NeuroNEXT Network

Standard Operating Procedure (SOP)

Protocol Working Group Formation, Extramural Science Committee Review, and Proposal Development

Version 3.0

SOP NN PD 302

Originators: NeuroNEXT CCC and DCC Personnel

Reviewed and Approved by:

Signature and Date: Christopher Coffey *Electronically signed by: Christopher Coffey Reason: I approve this document Date: Jan 24, 2025 07:36 CST* 24-Jan-2025
Name and Title: Christopher S. Coffey, PhD (DCC Principal Investigator)
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Name and Title: Merit E. Cudkowicz, MD MSc (CCC Principal Investigator) or Aleks Videnovic, MD (CCC Principal Investigator)
Signature and Date: Marianne Chase *Electronically signed by: Marianne Chase Reason: I approve this document Date: Dec 19. 2024 10:52 EST* 19-Dec-2024
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NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR PROTOCOL WORKING GROUP FORMATION AND PROPOSAL DEVELOPMENT

SOP: NN PD 302 Version No.: 3.0 Issue Date: 17 Nov 2024 Effective Date: 31 Dec 2024	PROTOCOL WORKING GROUP FORMATION AND PROPOSAL DEVELOPMENT	Supersedes Document : 2.0 Effective Date : 15Apr2024

Signature and Date:

Dixie Ecklund

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17-Dec-2024

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

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR PROTOCOL WORKING GROUP FORMATION AND PROPOSAL DEVELOPMENT

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1. POLICY

For OT: It is the policy of the NeuroNEXT Network that each proposal that is approved at OTA (Other Transaction Authority) Stage 1 and is deemed by the National Institute of Neurological Disorders and Stroke (NINDS) to be "suitable" for the NeuroNEXT Network will proceed to the formation of both the pre-award team with the goal of preparing and submitting for Extramural Science Committee (ESC) Review as needed, and the Protocol Working Group (PWG) whose goal is developing the protocol for full Stage 2 submission. Beyond ESC and protocol development, each of these groups, which make up the proposal team, prepare the proposal for the full OT submission by the CCC to Stage 2. The procedures outlined here for preparing for ESC, establishing a PWG, and developing the proposal were developed in collaboration with the National Institute of Neurological Disorders and Stroke (NINDS).

For U44(SBIR) Grants: It is the policy of the NeuroNEXT Network that each proposal that is deemed by the NINDS to be "suitable", be approved by the ESC (if needed), and proceed to a Protocol Working Group (PWG) that has been formed with the goal of developing the proposal into a full grant submission. The procedures outlined here are for submitting to ESC review, establishing a PWG and developing the proposal in collaboration with 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

For OT: The NINDS will provide notification to the NEC Chair and CCC PM team that an application has received for stage 1 approval. As needed, the proposal will move into preparation for an ESC submission. The PPI will work with the CCC PI to identify members for the PWG.

For proposals needing ESC submission, the proposal team will meet with the PPI to gather the necessary materials for submission. The first meetings of the PWG will establish the information needed to gather these materials. ESC materials will be handed off to the NINDS program officer no later than one week prior to the ESC meeting. These materials may include; a full study budget, budget justification, and other materials as requested by NINDS.

If a proposal does not require ESC approval, or if ESC approval has been obtained, the PWG is formed and begins work on the trial protocol.

For proposals approved at stage 1, but requiring additional revision of the study aims, the PPI will be notified that pre-PWG consultation with one or more disease specialists in the Network to revise the study aims will be required. The PWG will utilize information from the Proposal Concept form submitted at stage 1 to construct the first draft of the protocol.

Prior to the first full PWG meeting, appropriate members of the CCC and DCC will schedule a Stage 2 Proposal Kick-Off meeting teleconference with the PPI to provide guidance and review Network procedures. This meeting will review the curriculum for constructing the proposal protocol and the responsibilities of each team member in relation. In addition, a member of the CCC lead clinicians and DCC lead biostatisticians will communicate with the PPI to review the study aims and identify key items for discussion with the full PWG.

Each PWG will consist of the Protocol Principal Investigator (PPI), appropriate members of the PPI study team, appropriate members of the CCC and DCC including an available CCC Lead identified and an available DCC Lead

(biostatistician), a CCC Project Manager, appropriate subject matter experts, and a patient community advocate. PWG membership may vary depending on the needs of the study.

The CCC Project Manager is responsible for facilitating and participating in PWG meetings. The CCC PI may identify and invite appropriate members of the main PWG, CCC and/or DCC to serve on subgroups or subcommittees, as required by the project. Subgroups may include Study Design; Budget; Central Pharmacy and Laboratory; Recruitment, Retention and Diversity; and Regulatory/IND submission preparation. The CCC Project Manager also constructs the first draft of the protocol using the concept synopsis submitted in stage 1 and the NN Protocol Template (available on the public NeuroNEXT website). The PPI is responsible for reviewing the first full Protocol in accordance with the scheduled annotations and submitting it to the CCC PM for distribution to PWG members, prior to the first full PWG meeting. If additional revisions to the Protocol are indicated based on subsequent PWG discussion(s) the PPI will provide revised Protocols as indicated.

The CCC is responsible for working with the PPI and appropriate PWG members to develop the full protocol and working with the PPI, DCC, and vendors/subawards to develop the study budget for grant submission.

The CCC is responsible for developing the OT application and full budget with the input of the PPI and their team. The DCC and vendors/subawards provide their respective portions of the budget. The CCC and DCC leads will review components of the final grant application (i.e. Specific Aims, Research Strategy, Protocol) prior to submission, provide feedback, and communicate with the NEC regarding any concerns with providing a NEC letter of support for inclusion with the application. PWGs are disbanded once the final OT application has been submitted.

If after an OT application has been reviewed and not approved at Stage 2, the PWG may be reconvened, if the review summary statements raise specific points that require their assistance.

For U44 (SBIR) Grants:

Once a proposal is deemed suitable for the network, the proposal goes to the Network to begin budget development and PWG. Prior to the first full PWG meeting, appropriate members of the CCC and DCC schedule an Introduction to the Network teleconference with the PPI to provide guidance and review Network procedures. In addition, the CCC lead clinician and DCC lead biostatistician will communicate with the PPI to review the study aims and identify key items for discussion with the full PWG.

Each PWG will consist of the Protocol Principal Investigator (PPI), appropriate members of the PPI study team, appropriate members of the CCC and DCC, including a CCC Lead identified by the CCC PI (clinician) and a DCC Lead (biostatistician) identified by the DCC PI, a CCC Project Manager, appropriate subject matter experts, and a patient community advocate. PWG membership may vary depending on the needs of the study. A representative from the company will be included on the PWG, as a non-voting member.

The CCC Project Manager is responsible for facilitating and participating in PWG meetings. The CCC PI may identify and invite appropriate members of the main PWG, CCC and/or DCC to serve on subgroups or subcommittees, as required by the project. Subgroups may include Study Design; Budget; Central Pharmacy and Laboratory; Recruitment, Retention and Diversity; and Regulatory/IND submission preparation. The PPI is responsible for drafting a full Protocol preferably using the NN Protocol Template (available on the public NeuroNEXT website) and submitting it to the CCC PM for distribution to PWG members, prior to the first full PWG meeting. If additional revisions to the Protocol are indicated based on subsequent PWG discussion(s), the PPI will provide revised Protocols as indicated.

The PPI is responsible for working with the appropriate PWG members to develop the full protocol and working with the CCC and DCC to develop the study budget for grant submission.

The CCC and DCC are responsible for assisting the PPI with developing their grant application and full budget. The CCC and DCC leads review components of the final grant application (i.e. Specific Aims, Research Strategy, Protocol) prior to submission, provide feedback, and communicate with the NEC regarding any concerns with providing a NEC letter of support for inclusion with the application. PWGs are disbanded once the final grant application has been submitted.

After a grant application has been reviewed, the PWG may be reconvened, if the review summary statements raise specific points that require their assistance.

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 GA 102	Document Development and Change Control
NN PD 301	Proposal Review, Initial Feasibility Assessment and ESC Review
NN PM 502	Clinical Trial Budget 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
FDA	U.S. Food and Drug Administration
GCP	Good Clinical Practice
ICH	International Council for Harmonisation

IDE	Investigational Device Exemption
IND	Investigational New Drug application
OT	Other Transactions
PPI	Protocol Principal Investigator
PWG	Protocol Working Group

8. SPECIFIC PROCEDURES FOR OTA GRANTS

A. Creating a PWG

#	*Who*	*Task*	*Attachment/ References*	*Related SOP*
1.	CCC PI in consultation with PPI	Identify and invite appropriate members to serve on the PWG.		
2.	CCC PI or designee	Initiate scheduling of full PWG meetings and provide members with objectives.		
3.	CCC and DCC representatives	Conduct Introduction to the Network teleconference with PPI prior to first full PWG meeting.		
4.	PPI, CCC and DCC	Prior to full PWG, as needed, communicate regarding study aims and key items for full PWG discussion.		
5.	CCC PI or designee	Identify and invite appropriate members to serve on subgroups or subcommittees, as required by the project.		

B. Proposal Development

#	*Who*	*Task*	*Attachment/ References*	*Related SOP*
1.	CCC	Schedule initial PWG meeting, additional PWG meetings as needed, and appropriate subcommittee meetings.		
2.	DCC	Schedule study design subcommittee meetings.		
3.	PPI	Work with appropriate PWG members to refine and revise study objectives and statistical design parameters, as needed.		
4.	PPI	Work with appropriate PWG members to determine drug/pharmacy/central laboratory needs and issues for study, as needed.		

#	*Who*	*Task*	*Attachment/ References*	*Related SOP*
5.	PPI	Provide Schedule of Assessments and any other budgetary requirements for study to appropriate PWG members and assist in creation of draft study budget.		NN PM 502
6.	PPI	Once members of the PWG have agreed upon final study design, prepare a presentation of the study for the Network CSS		
7.	CCC	Schedule PPI presentation to the Network and notify all Network CSS		
8.	PPI	Develop study specific questionnaire, to be completed by each CSS, with questions related to feasibility and logistics of conducting the study at their CSS		
9.	CCC	Distribute study specific questionnaire and other required materials to each CSS		
10.	CCC	Collect all materials from CSS and provide information to PPI as agreed upon		
11.	CCC, DCC	Schedule and conduct calls with the PPI to provide guidance on the grant application process, including development of the detailed budget and justification.		
12.	PPI	Follow all Network guidelines in preparing the initial draft grant application, detailed budget and justification and provide them to appropriate members of the PWG and all NEC members for review		SOP 303
13.	CCC, DCC, and PWG	Review near final version of the Specific Aims, Research Strategy and Protocol, provide feedback to PPI, and communicate with NEC regarding any concerns with providing a NEC letter of support for inclusion with the application		
14.	CCC	Notify PWG members that their PWG has disbanded once final grant application is submitted		
15.	CCC and DCC	Once summary review statements are received on grant applications, work with the PPI to determine whether or not there are any specific points that require the PWG to reconvene		

9. SPECIFIC PROCEDURES FOR U44 (SBIR) GRANTS

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2.	CCC PI or designee	Initiate scheduling of full PWG meetings and provide members with objectives.		
3.	CCC and DCC representatives	Conduct Introduction to the Network teleconference with PPI prior to first full PWG meeting.		
4.	PPI, CCC, and DCC leads	Prior to full PWG, as needed, communicate regarding study aims and key items for full PWG discussion.		
5.	CCC PI or designee	Identify and invite appropriate members to serve on subgroups or subcommittees, as required by the project.		

B. Proposal Development

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Attachment NN PD 302 - A. Document History

NeuroNEXT Network Standard Operating Procedure (SOP) PWG Formation and Proposal Development SOP NN PD 302					
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	Edits for clarity	Periodic review	01Mar2024	15Apr2024	Preeti Paul
3.0	Revisions for process change	Process Update to include U44 and OTA	17 Nov 2024	31 Dec 2024	Tania Leeder

NN PD 302 PWG Formation ESC Submission and Proposal Development V3.0_2024_1107

Final Audit Report 2025-01-24

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By:	Tania Leeder (tleeder@mgb.org)
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Tania Leeder (tleeder@mgb.org) added alternate signer christopher-coffey@uiowa.edu. The original signer cscoffey@iowa.uiowa.edu can still sign.
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Signing reason: I approve this document

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Agreement completed.

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