

NeuroNEXT Network

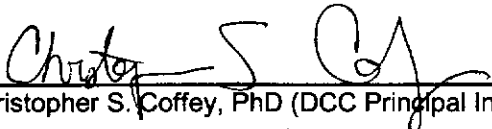
Standard Operating Procedure (SOP) Network Coordinating Center Capacity

Version 1.0

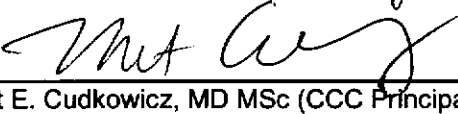
SOP NN GA 108

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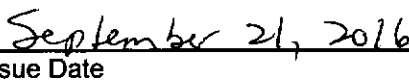
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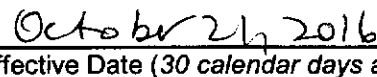
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Issue Date



Effective Date (30 calendar days after the Issue Date)

NN GA 108

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR NETWORK COORDINATING CENTER CAPACITY

SOP: NN GA 108 Version No.: 1.0 Effective Date: 21Oct2016	NETWORK COORDINATING CENTER CAPACITY	Supersedes Document: N/A Effective Date: N/A
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1. POLICY

The NIH Funding Opportunity Announcements (FOA) for the NeuroNEXT Clinical Coordinating Center (CCC) and Data Coordinating Center (DCC) were issued in December 2010. Each FOA described that the “network will provide a robust, standardized, and accessible infrastructure to facilitate rapid development and implementation of protocols in neurological disorders affecting adult and/or pediatric populations”. Moreover, the FOA described that, “Over a 7-year period, the network will conduct approximately 5 – 7 clinical research projects..”, and stated, “the exact number of protocols supported in the 7-year program will depend on the nature and extent of the investigations proposed and the availability of funds”.

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. As the Network continues to develop, the capacity for the Coordinating Centers to perform their designated activities will continue to be evaluated, 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, with submission dates in April, August, and December. 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

All studies conducted within the Network are Phase II trials that can vary quite substantially in size and scope. 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 as well as study-related activities. The budgetary models that are currently implemented were based on the assumptions of no more than 3 concurrent “small” studies at one time. 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

Based on Coordinating Center funding from the initial NIH infrastructure grants, the Network has the capacity to conduct 2 “small” studies and 1 “large” study concurrently, or up to 4 “small” studies concurrently.

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 as described in Section 1.D above, 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 7 years of funding, as described in the initial FOA.

2. SCOPE

This SOP has been developed to be in alignment with federal regulations and Good Clinical Practices (GCP) as set forth in the 1996 ICH E6 Consolidated Guidance. 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 work with NINDS leadership to develop a definition of “network capacity” to ensure that the Network meets the aims defined in the FOA and those that will be used by the External Oversight Board (EOB) convened by NINDS to oversee this project.

The EOB and NEC will 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
NN GA 108 – C	Budgeting Considerations for “Small” and “Large” NeuroNEXT Studies
NN GA 108 – D	Allocation of Effort for “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	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	Review proposals for optimization of Network efficiency and provide guidance on alignment of Network goals and funding capabilities.		

Attachment NN GA 108 - A. Document History

NeuroNEXT Network Standard Operating Procedure (SOP) Network Coordinating Center Capacity SOP NN GA 108				
Version	Description of Modification	Reason or Justification for Modification	Issue Date	Effective Date
1.0	New	N/A	21Sep2016	21Oct2016