NeuroNEXT Network

Standard Operating Procedure (SOP)

Site Selection and Qualification

Version 2.0

SOP NN SS 401

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September 21, 2016
Issue Date

October 21, 2016
Effective Date (*30 calendar days after the Issue Date*)

NN SS 401

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR SITE SELECTION AND QUALIFICATION

SOP: NN SS 401 Version No.: 2.0 Effective Date: 21Oct2016	SITE SELECTION AND QUALIFICATION	Supercedes Document: Version 1.0 Effective Date : 06May2012

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 Central Institutional Review Board (CIRB) 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. 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 CIRB RA with the CCC; and
- cede review for the study to the NeuroNEXT CIRB.

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 1996 ICH E6 Consolidated Guidance. 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 CIRB.

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	Central Institutional Review Board (CIRB) Reliance Process
NN SM 602	Central 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
CIRB	Central Institutional Review Board
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

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 CIRB.		NN SM 601 NN SM 602
2.	CSS	Must have executed MCTA and RA on file at CCC prior to consideration for site selection.		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	DCC/CCC	Perform site qualification visit (remotely or in person) prior to site participation in each study.		
2	DCC/CCC	Ensure that the investigator and his/her staff understand and accept: ➢ the roles and obligations as defined in the study contract and protocol; ➢ applicable regulatory requirements; and ➢ their responsibilities to the NeuroNEXT CIRB.		
3	DCC/CCC	Assess and verify that the investigator: ➢ meets experience and eligibility requirements; ➢ has sufficient time to complete the study; ➢ has support staff with the necessary training, experience, and credentials; and ➢ has facilities that are suitable to conduct the study.		

Attachment NN SS 401 - A. Document History

NeuroNEXT Network Standard Operating Procedure (SOP) Site Selection and Qualification SOP NN SS 401				
Version	**Description of Modification**	**Reason or Justification for Modification**	**Issue Date**	**Effective Date**
1.0	New	N/A	06Apr2012	06May2012
2.0	Clarified that the CCC participates in assessment and qualification of CSS. Minor edits and formatting corrections.	Updates for version 2.0	21Sep2016	21Oct2016