

NeuroNEXT Network

Standard Operating Procedure (SOP)




Proposal Review and Initial Feasibility Assessment

Version 2.0

SOP NN PD 301

Originators: NeuroNEXT CCC and DCC Personnel

Reviewed and Approved by:

Signature and Date:  <small>Electronically signed by: Christopher S. Coffey Reason: I approve this document Date: Mar 7, 2024 14:48 CST</small>		07-Mar-2024
Name and Title: Christopher S. Coffey, PhD (DCC Principal Investigator)		
Signature and Date:  <small>Electronically signed by: Merit Cudkowicz Reason: I approve this document Date: Feb 22, 2024 12:21 CST</small>		22-Feb-2024
Name and Title: Merit E. Cudkowicz, MD MSc (CCC Principal Investigator)		
Signature and Date:  <small>Electronically signed by: Marianne Chase Reason: I approve this document Date: Feb 22, 2024 14:57 EST</small>		22-Feb-2024
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 FEASIBILITY ASSESSMENT

SOP: NN PD 301 Version No.: 2.0 Issue Date: 01Mar2024 Effective Date: 15Apr2024	PROPOSAL REVIEW AND INITIAL FEASIBILITY ASSESSMENT	Supersedes Document Version : 1.0 Effective Date: 08Apr2023
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Signature and Date:*Dixie Ecklund*

Electronically signed by: Dixie Ecklund
Reason: I approve this document
Date: Feb 24, 2024 17:04 CST

24-Feb-2024

Name and Title: Dixie J. Ecklund, RN MSN MBA (DCC Associate Director)**Signature and Date:***Stacey Grabert*

Electronically signed by: Stacey Grabert
Reason: I approve this document
Date: Feb 22, 2024 13:52 EST

22-Feb-2024

Name and Title: Stacey Grabert, Pharm.D, MS, (CCC Director of Quality Assurance)**Signature and Date:***Joan Ohayon*

Electronically signed by: Joan Ohayon
Reason: I approve this document
Date: Mar 11, 2024 09:41 EDT

11-Mar-2024

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

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1. POLICY

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) and is subsequently reviewed and deemed feasible by the NEC will undergo review by the NINDS Extramural Science Committee (ESC) as deemed necessary by NINDS. The procedures outlined here for NEC and ESC review of each proposal have been developed in collaboration with the NINDS.

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

The NEC is composed of the CCC Principal Investigator (PI), DCC PI, three NN Site (NN) PIs, one NN Site Coordinator and Protocol PIs (PPI) of each funded study being conducted by the Network. The NEC is responsible for reviewing proposals that NINDS, through initial review, deemed appropriate for the mission and goals of the Network. The NINDS ESC is responsible for performing review of all proposals deemed necessary per NINDS guidelines.

The NEC Chair is responsible for assigning one member of the NEC (NEC Reviewer) to complete a feasibility review of each proposal. 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. This feasibility review is not an evaluation of the scientific merit of a proposal.

The NEC Reviewer may work with the CCC to obtain information from NeuroNEXT Clinical Study Sites (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 Clinical Study Site (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.

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Proposals are required to have both ESC and NEC approval prior to advancing to a Protocol Working Group (PWG), unless it is deemed by NINDS that the proposal does not require ESC review and approval.

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:

CCC	Clinical Coordinating Center at Massachusetts General Hospital
CCC PI	Clinical Coordinating Center Principal Investigator
DCC	Data Coordinating Center at The University of Iowa
DCC PI	Data Coordinating Center Principal Investigator
ESC	Extramural Science Committee
NEC	NeuroNEXT Executive Committee
PPI	Protocol Principal Investigator
PWG	Protocol Working Group

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8. SPECIFIC PROCEDURES

A. NEC Assessment of Feasibility

#	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	When requested by a NEC Reviewer, 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.		
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 brief summary of rationale for NEC decision.		
11.	NEC Chair	Communicate 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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B. ESC Review of Proposals

#	Who	Task	Attachment/ References	Related SOP
1.	NINDS Program Director	Schedule presentation of each Network proposal to the ESC, as needed.		
2.	NINDS Program Director	Communicate status of each proposal to CCC and DCC representative.		

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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









NN PD 301 Proposal Review Initial Feasibility and ESC Review v2.0 2feb2024 clean














Final Audit Report


2024-03-11

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-  Document created by Tania Leeder (tleeder@mgb.org)
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-  Document emailed to christopher-coffey@uiowa.edu for signature
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-  Document emailed to cudkowicz.merit@mgh.harvard.edu for signature
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-  Document emailed to Marianne Chase (mchase@mgh.harvard.edu) for signature
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Challenge: The user opened the agreement.
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-  Signer cudkowicz.merit@mgh.harvard.edu entered name at signing as Merit Cudkowicz
2024-02-22 - 6:21:06 PM GMT
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-  Stacey Grabert (SGrabert@mgh.harvard.edu) authenticated with Adobe Acrobat 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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-  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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Signature Date: 2024-03-11 - 1:41:53 PM GMT - Time Source: server- IP address: 72.83.187.43

 Agreement completed.

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