information pertaining to the nature and management of reported FCOIs that is specified in 42 CFR § 50.605(b)(3) as will be in effect as of August 24, 2012, whether or not required under the current Public Health Service Regulations or included in such FCOI Report; and

   c. A description of any other steps (together with supporting information) that the CSS has determined necessary to address financial interests of its investigators relating to the specific trial.

Comments and information from the CSS (including any questionnaire on state/local requirements provided by the CCC-SIRB Liaison) must be submitted in writing to the SIRB via the CCC-SIRB Liaison within 2 weeks of the date the protocol was sent to the CSS.

v. Upon receipt of the comments/information from participating CSSs, the SIRB will review the protocol.

vi. While the protocol is under SIRB review, the CSS of the PPI will conduct relevant Local Ancillary Committee (AC) review as required by its policies. Relevant committees may vary by protocol and may include: nursing, radiation safety, pharmacy, biomedical engineering, biosafety, Medicare or other cost/billing analysis, and contract review.

vii. The SIRB will work with the PPI via the CCC-SIRB Liaison to address any modifications or other issues necessary to approve the protocol. If the protocol is approved by the SIRB, the approval will be approval of the parent protocol.

viii. The SIRB via the CCC-SIRB Liaison will provide the approved protocol and a model informed consent form (ICF) (which will include a model form of HIPAA authorization for use and disclosure of Protected Health Information) to the study Project Management team who will then distribute to all CSSs who submitted the information required in section B.a.iv above.

ix. Each CSS will then decide whether or not to participate in the protocol as approved. CSSs that decide to participate will:

   1. Coordinate relevant Local AC review as required by local policies;

   2. Customize the approved study-wide model ICF in the areas permitted by the form to include/reflect information specific to the CSS. Attach or include any CSS form of HIPAA authorization if the CSS elects to use its own form/language in place of the model HIPAA form/language included in the study-wide ICF; and

3. Submit an application via the CCC-SIRB liaison to be added as a study site, along with the customized model ICF and HIPAA authorization), to the SIRB via the CCC-SIRB Liaison.

ii. The SIRB will review the customized ICF including authorization language for consistency with the approved model ICF and will review all other local information provided and, if all parts of the application are satisfactory, will approve each CSS as a site amendment to the parent protocol. The SIRB will provide an approved and stamped ICF for the CSS via the CCC-SIRB Liaison and Project Management team.

b. Continuing review

i. Dates for continuing review (expiration of SIRB approval) will be determined by date of parent protocol review;

ii. The SIRB via the CCC-SIRB Liaison will notify the study Project Manager who will contact each participating CSS regarding information required for continuing review. Each participating CSS will submit its responsive information for continuing review to the CCC-SIRB Liaison via the Project Manager;

iii. The CCC-SIRB Liaison will submit a single continuing review application to the SIRB that includes continuing review information from all participating CSSs; and

iv. The SIRB will conduct continuing review and communicate results to participating CSSs via the CCC-SIRB Liaison and Study Project Manager.

c. Amendments

i. The PPI will submit any study-wide protocol amendments to the SIRB via the CCC-SIRB Liaison;

ii. The PI at each participating CSS may submit site-specific administrative amendments (e.g., study staff changes) and requests for protocol exceptions to the SIRB via the CCC-SIRB Liaison. Any amendments proposed to the substantive content of the protocol must be coordinated with and submitted through the PPI; and

iii. The SIRB will review amendments and communicate regarding their approval status with the relevant CSS(s) via the CCC-SIRB Liaison. Amendments requiring notification of all participating CSSs, as determined by the SIRB, will also be communicated via the CCC-SIRB Liaison.

d. Non-Compliance, subject injuries, unanticipated problems, protocol deviations/violations, complaints, cessation/suspension/termination of protocol, changes made without SIRB approval to eliminate apparent immediate hazards to subject/s: see the Central IRB Reporting SOP 602

e. Study closure

i. The PPI will submit relevant material for study closure to the SIRB via the CCC-SIRB Liaison.

2. SCOPE

The policies and procedures described in this SOP apply to the NeuroNEXT Clinical Coordinating Center (CCC), including the CCC Central IRB, and the Data Coordinating Center (DCC) and to all NeuroNEXT Clinical Study Site investigators and staff (Network CSS), PPIs, and Non-NeuroNEXT Clinical Study Site investigators and staff (Non-Network CSS) who participate in a NeuroNEXT clinical trial.

3. ROLES AND RESPONSIBILITIES

Roles and responsibilities for the CCC, DCC and SIRB as they relate to SIRB Reliance are detailed in section 8.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.114

21 CFR 56.114

5. REFERENCES TO OTHER APPLICABLE SOPS

NN SM 602: Reporting SOP

NN GA 104: Conflict of Interest and Financial Disclosure Requirements SOP

6. ATTACHMENTS

NN SM 601 – A Document History

7. TERMS AND ABBREVIATIONS

The following terms and abbreviations are used in this document:

AC	Ancillary Committee
CCC	NeuroNEXT Clinical Coordinating Center at Massachusetts General Hospital
CCC-SIRB Liaison	NeuroNEXT Clinical Coordinating Center Central Institutional Review Board Liaison
CFR	Code of Federal Regulations
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
FCOI	Financial Conflict of Interest
HIPAA	Health Insurance Portability and Accountability Act
ICF	Informed Consent Form
MGBHRC	Mass General Brigham Human Research Committee
Network CSS	CSS that is within the NeuroNEXT Network
Non-Network CSS	CSS that is not a member of the NeuroNEXT Network
NINDS	National Institute of Neurological Disorders and Stroke
PM	Project Manager or Project Management
PPI	Protocol Principal Investigator of a NeuroNEXT protocol
RA	Reliance Agreement/NeuroNEXT SIRB IRB Authorization Agreement
SIRB	NeuroNEXT Single Institutional Review Board

8. SPECIFIC PROCEDURES

#	*Who*	*Task*	*Attachment/ Reference*	*Related SOP*
1.	CSS Institutional Official	Sign Reliance Agreement	Reliance Agreement	
2.	PPI	Submit draft protocols to CCC-SIRB Liaison	Reliance Agreement	
3.	CCC-SIRB Liaison	Submit draft protocols to SIRB		
4.	SIRB	Review draft protocol for readiness for SIRB review	Reliance Agreement	
5.	PM team	Send IRB-ready draft protocol to interested CCSs for local comments		
6.	CSS PI and Local Institutional Designee*	Review draft protocol and submit local comments to CCC-SIRB Liaison		
7.	CCC-SIRB Liaison	Submit Initial Review application to SIRB including final parent protocol, ICF(s), local comments and all appliable supporting documents		
8.	SIRB	Review final parent protocol and ICF. SIRB review may include required modifications or deferral. SIRB will work with CSS PPI through CCC-SIRB Liaison to secure IRB approval. SIRB will communicate approval status to CSS PPI via the CCC-SIRB Liaison.	Reliance Agreement	
9.	CCC-SIRB Liaison	Submit final approved protocol and template ICF to all interested CSSs for final decision to participate		
10.	CSS PI	Communicate final decision to participate to CCC-SIRB Liaison		
11.				
12.				
13.				
14.	CCC-SIRB Liaison	Submit each additional CSS protocol and site-specific ICF to SIRB as ‘child’ amendments for approval		
15.	SIRB	Review each CSS ‘child’ amendment and ICF and communicate approval status to relevant CSSs via the CCC-SIRB Liaison		
16.	CCC-SIRB Liaison	Communicate SIRB approval status to relevant CSSs		

17.	CSS PI/Designee	Report non-compliance, subject injuries, unanticipated problems, protocol deviations/violations, complaints, cessation of research activities, changes made without SIRB approval to eliminate apparent immediate hazards to subject/s to CCC-SIRB Liaison	SIRB Reporting SOP 602 Reliance Agreement	SIRB Reporting SOP 602
18.	CCC-SIRB Liaison	Submit CSS reports of non-compliance, subject injuries, unanticipated problems, protocol deviations/violations, complaints, cessation of research activities, changes made without SIRB approval to eliminate apparent immediate hazards to subject/s to SIRB	SIRB Reporting SOP 602	SIRB Reporting SOP 602
19.	SIRB, CCC, DCC	Communicate all reportable events to CSS that may affect subject safety or the conduct of the clinical trial at all sites	SIRB Reporting SOP 602 Reliance Agreement	SIRB Reporting SOP 602
20.	CSS PI	Submit continuing review applications to CCC-SIRB Liaison	Reliance Agreement	
21.	CCC-SIRB Liaison	Submit continuing review applications to SIRB	Reliance Agreement	
22.	SIRB	Review continuing review applications for all CSS. Communicate approval status to participating CSSs via CCC-SIRB Liaison.	Reliance Agreement	
23.	CCC-SIRB Liaison	Communicate SIRB approval status of continuing review applications to participating CSSs		
24.	PPI	Submit study-wide protocol amendments to the SIRB via the CCC-SIRB Liaison	Reliance Agreement	
25.	CCC-SIRB Liaison	Submit study-wide protocol amendments to the SIRB	Reliance Agreement	
26.	SIRB	Review study-wide protocol amendments and communicate approval status to participating CSSs via CCC-SIRB Liaison	Reliance Agreement	
27.	CCC-SIRB Liaison	Communicate SIRB approval status of study-wide amendments to participating CSSs		
28.	CSS PI	Submit site-specific administrative amendments (e.g., study staff changes) and requests for protocol exceptions to the SIRB via the CCC-SIRB Liaison	Reliance Agreement	
29.	CCC-SIRB Liaison	Submit site-specific administrative amendments and requests for protocol exceptions to the SIRB	Reliance Agreement	
30.	SIRB	Review site-specific administrative amendments and requests for protocol exceptions and communicate approval status to relevant CSS(s) via the CCC-SIRB Liaison	Reliance Agreement	

31.	CCC-SIRB Liaison	Communicate SIRB approval status of site-specific administrative amendments and requests for protocol exceptions to participating CSSs		
32.	PPI	Coordinate and submit substantive content amendments to the protocol as requested by CSS to the SIRB via the CCC-SIRB Liaison	Reliance Agreement	
33.	CCC-SIRB Liaison	Submit substantive content amendments to the protocol to the SIRB	Reliance Agreement	
34.	SIRB	Review substantive content amendments and communicate approval status to relevant CSS(s) via the CCC-SIRB Liaison.	Reliance Agreement	
35.	CCC-SIRB Liaison	Communicate SIRB approval status of substantive content amendments to the protocol to the CSSs [Amendments requiring notification of all participating CSSs, as determined by the SIRB, will also be communicated via the CCC-SIRB Liaison]		
36.	PPI	Submit relevant material for study closure to the SIRB via the CCC-SIRB Liaison		
37.	SIRB	Review relevant material for study closure and communicate approval status to the PPI via the CCC-SIRB Liaison		
38.	CCC-SIRB Liaison	Communicate approval status of study closure material to the PPI		

*Institutional Representative may be a site/local IRB member.

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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 8:43:07 AM Viewed: 2/15/2023 3:05:17 PM Signed: 2/15/2023 3:26:41 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 8:43:07 AM Viewed: 2/15/2023 8:36:57 PM Signed: 2/15/2023 8:37:48 PM
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