NeuroNEXT Network

Standard Operating Procedure (SOP)

Protocol Working Group Formation and Proposal Development

Version 2.0

SOP NN PD 302

Originators: NeuroNEXT CCC and DCC Personnel

Reviewed and Approved by:

Signature and Date: Christopher S. Coffey *Electronically signed by: Christopher S. Coffey Reason: I approve this document Date: Mar 7. 2024 14:48 CST* 07-Mar-2024
Name and Title: Christopher S. Coffey, PhD (DCC Principal Investigator)
Signature and Date: Merit Cudkowicz *Electronically signed by: Merit Cudkowicz Reason: I approve this document Date: Feb 22, 2024 12:22 CST* 22-Feb-2024
Name and Title: Merit E. Cudkowicz, MD MSc (CCC Principal Investigator)
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NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR PROTOCOL WORKING GROUP FORMATION AND PROPOSAL DEVELOPMENT

SOP: NN PD 302 Version No.: 2.0 Issue Date: 01Mar2024 Effective Date: 15Apr2024	PROTOCOL WORKING GROUP FORMATION AND PROPOSAL DEVELOPMENT	Supersedes Document : 1.0 Effective Date : 08Apr2023

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Dixie Ecklund

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22-Feb-2024

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Joan Ohayon

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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 that is deemed by the NeuroNEXT Executive Committee (NEC) to be "feasible" and has been approved by the ESC (if needed), will 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 for establishing a PWG and developing the proposal were developed in collaboration with the National Institute of Neurological Disorders and Stroke (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 NeuroNEXT Executive Committee (NEC) is responsible for reviewing proposals that NINDS has deemed appropriate for the mission and goals of the Network, to determine if the proposal is "feasible" to be conducted in the Network. If the NEC determines that a proposal is feasible for the Network and it is approved, as needed, by the ESC, the CCC PI will work with the PPI to identify members for the PWG. For proposals deemed feasible, 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 PPI will be responsible for submitting a revised Proposal Concept form, reflecting the revisions discussed during the pre-PWG consultation period, to the CCC Project Manager (PM) for distribution to the full PWG prior to the first full PWG meeting.

Prior to the first full PWG meeting, appropriate members of the CCC and DCC will 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.

For proposals seeking U01 funding, representatives from industry will not be included on PWGs.

For protocols seeking U44 funding, 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 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 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
PPI	Protocol Principal Investigator
PWG	Protocol Working Group

8. SPECIFIC PROCEDURES

A. Creating a PWG

#	*Who*	*Task*	*Attachment/ References*	*Related SOP*
1.	CCC/DCC PI	For a proposal deemed feasible by the NEC, but requiring revision of study aims, notify the PPI that pre-PWG consultation with Network disease experts will be required prior to the first full PWG meeting.		
2.	PPI of proposals requiring pre-PWG consultation	Revise Protocol Concept form based on pre-PWG consultation and submit to CCC PM for distribution to PWG members prior to first full PWG meeting.		
3.	CCC PI in consultation with PPI	Identify and invite appropriate members to serve on the PWG.		
4.	CCC PI or designee	Initiate scheduling of full PWG meetings, and provide members with objectives.		
5.	CCC and DCC representatives	Conduct Introduction to the Network teleconference with PPI prior to first full PWG meeting.		
6.	PPI, CCC and DCC leads	Prior to full PWG, as needed, communicate regarding study aims and key items for full PWG discussion.		
6.	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.		

#	*Who*	*Task*	*Attachment/ References*	*Related SOP*
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.		
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 and DCC PWG leads	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		

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#	*Who*	*Task*	*Attachment/ References*	*Related SOP*
		whether or not there are any specific points that require the PWG to reconvene		

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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

NN PD 302 PWG Formation and Proposal Development V2.0 02feb2024 clean

Final Audit Report 2024-03-11

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