NeuroNEXT Network

Standard Operating Procedure (SOP)

Site Selection and Qualification

Version 3.0

SOP NN SS 401

Originators: NeuroNEXT CCC and DCC Personnel

Reviewed and Approved by:

Signature and Date: DocuSigned by Christopher Coffey Christopher Coffey | I approve this document 14-Feb-2023 | 12:34:29 PM PST C68AC8DD80334CF982AED1200765F147	14-Feb-2023
Name and Title: Christopher S. Coffey, PhD (DCC Principal Investigator)	
Signature and Date: DocuSigned by Merit Cudkowicz Merit Cudkowicz | I approve this document 21-Feb-2023 | 8:01:48 AM EST 9F8FE4180E504C6AB0A67B835E80C644	21-Feb-2023
Name and Title: Merit E. Cudkowicz, MD MSc (CCC Principal Investigator)	
Signature and Date: DocuSigned by Marianne Chase Marianne Chase | I approve this document 14-Feb-2023 | 9:46:08 AM EST 58FE690F6BCA4F2390E3DA15BCE3F578	14-Feb-2023
Name and Title: Marianne Chase, BA (CCC Senior Director of Clinical Trials Operations)	

Signature and Date:

DocuSigned by DIXIE ECKLUND

I approve this document
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Name and Title: Dixie J. Ecklund, RN MSN MBA (DCC Associate Director)

Signature and Date:

DocuSigned by Stacey Grabert

I approve this document
22-Feb-2023 | 11:27:34 AM EST

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22-Feb-2023

Name and Title: Stacey Grabert, Pharm.D, MS, (CCC Director of Quality Assurance)

Signature and Date:

DocuSigned by Joan Ohayon

I approve this document
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14-Feb-2023

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

NN SS 401

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR SITE SELECTION AND QUALIFICATION

1. POLICY

The NeuroNEXT Executive Committee (NEC) will select Clinical Study Sites (CSS) for participation in each Network study, based on the following criteria:

- Scientific expertise in the disease indication
- Projections of patient availability
- Geographic distribution
- History of productivity (when available)
- Site capacity

For the purposes of site selection, the 25 funded NeuroNEXT Clinical Study Sites (CSS) are each considered as a single unit. NeuroNEXT CSS that do not have a fully-executed Master Clinical Trial Agreement (MCTA) and Single Institutional Review Board (SIRB) Reliance Agreement (RA) on file at the Clinical Coordinating Center (CCC) will not be considered for participation in a NeuroNEXT study until such agreements are executed.

If a NeuroNEXT CSS previously indicated interest for two studies and was not selected for either, that CSS will automatically be placed on the list of initial sites for the third study for which they indicate interest.

The Protocol Principal Investigator (PPI) may request the addition of non-NeuroNEXT CSS for participation to ensure adequate recruitment. If the NEC determines that there is a need for additional non-Network CSS, the NEC may make this recommendation to the NINDS. The addition of non-NeuroNEXT CSS is dependent upon NINDS approval. In the event that the PPI requests inclusion of non-US sites, this would require NINDS approval prior to NEC review of the request.

Any Non-NeuroNEXT CSS under consideration will be required to:

- confirm their interest in participating in the study;
- confirm the willingness of their Institution to sign a MCTA and SIRB RA with the CCC; and
- cede review for the study to the NeuroNEXT SIRB.

Each CSS selected to participate in a study will be qualified by the NeuroNEXT Data Coordinating Center (DCC) study monitor and/or Clinical Coordinating Center staff (CCC), unless prior qualification of the CSS is deemed to be sufficient. A qualification telephone screening process and/or pre-study site visit will be used to review the appropriateness of the investigator, his/her staff, facility and resources, and to gauge the understanding of NeuroNEXT policies and applicable regulatory requirements by the investigator and his/her key research staff.

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

Upon receipt of funding, the NEC is responsible for selecting CSS and communicating its final decision to all interested CSS.

The NEC is responsible for determining if there is a need for participation of additional non-NeuroNEXT CSS in a Network study, and if so, recommending those CSS to NINDS for approval according to the criteria described the Policy section of this SOP.

NINDS is responsible for reviewing and approving/disapproving the addition of any non-NeuroNEXT CSS.

Prior to their consideration as a CSS, each CSS is responsible for: completing a study-specific questionnaire, confirming their interest in participating in the study, and confirming the willingness of their Institution to cede review for the study to the NeuroNEXT SIRB.

After site selection by the NEC, the DCC/CCC is responsible for conducting assessments of each CSS to determine if the investigator is appropriate and if the site is adequately prepared to conduct the study.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.50	General Responsibilities of Sponsors
21 CFR 312.53	Selecting Investigators and Monitors
21 CFR 312.70	Disqualification of a Clinical Investigator
ICH E6, 2.7	The Principles of ICH GCP
ICH E6, 5.1	Quality Assurance and Quality Control
ICH E6, 5.6	Investigator Selection
ICH E6, 5.7	Allocation of Responsibilities
FDA	Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors: FDA Inspections of Clinical Investigators (June 2010)
FDA	Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors: Clinical Investigator Administrative Actions – Disqualification (May 2010)

5. REFERENCES TO OTHER APPLICABLE SOPS

NN GA 104	Conflict of Interest and Financial Disclosure Requirements for Clinical Study Sites
NN GA 106	Publication Policy Development
NN GA 107	Data Sharing
NN GA 109	Sharing Data with Industry Collaborators
NN SM 601	Single Institutional Review Board (SIRB) Reliance Process
NN SM 602	Single Institutional Review Board Reporting

6. ATTACHMENTS AND REFERENCES

NN SS 401 – A	Document History

7. TERMS AND ABBREVIATIONS

The following terms and abbreviations are used in this document:

CCC	Clinical Coordinating Center at Massachusetts General Hospital
CSS	Clinical Study Site(s)
DCC	Data Coordinating Center at The University of Iowa
FDA	U.S. Food and Drug Administration
ICH	International Council for Harmonisation
MCTA	Master Clinical Trial Agreement
NEC	NeuroNEXT Executive Committee
PPI	Protocol Principal Investigator
RA	Reliance Agreement
SIRB	Single Institutional Review Board

8. SPECIFIC PROCEDURES

A. Site Selection

#	*Who*	*Task*	*Attachment / References*	*Related SOP*
1.	CSS	Prior to site selection, the CSS must confirm its interest in participation and willingness to cede review of the study to the SIRB.		NN SM 601 NN SM 602
2.	CSS	Must have executed MCTA and RA on file at CCC prior to consideration for site selection. Non-NN sites must provide in writing that they would be willing to enter into study specific CTA and RA prior to being considered for site selection. The CTA and RA for non-NN sites must be fully executed prior to site activation.		NN GA 104 NN GA 106 NN GA 107 NN GA 109 NN SM 601 NN SM 602
3.	NEC	Select sites for each Network study based on criteria stated in the Policy section of this SOP, and communicate final site selection to all interested CSS.		

B. Site Qualification

#	*Who*	*Task*	*Attachment / References*	*Related SOP*
1	NINDS	General site qualification is part of the NN grant review process. Sites awarded NN site grants have provided documentation of their training and qualification to participate is clinical trials across a spectrum of neurological disorders and diseases.		
2	PPI/NEC/DCC/CCC	During the site selection process sites provide information via study specific study site survey regarding training, qualifications and feasibility of performing as a participating site.		
3	DCC/CCC	A Site Initiation Webinar/Visit (SIW/SIV) is conducted for each CSS selected for each trial during with regulatory, SIRB, NeuroNEXT and protocol requirements are reviewed with CSS staff.		NN SS 402

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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: 2/14/2023 9:44:55 AM Viewed: 2/15/2023 1:45:38 PM Signed: 2/15/2023 1:48:08 PM
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Signer Events	Signature	Timestamp
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: 2/14/2023 9:44:57 AM Viewed: 2/14/2023 12:36:01 PM Signed: 2/14/2023 12:36:24 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), Logged in	 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: 2/14/2023 9:44:56 AM Viewed: 2/14/2023 9:45:44 AM Signed: 2/14/2023 9:46:13 AM
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Merit Cudkowicz cudkowicz.merit@mgh.harvard.edu Chief of Neurology Security Level: Email, Account Authentication (Required)	 DocuSigned by Merit Cudkowicz I approve this document 21-Feb-2023 | 8:01:48 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: 2/14/2023 9:44:57 AM Viewed: 2/21/2023 8:01:39 AM Signed: 2/21/2023 8:01:50 AM
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Stacey Grabert sgrabert@mgh.harvard.edu Director QA Stacey Grabert Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: 60CC52B0-747A-44E6-B220-8D8D880698C0 Using IP Address: 132.183.56.49 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 2/14/2023 9:44:57 AM Viewed: 2/22/2023 11:27:23 AM Signed: 2/22/2023 11:27:37 AM
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