

NeuroNEXT Network

Standard Operating Procedure (SOP)


Vendor Selection and Agreements

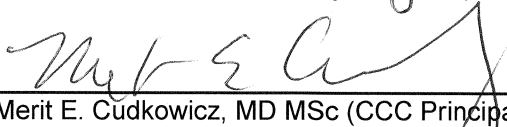
Version 1.0

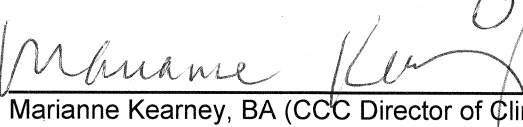
SOP NN GA 105

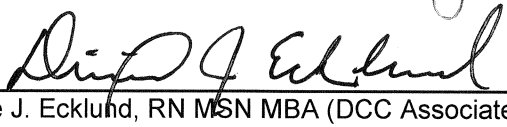
Originators: NeuroNEXT CCC and DCC Personnel

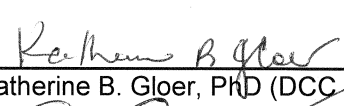
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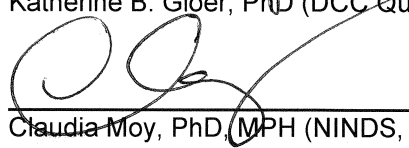

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NN GA 105

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR VENDOR SELECTION AND AGREEMENTS

SOP: NN GA 105 Version No.: 1.0 Effective Date: [insert]	VENDOR SELECTION AND AGREEMENTS	Supercedes Document: N/A Effective Date : NA
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1. POLICY

The NeuroNEXT Protocol Principal Investigator (PPI) / Sponsor, Clinical Coordinating Center (CCC) and Data Coordinating Center (DCC) may require the services of an outside contractor to perform such activities as:

- conducting required laboratory testing (contract laboratory);
- conducting investigational product labeling and distribution (central pharmacy);
- manufacturing product components or finished products (contract manufacturer); and
- providing consulting services (central ECG or imaging analysis).

The NeuroNEXT Network has established the following preferred vendor relationships. All projects are encouraged to utilize these vendors, as applicable.

- Central Laboratory: University of Rochester Medical Center, Clinical Trial Central Laboratories (CTCL)
- Central Pharmacy: University of Rochester Medical Center, Clinical Materials Services Unit (CMSU)
- Contract Manufacturer: University of Iowa Pharmaceuticals (UIP)

When any other outside vendor is used to provide services, the PPI, CCC and/or DCC will perform a qualification check to ensure that the vendor complies with regulations that relate to the services delegated, and that the vendor has the requisite skills and capabilities to perform the work. If appropriate, the PPI, CCC and/or DCC may conduct an audit or review of the proposed vendor before a contract is signed.

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 PPI / Sponsor are ultimately responsible for all research-related work conducted on their behalf by a vendor, and may transfer responsibility of any or all obligations or functions for conducting human subject research to a vendor after determining the vendor has the requisite skills, facilities, and resources to conduct the contracted activities, and with appropriate documentation of which activities are to be delegated.

Vendor Agreements for services by NeuroNEXT Central Pharmacy or Central Laboratory (University of Rochester) preferred vendors, will be established per study between the vendor and the CCC. Vendor Agreements for services by the NeuroNEXT Contract Manufacturer preferred vendor or any other vendor for study drug supply will be between the vendor and the PPI. Vendor Agreements for other vendors will be established between the vendor and either the PPI Institution, the CCC or the DCC, with the decision being made on a per study basis for each vendor. Vendor Agreements established between a vendor and the PPI Institution will follow all applicable Institutional vendor selection policies and procedures; those established between a vendor and the CCC, will follow all applicable Massachusetts General Hospital Institutional vendor selection policies and procedures and those

between the vendor and the DCC will follow all applicable University of Iowa Institutional vendor selection policies and procedures.

In the event the protocol requires that the vendor's own procedures are to be used in the conduct of contracted activities, the party responsible for the subcontract is responsible for verifying that the vendor's SOPs are adequate and in harmony and compliance with NeuroNEXT Network SOPs.

The responsibility to conduct any or all of these activities may be delegated at the discretion of the Sponsor to the NeuroNEXT CCC and/or DCC or to their subcontractors. Those individuals and entities take on responsibility for meeting regulatory requirements on behalf of the Sponsor, but the Sponsor has the ultimate responsibility and must therefore, supervise those delegated activities effectively.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.50	General Responsibilities of Sponsors
21 CFR 312.52	Transfer of Obligations to a Contract Research Organization
ICH E6, 5.1	Quality Assurance and Quality Control
ICH E6, 5.2	Contract Research Organizations
ICH E6, 5.5	Trial Management, Data Handling, Recordkeeping, and Independent Data Monitoring Committees
ICH E6, 5.7	Allocation of Duties and Functions

5. REFERENCES TO OTHER APPLICABLE SOPS

NN GA 101	Development and Maintenance of SOPs
NN GA 102	SOP Training
NN RA 202	Trial Master File Maintenance
NN PM 501	Communications

6. ATTACHMENTS AND REFERENCES

NN GA 105 – A	Document History
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7. TERMS AND ABBREVIATIONS

The following terms and abbreviations are used in this document:

CCC	Clinical Coordinating Center at Massachusetts General Hospital
DCC	Data Coordinating Center at The University of Iowa
FDA	U.S. Food and Drug Administration
ICH	International Conference on Harmonisation
PPI	Protocol Principal Investigator
SOP	Standard Operating Procedure
PWI	Project Work Instructions

8. SPECIFIC PROCEDURES

A. Vendor Requirements

#	Who	Task	Attachment / References	Related SOP
1.	PPI / Sponsor and CCC / DCC designees	Determine the need for a vendor for particular goods or service.		
2.	PPI / Sponsor and CCC / DCC designees	Determine if each vendor will establish a subcontract with the PPI Institution or CCC for services.		
3.	PPI / Sponsor and CCC / DCC designees	The responsible party follows all applicable institutional vendor selection and contracting policies and procedures.		

B. Regulatory Aspects

#	Who	Task	Attachment / References	Related SOP
1.	PPI/ Sponsor and/or CCC / DCC designees	Establish a file of acceptable vendors (based on prior performance or recent assessments) for key activities.		
2.	PPI/ Sponsor and/or CCC / DCC designees	Review applicable regulations that pertain to conduct and completion of key activities specified in the list of deliverables.		
3.	PPI/ Sponsor and/or CCC / DCC designees	Through the contractual process, ensure that the prospective vendor has the skills, facilities and resources to complete the activities in compliance with existing regulations.		

C. Vendor Evaluations

#	Who	Task	Attachment / References	Related SOP
1.	PPI/ Sponsor and/or CCC / DCC designees	The responsible party will assign a knowledgeable and qualified individual to evaluate the prospective vendor.		
2.	PPI/ Sponsor and/or CCC / DCC designees	If applicable, the responsible party will assess vendor's compliance with Good Laboratory Practice (GLP), Quality System regulation and GCP.		
3.	PPI/ Sponsor and/or CCC / DCC designees	If the vendor's own SOPs are to be used in the conduct of delegated activities, the responsible party will review the vendor's SOPs for adequacy and regulatory compliance.		