NeuroNEXT Network

Standard Operating Procedure (SOP)

Vendor Selection and Agreements

Version 3.0

SOP NN GA 105

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: Feb 23, 2024 13:48 CST* 23-Feb-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 12:14 CST* 22-Feb-2024
Name and Title: Merit E. Cudkowicz, MD MSc (CCC Principal Investigator)
Signature and Date: Marianne Chase *Electronically signed by: Marianne Chase Reason: I approve this document Date: Feb 22. 2024 12:56 EST* 22-Feb-2024
Name and Title: Marianne Chase, BA (CCC Senior Director of Clinical Trials Operations)

NN GA 105
NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR VENDOR SELECTION AND AGREEMENTS

SOP: NN GA 105 Version No.: 3.0 Issue Date: 01Mar2023 Effective Date: 15Apr2024	VENDOR SELECTION AND AGREEMENTS	Supersedes Document Version : 2.0 Effective Date : 08Apr2023

Signature and Date:

Dixie Ecklund

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24-Feb-2024

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22-Feb-2024

Name and Title: Stacey Grabert, Pharm.D, MS, (CCC Director of Quality Assurance)

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Joan Ohayon

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Date: Mar 11, 2024 09:40 EDT

11-Mar-2024

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

NN GA 105
NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR VENDOR SELECTION AND AGREEMENTS

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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);
- 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)

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

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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.		

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#	***Who***	***Task***	***Attachment / References***	***Related SOP***
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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Attachment NN GA 105 - A. Document History

NeuroNEXT Network Standard Operating Procedure (SOP) **Vendor Selection and Agreements** **SOP NN GA 105**					
Version	**Description of Modification**	**Reason or Justification for Modification**	**Issue Date**	**Effective Date**	**Reviewer(s)**
1.0	New	N/A	22Mar2012	21Apr2012	N/A
1.0	Reviewed – no changes (2016)	N/A	22Mar2012	21Apr2012	N/A
2.0	Updated “1996 ICH E6 Consolidated Guidance” to “2016 Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)” Updated signature block to accommodate for electronic signatures. Additional minor updates throughout.	Updated for version 2.0	22Feb2023	08Apr2023	Catherine Gladden
3.0	Added reference to FDA BIMO Manual: SPONSORS AND CONTRACT RESEARCH ORGANIZATIONS: 7348.810	Periodic Review	0Mar2024	15Apr2024	Preeti Paul

NN GA 105 Vendor Selection and Agreements v3.0 clean

Final Audit Report 2024-03-11

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Tania Leeder (tleeder@mgb.org) added alternate signer ecklundd@uiowa.edu. The original signer dixie-ecklund@uiowa.edu can still sign.

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Signature Date: 2024-03-11 - 1:40:46 PM GMT - Time Source: server- IP address: 72.83.187.43

Agreement completed.

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