



# NeuroNEXT Network

## Standard Operating Procedure (SOP) Network Coordinating Center Capacity Version 2.0 SOP NN GA 108

Originators: NeuroNEXT CCC and DCC Personnel

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## NN GA 108

### NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR NETWORK COORDINATING CENTER CAPACITY

#### 1. POLICY

The CCC and DCC, in collaboration with NINDS, will evaluate and determine the Network Coordinating Center capacity for evaluating proposals, assisting Protocol Principal Investigators (PPIs) with protocol design/development and grant applications, and implementing funded studies. The capacity for the Coordinating Centers to perform their designated activities will continue to be evaluated on an ongoing basis, and the number, size, and complexity of future studies that are funded under the Network may be adjusted as necessary.

The CCC and DCC will evaluate Network Coordinating Center capacity in relation to the following criteria:

##### A. Number of proposals in the grant application phase

Applicants may submit proposals to NINDS during one of three grant cycles per year. In consultation with the CCC and DCC, the NINDS will evaluate and “batch” concept proposals and release them to the CCC/DCC for development within agreed upon timeframes, as needed.

##### B. Size and scope of studies being conducted

Studies conducted within the Network are Phase II trials. that can vary quite substantially in size and scope. In the case of a rare disease there is the potential to conduct a Phase II/III study if the premise is supported by NINDS. A Phase II/III would potentially be even more complex and require additional resources. For the purposes of determining Network Coordinating Center capacity and resource allocation requirements, proposed studies are classified according to their size and complexity. The following factors must be considered when evaluating size and scope of proposed studies:

- Number of subjects screened/enrolled
- Number of participating sites
- Length of study
- Intensity of visit schedule
- Complexity of intervention, including:
  - Drug distribution
  - Route of administration
  - Laboratory requirements
- Complexity related to outcome assessments, including:
  - Number of assessments
  - Requirements for EDC programming
  - Site training/certification
  - Study monitoring
- Complexity related to vendors, including:
  - Number of vendors
  - Site training/certification requirements
  - Requirements for data downloads
  - Impact on study monitoring
- Safety considerations, including:

- Known risks associated with intervention
- FDA regulated or IND/IDE exempt
- Extent and complexity of secondary and exploratory outcomes, including:
  - Number of secondary and exploratory outcomes
  - Types of analysis required for these outcomes.

Metrics and other criteria that are used to classify proposed studies as “small” or “large” are presented in Attachment B.

C. Resources required from the CCC and DCC to conduct “small” and “large” studies:

Assumptions that were made during the budgeting process for NeuroNEXT studies are presented in Attachment C, and were based on NINDS FOAs. The CCC and DCC infrastructure grants provide salary support for Network activities and support for some study-related activities. If a proposed study is characterized as “small” based on the criteria described in Attachment B and falls below a minimal threshold (e.g. non-interventional, surveillance /biomarker study with minimal data collection and no requirement for study monitoring), the CCC and DCC staff efforts may be assessed and reduced accordingly. If a proposed study is characterized as “large” based on the criteria described in Attachment B and falls above a maximum threshold for size or scope, the CCC and DCC staff efforts may be assessed and increased accordingly. Not including faculty and leadership effort, effort is allocated toward studies as described in Attachment D.

D. Studies conducted concurrently within the Network

Funding for study specific Network Coordinating Centers personnel is included in each study grant, as such the Network can sustain multiple concurrent funded studies. However, all pre-award activities (proposal development through release of Notice of Grant Award) are funded through infrastructure grants awarded separately to the Network Coordinating Centers.

E. Size and scope of potentially fundable studies and impact on Network capacity

As new studies are evaluated, feasibility conducted by the NeuroNEXT Executive Committee (NEC) will include consideration of the size and scope of the proposed study. As trials are completed, the Network Coordinating Centers will have the capacity to take on additional studies, dependent upon additional funding.

An additional evaluation of feasibility by the NEC will include consideration of whether the proposed trial can be completed within the funding period for the Network.

## 2. SCOPE

This SOP has been developed to be in alignment with federal regulations and Good Clinical Practices (GCP) as set forth in the 2016 Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2). 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 regulated by FDA and/or applicable review committees.

## 3. ROLES AND RESPONSIBILITIES

The CCC and DCC leadership team will communicate with NINDS leadership on an ongoing basis regarding the pipeline of proposal submissions, grant applications and funded grants to review network capacity issues that may arise. These communications may also be used by the External Oversight Board (EOB) convened by NINDS to oversee this project.

The EOB and NEC may evaluate the Network capacity proposals presented by the CCC, DCC, and NINDS leadership teams and offer strategies as to align goals between the FOA and the funding capabilities.

#### **4. APPLICABLE REGULATIONS AND GUIDELINES**

FDA                      FDAAA 801 - Food and Drug Administration Amendments Act of 2007

#### **5. REFERENCES TO OTHER APPLICABLE SOPS**

NN GA 105	Vendor Selection and Agreements
NN SS 401	Site Selection and Qualification
NN SS 402	Site Initiation Visits and Site Training
NN SS 403	Routine Monitoring Visits
NN SS 404	Site Performance Monitoring
NN SS 405	Study Closeout Visits
NN PM 502	Clinical Trial Budget Development
NN PM 504	Investigational Site Staff Training
NN PM 505	Investigational Product Management
NN PM 506	Site Invoicing and Payments
NN SM 601	Central Institutional Review Board (CIRB) Reliance Process
NN SM 603	Subject Eligibility and Enrollment
NN BIO 902	Statistical Analysis Plan Development
NN DM 1003	Case Report Form Development

#### **6. ATTACHMENTS AND REFERENCES**

NN GA 108 – A	Document History
NN GA 108 – B	Definitions of “Small” and “Large” NeuroNEXT Studies

#### **7. TERMS AND ABBREVIATIONS**

The following terms and abbreviations are used in this document:

CCC	Clinical Coordinating Center at Massachusetts General Hospital
CSS	Clinical Study Site
DCC	Data Coordinating Center at The University of Iowa
EOB	External Oversight Board
FTE	Full-time Equivalent
GCP	Good Clinical Practice
NEC	NeuroNEXT Executive Committee
NIH	National Institutes of Health
PPI	Protocol Principal Investigator
SOP	Standard Operating Procedure

## 8. SPECIFIC PROCEDURES

### A. Network Capacity Evaluation

#	Who	Task	Attachment/ Reference	Related SOP
1.	CCC and DCC	Assess overall Network Coordinating Center capacity and present potential strategies for optimization of Network efficiency to NINDS, the NEC, and the EOB for review.		
2.	CCC and DCC	Provide NEC members with periodic updates on Network Coordinating Center capacity to facilitate new proposal feasibility reviews.		
3.	CCC and DCC	Evaluate each new proposal to determine the appropriate study “size” based on criteria defined above and in Attachments B-D. After sample size and overall study design has been determined, communicate the determination to the NEC.		
4.	CCC and DCC PIs	Evaluate the CCC/DCC recommendation of study size based on criteria listed above and in Attachments B-D. Communicate to applicable NeuroNEXT PPIs any requirements for additional funding that are to be included in study-specific grant applications.		
5.	NINDS	May review CCC/DCC proposals for optimization of Network efficiency with regard to Network Coordinating Center capacity.		
6.	NINDS	“Batch” new proposals that are submitted to the Network as needed based upon Network Coordinating Center capacity.		
7.	EOB	May review proposals for optimization of Network efficiency and provide guidance on alignment of Network goals and funding capabilities.		

## Attachment NN GA 108 - Definitions of “Small” and “Large” NeuroNEXT Studies

### Network Capacity Worksheet

**PI Name:** [insert PPI name]

**Date:** [insert date form completed]

The CCC and DCC will evaluate the “network capacity” with relation to:

- Number of proposals in the grant application phase

There are 3 grant cycles that applicants may submit to NINDS (April, August and December). In consultation with the CCC and DCC, the NINDS will evaluate and “batch” concept proposals and release to the CCC/DCC within agreed upon timeframes, as needed.

- Size and scope of studies being conducted

All studies conducted within the network are phase 2 trials that can vary quite substantially with relationship to size and scope which impacts on the capacity of the network coordinating centers. The following must be considered when evaluating size and scope of studies:

- Number of subjects screened/enrolled
- # of participating sites
- Length of study
- Intensity of visit schedule
- Complexity of intervention, including:
  - Drug distribution
  - Route of administration
  - Laboratory requirements
- Complexity of outcome assessments, including:
  - Number of assessments
  - Requirements for EDC programming
  - Site training/certification
  - Study monitoring
- Complexity of vendors, including:
  - Number of vendors
  - Requirements for data downloads
  - Site training/certification
  - Study monitoring
- Safety considerations, including:
  - Known risks associated with intervention
  - FDA regulated or IND/IDE exempt

- Extent and complexity of secondary and exploratory outcomes, including:
  - Number of secondary and exploratory outcomes
  - Types of analysis required for these outcomes

For the purposes of the Network, we will define “small and “large” studies based on these criteria.

“Small” study			“Large” study		
Sample Size	<=100		Sample Size	>100	
# of sites	<=15		# of sites	>15	
Length of Study	2 years or less		Length of Study	Greater than 2 years	
Visit schedule	<= 12 visits		Visit schedule	>12 visits	
Complexity of intervention <ul style="list-style-type: none"> <li>• Route of administration</li> <li>• Drug distribution</li> <li>• Laboratory requirements</li> </ul>	Simple		Complexity of intervention <ul style="list-style-type: none"> <li>• Route of administration</li> <li>• Drug distribution</li> <li>• Laboratory requirements</li> </ul>	Complex	
Complexity of outcome assessments <ul style="list-style-type: none"> <li>• # of assessments</li> <li>• Training/Cert requirements</li> <li>• Requirement for EDC programming</li> <li>• Monitoring impact</li> </ul>	Simple		Complexity of outcome assessments <ul style="list-style-type: none"> <li>• # of assessments</li> <li>• Training/Cert requirements</li> <li>• Requirement for EDC programming</li> <li>• Monitoring impact</li> </ul>	Complex	•
Vendor Complexity <ul style="list-style-type: none"> <li>• # of vendors</li> <li>• Training/Cert requirements</li> <li>• Frequency of data downloads</li> <li>• Monitoring impact</li> </ul>	Simple		Vendor Complexity <ul style="list-style-type: none"> <li>• # of vendors</li> <li>• Training/Cert requirements</li> <li>• Frequency of data downloads</li> </ul>	Complex	•



			<ul style="list-style-type: none"> <li>Monitoring impact</li> </ul>		
<b>Safety Considerations</b> <ul style="list-style-type: none"> <li>Known risks</li> <li>FDA regulated or exempt</li> </ul>	Minimal risk	•	<b>Safety Considerations</b> <ul style="list-style-type: none"> <li>Known risks</li> <li>FDA regulated or exempt</li> </ul>	More than minimal risk	•
<b>Extent of secondary and exploratory outcomes</b> <ul style="list-style-type: none"> <li>Number</li> <li>Type of analysis</li> </ul>	Minimal		<b>Extent of secondary and exploratory outcomes</b> <ul style="list-style-type: none"> <li>Number</li> <li>Type of analysis</li> </ul>	Extensive	•
Total checked =			Total checked =		

If a study is evaluated as meeting 5 of 9 of the criteria within the “small” study category, it will be considered a small study. Alternatively, if it meets 5 of the 9 criteria within the “large” study category, it will be considered a large study.

- Resources required from the CCC and DCC to conduct “small” and “large” studies:

The CCC and DCC infrastructure grants provide salary support for network as well as study-related activities. The budgetary models were based on the assumptions stated above of no more than 3 concurrent “small” studies at one time. If there is a study that is characterized as a “small” study, based on the criteria above, which falls below a minimal threshold (e.g. non-interventional, surveillance /biomarker study with minimal data collection and no requirement for study monitoring), the CCC and DCC staff efforts may be assessed and reduced accordingly. Not including faculty and leadership effort, current funding results in effort allocated towards studies as below:

DCC	Small Study effort	Large Study effort	CCC	Small Study effort	Large Study effort
DCC IT	0.4 FTE	0.5 FTE	CCC Project Manager	0.50 FTE	1.0 FTE
DCC Data Management	0.45 FTE	0.5 FTE	CCC Assistant Project Manager	0.50 FTE	1.0 FTE
DCC Biostat	0.45 FTE	0.5 FTE	CCC Grant Administrator	0.25 FTE	0.25 FTE
DCC Protocol Coordinator/Study Monitor	0.5 FTE	1.1 FTE	CCC Administrative Assistant	0.25 FTE	0.25 FTE
DCC Data Sharing	0.2 FTE	0.2 FTE	Quality Assurance	0.25 FTE	0.50 FTE

DCC Research Support	0.05 FTE	0.1 FTE			
Total FTE	2.05 FTE	2.9 FTE		1.75 FTE	3.0 FTE

#### Length of grant and recruitment:

Total participants =

Number of participating sites =

Startup =

Recruitment =

Follow up=

Close out=

Screen failure rate

Length of Participants" active" on the study=

#### Study Design and Outcomes

Study Title

Objectives

Primary aim of the trial:

Secondary aims:

Hypothesis:

Design and Outcomes

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Certified Delivery Events	Status	Timestamp
Carbon Copy Events	Status	Timestamp
Witness Events	Signature	Timestamp
Notary Events	Signature	Timestamp
Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	2/13/2023 8:23:22 AM
Certified Delivered	Security Checked	2/22/2023 11:34:43 AM
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