

# NeuroNEXT Network

## Standard Operating Procedure (SOP)




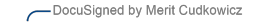





### Proposal Review and Initial Feasibility Assessment

Version 1.0

SOP NN PD 301

Originators: NeuroNEXT CCC and DCC Personnel

Reviewed and Approved by:

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| <b>Name and Title:</b> Christopher S. Coffey, PhD (DCC Principal Investigator)   |
| <b>Signature and Date:</b><br><br>   I approve this document<br>17-Feb-2023   1:47:28 AM EST<br>17-Feb-2023<br> |
| <b>Name and Title:</b> Merit E. Cudkowicz, MD MSc (CCC Principal Investigator)   |
| <b>Signature and Date:</b><br><br>   I approve this document<br>14-Feb-2023   9:47:08 AM EST<br>14-Feb-2023<br> |
| <b>Name and Title:</b> Marianne Chase, BA (CCC Senior Director of Clinical Trials Operations)  |

**Signature and Date:**

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*Dixie J Ecklund*

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

**Signature and Date:**

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*Stacey Grabert*

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

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*Joan Ohayon*

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

## NN PD 301

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

### 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.

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 |
|-----------|---|

#### 6. ATTACHMENTS AND REFERENCES

|             |                  |
|-------------|------------------|
| NN PD 301-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 |
| 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   |

#### 8. SPECIFIC PROCEDURES

##### A. NEC Assessment of Feasibility

| # | Who          | Task  | Attachment/<br>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.  |  |  |

## 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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ohayonj@ninds.nih.gov  
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Marianne Chase  
MCHASE@mgh.harvard.edu  
Sr Director, Clinical Trial Operations  
Insight OBO The Massachusetts General Hospital  
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*Marianne Chase*


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