

NeuroNEXT Network

Standard Operating Procedure (SOP)

Proposal Review and Initial Feasibility or Suitability Assessment

Version 3.0

SOP NN PD 301

Originators: NeuroNEXT CCC and DCC Personnel


Reviewed and Approved by:

Signature and Date: <i>Christopher Coffey</i> <small>Electronically signed by: Christopher Coffey Reason: I approve this document Date: Jan 24, 2025 07:37 CST</small>	24-Jan-2025
Name and Title: Christopher S. Coffey, PhD (DCC PI)	
Signature and Date: <i>Merit Cudkowicz</i> <small>Electronically signed by: Merit Cudkowicz Reason: I approve this document Date: Dec 17, 2024 18:17 GMT-3</small>	17-Dec-2024
Name and Title: Merit E. Cudkowicz, MD MSc (CCC PI) or Aleks Videnovic, MD (CCC PI)	
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Name and Title: Marianne Chase, BA (CCC Senior Director of Clinical Trials Operations)	

NN PD 301

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR
PROPOSAL REVIEW AND INITIAL SUITABILITY OR FEASIBILITY ASSESSMENT

SOP: NN PD 301 Version No.: 3.0 Issue Date: 17 Dec 2024 Effective Date: 31 Dec 2024	PROPOSAL REVIEW AND INITIAL FEASIBILITY ASSESSMENT	Supersedes Document Version : 2.0 Effective Date: 15Apr2024
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Signature and Date: <i>Dixie Ecklund</i> <small>Electronically signed by: Dixie Ecklund Reason: I approve this document Date: Dec 17, 2024 11:25 CST</small> 17-Dec-2024
Name and Title: Dixie J. Ecklund, RN MSN MBA (DCC Associate Director)
Signature and Date:  <small>Electronically signed by: Stacey Grabert Reason: I approve this document Date: Dec 17, 2024 12:50 EST</small> 17-Dec-2024
Name and Title: Stacey Grabert, Pharm.D, MS, (CCC Director of Quality Assurance)
Signature and Date: <i>Joan Ohayon</i> <small>Electronically signed by: Joan Ohayon Reason: I approve this document Date: Jan 14, 2025 09:33 EST</small> 14-Jan-2025
Name and Title: Joan Ohayon, RN, MSN, CRNP, MSCN (NINDS, NeuroNEXT Program Official)

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1. POLICY

For OT: It is the policy of the NeuroNEXT Network that each proposal submitted to the Network that passes initial review by the National Institute of Neurological Disorders and Stroke (NINDS), is subsequently reviewed for suitability by the network. Suitability is determined via a site suitability questionnaire that informs such questions as preliminary site interest, potential for positive impact on the field of study related to the indication of the application, enthusiasm of the disease experts at each respective site, and rationale or feedback for responses. Answer summaries are submitted to NINDS as supplemental information for ESC prior to the Other Transaction (OT) Stage 1 Submission. The suitability review is NOT an evaluation of the scientific merit of a proposal.

For U44 (SBIR) grants: It is the policy of the NeuroNEXT Network that each proposal submitted to the Network under this grant mechanism that passes initial review by the NINDS is subsequently reviewed for feasibility by the network. The feasibility review should take into consideration issues such as availability of patient population within the network, availability of study drug, availability of any required equipment to conduct the study, potential regulatory issues, and any other relevant issues. The feasibility review is NOT an evaluation of the scientific merit of a proposal.

2. SCOPE

The policies and procedures described in this SOP apply to the NeuroNEXT Clinical Coordinating Center (CCC) and Data Coordinating Center (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 in the Network.

3. ROLES AND RESPONSIBILITIES

For OT:

The DCC or CCC PM group is responsible for creating and sending the questionnaire to network sites in collaboration with the DCC team lead and systems support, who create an online survey link for sites.

It is the responsibility of each NeuroNEXT Clinical Study Site (CSS), to complete each requested suitability questionnaire within the timeframe of the request.

The DCC Principal Investigator (DCC PI), or designee, is responsible for compiling the suitability summary from the site suitability questionnaire.

The NEC Chair is responsible for providing the suitability summary from the site suitability questionnaire to the NINDS for a given application.

Proposals that submit for OT stage 1 are not required to be suitable, but suitability must be submitted to NINDS. Additionally, Stage 1 approval must be obtained prior to preparing the proposal budget for Extramural Science Committee (ESC) review and Protocol Working Group (PWG) formation. See SOP NN PD 302.

For U44 (SBIR) grants: The NeuroNEXT Executive Committee (NEC) is responsible for reviewing proposals that NINDS, through initial review, deemed appropriate for the mission and goals of the Network.

The NEC is composed of the CCC PI, DCC PI, three NN Site PIs, two NN Site Program Managers (PMs), and Protocol PIs (PPIs) of each funded study being conducted by the Network. The NEC Chair is responsible for assigning one member of the NEC (NEC Reviewer) to complete a feasibility review of each proposal.

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The NEC Reviewer may work with the CCC to obtain information from each NeuroNEXT CSS that would assist in his/her ability to assess the feasibility of a proposal. If needed, the CCC project management group will request information from each CSS, collect and collate the information received, and provide this information to the NEC Reviewer prior to the NEC meeting where the proposal will be discussed.

It is the responsibility of each NeuroNEXT CSS to complete each requested feasibility questionnaires within the timeframe of the request.

The DCC Principal Investigator (DCC PI), or designee, is responsible for reviewing the statistical feasibility of the proposal.

The NEC Reviewer and DCC PI, or designee, are responsible for presenting their review of the proposal to the NEC, and the Committee will then vote on the feasibility of conducting the study through the Network. The NEC may deem a proposal feasible, feasible but requires revision of the study aims by the PPI with input from Network disease specialists prior to moving to PWG, or not-feasible as submitted. A proposal can be submitted a maximum of 3 times to the NEC for review.

In order for a vote to occur on any proposal, a quorum of NEC members who are eligible to vote must be present. A quorum consists of either the CCC PI and/or DCC PI and at least half of the other members eligible to vote. If a proposal under review is from a NEC member's CSS, that member may participate in the discussion but may not vote on the proposal. If a proposal is submitted by a NEC member, that member will recuse him/herself from the discussion and subsequent vote on that proposal.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 314.126	Adequate and Well-Controlled Studies
ICH E6 2.2, 2.4 – 2.6	The Principles of ICH GCP
ICH E6, 2.10, 2.11	The Principles of ICH GCP
ICH E6, 5.4	Trial Design
ICH E6, 5.23	Multicentre Trials
ICH E8	General Considerations for Clinical Trials (December 1997)
ICH E9	Statistical Principles for Clinical Trials (September 1998)
ICH E10	Choice of Control Group and Related Issues in Clinical Trials (May 2001)

5. REFERENCES TO OTHER APPLICABLE SOPS

NN PD 302	Protocol Working Group Formation and Proposal Development
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6. ATTACHMENTS AND REFERENCES

NN PD 301-A	Document History
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7. TERMS AND ABBREVIATIONS

The following terms and abbreviations are used in this document:

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CCC	Clinical Coordinating Center at Massachusetts General Hospital
CCC PI	Clinical Coordinating Center Principal Investigator
CSS	Clinical Study Site
DCC	Data Coordinating Center at The University of Iowa
DCC PI	Data Coordinating Center Principal Investigator
ESC	Extramural Science Committee
NEC	NeuroNEXT Executive Committee
NINDS	National Institute of Neurological Disorders and Stroke
OT	Other Transaction
PM	Program Manager
PPI	Protocol Principal Investigator
PWG	Protocol Working Group
SBIR	Small Business Innovation Research

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8. SPECIFIC PROCEDURES

A. NEC Assessment of Suitability for OTA Grants:

#	Who	Task	Attachment/ References	Related SOP
1	NEC Chair	Receive new proposals and communicate to the CCC and DCC teams if not aware already.		
2	CCC or DCC	Drafts and finalizes the suitability questionnaire		
3	DCC	Set up an online suitability survey and provide the survey link to the CCC for distribution		
4	CCC	, Distribute suitability questionnaire to each CSS with a proposal summary and 10 business day due date		
5	DCC	Collect and collate electronic responses and provide summary to NEC chair		
6	NEC Chair	Reviewing suitability results and providing the summary to NINDS		

B. NEC Assessment of Feasibility for U44 (SBIR) Grants

#	Who	Task	Attachment/ References	Related SOP
1	NEC Chair	Assign a NEC member to act as Reviewer to conduct the primary feasibility assessment. Assign the DCC PI or appropriate designee to assess the statistical feasibility of the proposal.		
2	NEC Reviewer	Assess the feasibility of conducting the proposed study through the Network, based upon availability of patient population, drug supply, ability of sites to conduct the study, and any other relevant factors.		
3	NEC Reviewer	Develop feasibility-related questions for CSS and communicate with CCC to request feasibility questionnaire be sent to CSS, as needed.		
4	CCC & DCC	When requested by a NEC Reviewer, CCC works with DCC to set up an online feasibility questionnaire, distribute feasibility questionnaire to each CSS, collect and collate responses and provide summary to NEC Reviewer prior to meeting when proposal is to be reviewed.		
5	NEC Reviewer	Complete feasibility form and present findings to NEC members and make recommendation regarding feasibility.		

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6	DCC PI	Assess the statistical feasibility of proposal and present the results to NEC members.		
7	NEC Member Submitting a Proposal	Recuse himself/herself from discussion and voting.		
8	NEC Member(s) from a CSS Submitting the Proposal under Review	Recuse themselves from voting.		
9	NEC Members	Vote on feasibility of each proposal, based upon relevant data and discussion, as long as a quorum is present (either the CCC PI or DCC PI and at least half of other committee members eligible to vote).		
10.	NEC Reviewer	Provide a brief summary of rationale for NEC decision.		
11.	NEC Chair	Communicates results of feasibility review to PPI.		
12.	CCC PI and DCC PI	Communicate status of each proposal to CCC and DCC representatives.		

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Attachment NN PD 301 - A. Document History

NeuroNEXT Network Standard Operating Procedure (SOP) Proposal Review and Initial Feasibility Assessment SOP NN PD 301					
Version	Description of Modification	Reason or Justification for Modification	Issue Date	Effective Date	Reviewer(s)
1.0	New	N/A	22Feb2023	08Apr2023	Catherine Gladden
2.0	Minor edits for clarity	Periodic Review	01Mar2024	15Apr2024	Preeti Paul
3.0	Major revisions for process change	Process update to include separate OTA and U44(SBIR) processes	17 Dec 2024	31 Dec 2024	Tania Leeder









NN PD 301 Proposal Review Initial Suitability or Feasibility v3.0_2024_1107














Final Audit Report


2025-01-24


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By:	Tania Leeder (tleeder@mgb.org)
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-  Document created by Tania Leeder (tleeder@mgb.org)
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-  Document emailed to Marianne Chase (mchase@mgh.harvard.edu) for signature
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