

NeuroNEXT Network

Standard Operating Procedure (SOP)

Vendor Selection and Agreements

Version 2.0

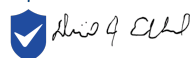
SOP NN GA 105

Originators: NeuroNEXT CCC and DCC Personnel

Reviewed and Approved by:

Signature and Date:   I approve this document 14-Feb-2023 12:46:44 PM PST 14-Feb-2023 <small>C68AC8DD80334CF982AED1200765F147</small>
Name and Title: Christopher S. Coffey, PhD (DCC Principal Investigator)
Signature and Date:   I approve this document 13-Feb-2023 8:23:13 AM EST 13-Feb-2023 <small>9F8FE4180E504C6AB0A67B835E80C644</small>
Name and Title: Merit E. Cudkowicz, MD MSc (CCC Principal Investigator)
Signature and Date:   I approve this document 13-Feb-2023 8:50:19 AM EST 13-Feb-2023 <small>58FE690F6BCA4F2390E3DA15BCE3F578</small>
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Name and Title: Stacey Grabert, Pharm.D, MS, (CCC Director of Quality Assurance)

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

**NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR
VENDOR SELECTION AND AGREEMENTS**

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);
- providing consulting services (central ECG or imaging analysis)
- providing on-site study monitoring services

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

- Central Laboratory: ACM Global Laboratory preferred vendor
- Central Pharmacy: University of Rochester Medical Center, Clinical Materials Services Unit (CMSU)
- Contract Manufacturer: University of Iowa Pharmaceuticals (UIP)
- Contract On-Site Monitoring: Barrows Neurological Institute

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 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 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 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 and documenting 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

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

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, CCC or DCC 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	If applicable, establish or review 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 described in the Scope of Work document.		
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 and within defined timelines.		

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 and document the review.		


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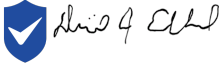
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ohayonj@ninds.nih.gov
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Joan Ohayon

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Marianne Chase
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Marianne Chase

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