NeuroNEXT Network

Standard Operating Procedure (SOP)

Conflict of Interest and Financial Disclosure Requirements for Clinical Study Sites

Version 3.0

SOP NN GA 104

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
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NN GA 104
NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR CONFLICT OF INTEREST AND FINANCIAL DISCLOSURE REQUIREMENTS FOR CLINICAL STUDY SITES

SOP: NN GA 104 Version No.: 3.0 Issue Date: 01Mar2024 Effective Date: 15Apr2024	Conflict of Interest and Financial Disclosure Requirements for Clinical Study Sites	Supersedes Document Version : 2.0 Effective Date : 08Apr2023

Signature and Date:

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22-Feb-2024

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11-Mar-2024

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NN GA 104
NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR CONFLICT OF INTEREST AND FINANCIAL DISCLOSURE REQUIREMENTS FOR CLINICAL STUDY SITES

SOP: NN GA 104 Version No.: 3.0 Issue Date: 01Mar2024 Effective Date: 15Apr2024	Conflict of Interest and Financial Disclosure Requirements for Clinical Study Sites	Supersedes Document Version : 2.0 Effective Date : 08Apr2023

1. POLICY

It is the Policy of the NeuroNEXT network that all entities and individuals participating in a NeuroNEXT trial must be compliant with U.S. Public Health Service and Food and Drug Administration (FDA) regulations pertaining to objectivity in research, and with relevant requirements of the NeuroNEXT Single IRB (SIRB) regarding protection of human subjects.

2. SCOPE

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 Clinical Study Sites (CSS), NeuroNEXT investigators, staff, subcontractors, or other entities associated with the NeuroNEXT Network who manage, oversee, or conduct research through the Network.

3. ROLES AND RESPONSIBILITY

A. INSTITUTIONAL RESPONSIBLITES AND PROCEDURES UNDER PUBLIC HEALTH SERVICE REGULATIONS:

a. GOVERNING REGULATIONS: Title 42 Code of Federal Regulations (CFR) Part 50 Subpart F and 45 CFR Part 94 (“Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors”) apply to all Institutions applying for, or receiving funds through, the NeuroNEXT network, with the exception of SBIR Program Phase I applicants. Effective no later than August 24, 2012, the applicable regulations shall be Title 42 CFR Part 50 Subpart F “Promoting Objectivity in Research” and 45 CFR Part 94 “Responsible Prospective Contractors” as published in the Federal Register, Vol. 76, No. 165, pp. 5236 et seq. on August 25, 2011. (Hereinafter, “Regulations” refers to either the current or revised regulations, as applicable.)

b. APPLICABLE POLICY AND IMPLEMENTATION:

i. Each Clinical Study Site (CSS) shall have, or be subject to, a policy on financial conflicts of interest that complies with the Regulations and shall be responsible for fulfilling its obligations under the Regulations.

ii. In the event that a CSS does not itself have a compliant policy, it shall so inform the CCC prior to the CCC agreeing to transfer funds to said CSS and the CCC shall confer with the NeuroNEXT Network Conflicts of Interest Committee to determine the policy applicable to the otherwise non-compliant site.

c. CERTIFICATION AND REPORTING: The following procedures shall be followed with respect to certification of compliance with the Regulations and reporting of any identified financial conflict of interest as defined by the Regulations (“FCOI”):

i. Each CSS that is a prime recipient Institution (“Protocol Institution”):

1. Shall certify to NINDS its compliance with the Regulations in its application for NeuroNEXT grant funding; and

2. Shall report, at such time and with such information as required by the Regulations, to NINDS each of its identified FCOIs.

ii. With respect to a CSS that is not a Protocol Institution:

1. If the CSS is a member of the NeuroNEXT Network ("Network CSS"), it

   a. Shall have certified in its Master Clinical Trial Agreement (MCTA) with the CCC that it is in compliance with the Regulations, and shall remain so throughout its participation in the Network;

   b. Shall be reminded via the NeuroNEXT website through which the CSS enters data for a NeuroNEXT clinical study that the CSS's participation in that study is subject to the terms of the MCTA, and therefore entering of data into the NeuroNEXT website by the CSS shall be evidence of the CSS's compliance with all regulatory requirements in connection with the specific study; and

   c. Shall report, at such time and with such information as required by the Regulations, to NINDS each of the Network CSS's identified FCOIs.

2. If the CSS is not a member of the NeuroNEXT network ("Non-Network CSS"), but has a policy that complies with the Regulations, it:

   a. Shall certify to the Protocol Institution the Non-Network CSS's compliance with the Regulations no later than the time of the Protocol Institution's application for NeuroNEXT grant funding;

   b. Shall be reminded via the NeuroNEXT website through which the CSS enters data for a NeuroNEXT clinical study that the CSS's participation in that study is subject to the terms of the subcontract, and therefore entering of data into the NeuroNEXT website by the CSS shall be evidence of the CSS's compliance with all regulatory requirements in connection with the specific study; and

   c. Shall enter into such agreement with the CCC regarding reporting of FCOI's as is required under the Regulations pursuant to 50.604(c); and

   d. Shall report to the Protocol Institution, at such time and with such information as required by the aforementioned agreement and in accordance with the Regulations, each of the Non-Network CSS's identified FCOIs.

3. If the CSS is a Non-Network CSS that does not have a policy that complies with the Regulations ("Non-Compliant CSS"), it:

   a. Shall notify the CCC during negotiation of the subcontract between the Non-Network CSS and the CCC

b. Shall be reminded via the NeuroNEXT website through which the CSS enters data for a NeuroNEXT clinical study that the CSS's participation in that study is subject to the terms of the subcontract, and therefore entering of data into the NeuroNEXT website by the CSS shall be evidence of the CSS's compliance with all regulatory requirements in connection with the specific study; and

c. Agree to comply with such policy as the CCC, together with the NeuroNEXT Network Conflicts of Interest Committee, shall determine is the applicable policy; and

d. Enter into such agreement with the relevant institution regarding reporting of significant financial interests as is required under the Regulations pursuant to 50.604(c); and

e. Shall report to the relevant institution, at such time and with such information as required by the aforementioned agreement and in accordance with the Regulations, all significant financial interests of the Non-Network CSS investigators.

B. COMPLIANCE WITH FDA FINANCIAL DISCLOSURE REQUIREMENTS:
The IND/IDE sponsor of a Network study that is covered by the FDA regulations regarding Financial Disclosure by Clinical Investigators, 21 CFR Part 54, is responsible for obtaining and maintaining documentation of financial information from clinical investigators in compliance with 21 CFR 312.53 and 21 CFR 812.43, as applicable. The NeuroNEXT CCC may, upon request, assist Protocol Principal Investigators (PPI) who are IND/IDE sponsors with their implementation of these requirements.

C. PROVISION OF COI INFORMATION TO THE NeuroNEXT Single IRB:
Each CSS will be responsible for providing to the NeuroNEXT Single IRB (via the CCC) in connection with each Network study the information regarding its investigator conflicts of interest analysis required by the NeuroNEXT Central Institutional Review Board Authorization Agreement (Reliance Agreement).

D. RESOURCES:
The Network Committee on Conflicts of Interest shall be a resource available to each CSS and to any Investigator participating in a Network study with respect to compliance with this SOP.

4. APPLICABLE REGULATIONS AND GUIDELINES

42 CFR 50 Subpart F	Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought
45 CFR 92	Uniform Administrative Requirements for Grants and Cooperative Agreements to State, Local, and Tribal Governments
21 CFR 54	Financial Disclosure by Clinical Investigators

21 CFR 812.43	Selecting Investigators and Monitors
21 CFR 312.53	Selecting Investigators and Monitors

5. REFERENCES TO OTHER APPLICABLE SOPS

None

6. ATTACHMENTS AND REFERENCES

NN GA-104 - A Document History

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7. TERMS AND ABBREVIATIONS

The following terms are used in this document:

CCC	NeuroNEXT Clinical Coordinating Center at Massachusetts General Hospital
CFR	Code of Federal Regulations
CSS	Clinical Study Site that conducts research for a NeuroNEXT protocol
DCC	NeuroNEXT Data Coordinating Center at The University of Iowa
FCOI	Financial Conflict of Interest
FDA	US Food and Drug Administration
IND/IDE	Investigational New Drug Application/ Investigational Device Exemption
MCTA	Master Clinical Trial Agreement
Network CSS	CSS that is within the NeuroNEXT Network
NeuroNEXT PI	Principal Investigator who has been awarded the NeuroNEXT site (infrastructure) grant and has oversight over all NeuroNEXT projects at a Clinical Study Site
NINDS	National Institute of Neurological Disorders and Stroke
Non-Compliant CSS	CSS that is not within the NeuroNEXT Network, and does not have a policy that complies with the Regulations
Non-Network CSS	CSS that is not within the NeuroNEXT Network, and does have a policy that complies with the Regulations
PPI	Protocol Principal Investigator who is responsible for the implementation and conduct of a specific NeuroNEXT protocol at a Clinical Study Site
Protocol Institution	Institution awarded grant for a specific NeuroNEXT protocol/study
SIRB	NeuroNEXT Single Institutional Review Board

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8. SPECIFIC PROCEDURES

A. Certification and Reporting

#	*Who*	*Task*	*Attachment/ Reference*	*Related SOP*
1.	Protocol Institution	Certify to NINDS its compliance with Regulations in grant application		
2.	Protocol Institution	Report to NINDS each of its identified FCOIs, in accordance with Regulations		
3.	Network CSS	Certify in MCTA with CCC, compliance with Regulations throughout participation in the Network		
4.	Network CSS	Be reminded that study data entry shall be evidence of CSS compliance with all regulatory requirements in connection with the study		
5.	Network CSS	Report to NINDS each of its identified FCOIs, in accordance with Regulations		
6.	Non-Network CSS that is not a Protocol Institution, but has policy that complies with Regulations	Certify to Protocol Institution, compliance with Regulations prior to grant application		
7.	Non-Network CSS that is not a Protocol Institution, but has policy that complies with Regulations	Enter into agreement with CCC as required under Regulations		
8.	Non-Network CSS that is not a Protocol Institution, but has policy that complies with Regulations	Report to CCC each of its identified FCOIs, in accordance with Regulations		
9.	Non-Network CSS that is not a Protocol Institution, and does NOT have a policy that complies with Regulations	Notify the CCC during negotiation of the subcontract between the non-Network CSS and the CCC		
10.	Non-Network CSS that is not a Protocol Institution, and does NOT have a policy that complies with Regulations	Agree to comply with such policy as the CCC, together with Committee on Conflicts of Interest, shall determine is applicable to the policy		

#	Who	Task	Attachment/ Reference	Related SOP
11.	Non-Network CSS that is not a Protocol Institution, and does NOT have a policy that complies with Regulations	Enter into agreement with relevant institution as required under Regulations		
12.	CCC	Certify to Protocol Institution, compliance with Regulations at the time of grant application		
13.	CCC	Report to NINDS each of its identified FCOIs, in accordance with Regulations		
14.	DCC	Certify to Protocol Institution, compliance with Regulations at the time of grant application		
15.	DCC	Report to NINDS each of its identified FCOIs, in accordance with Regulations		

B. Compliance with FDA Financial Disclosure Requirements

#	Who	Task	Attachment/ Reference	Related SOP
1.	Each CSS	Provide CCC with documentation of financial information (i.e., financial disclosure form) upon request, for any trial that the PPI who is an IND/IDE sponsor requests such information, to be in compliance with 21 CFR Part 54		

C. Provision of COI Information to the Single IRB

#	Who	Task	Attachment/ Reference	Related SOP
1.	Each CSS	Provide NeuroNEXT SIRB, via the CCC, information regarding its investigator conflict of interest analysis, for each NeuroNEXT Network study, as required by the Reliance Agreement	Reliance Agreement	

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Attachment NN GA 104 - A. Document History

NeuroNEXT Network Standard Operating Procedure (SOP) Conflict of Interest and Financial Disclosure Requirements SOP NN GA 104					
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 signature block to accommodate for electronic signatures. Additional minor updates throughout.	Updated for version 3.0	22Feb2023	08Apr2023	Catherine Gladden
3.0	Minor edits for clarity	Periodic review	01Mar2024	15Apr2024	Preeti Paul

NN GA 104 Conflict of Interest and Financial Disclosure Requirements v3.0 clean

Final Audit Report 2024-03-11

Created:	2024-02-22
By:	Tania Leeder (tleeder@mgb.org)
Status:	Signed
Transaction ID:	CBJCHBCAABAAQ8_ERcnVQLqKQ74-K3CVP1HyXnD95bba
Number of Documents:	1
Document page count:	10
Number of supporting files:	0
Supporting files page count:	0

"NN GA 104 Conflict of Interest and Financial Disclosure Requirements v3.0 clean" History

Document created by Tania Leeder (tleeder@mgb.org)
2024-02-22 - 5:46:02 PM GMT

Document emailed to christopher-coffey@uiowa.edu for signature
2024-02-22 - 5:51:25 PM GMT

Document emailed to cudkowicz.merit@mgh.harvard.edu for signature
2024-02-22 - 5:51:25 PM GMT

Document emailed to mchase@mgh.harvard.edu for signature
2024-02-22 - 5:51:25 PM GMT

Document emailed to dixie-ecklund@uiowa.edu for signature
2024-02-22 - 5:51:26 PM GMT

Document emailed to Stacey Grabert (SGrabert@mgh.harvard.edu) for signature
2024-02-22 - 5:51:26 PM GMT

Document emailed to ohayonj@ninds.nih.gov for signature
2024-02-22 - 5:51:26 PM GMT

Email viewed by mchase@mgh.harvard.edu
2024-02-22 - 5:52:25 PM GMT

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Challenge: The user opened the agreement.

2024-02-22 - 5:52:47 PM GMT

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2024-02-22 - 5:53:20 PM GMT

Document e-signed by Marianne Chase (mchase@mgh.harvard.edu)

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Signature Date: 2024-02-22 - 5:53:22 PM GMT - Time Source: server

Email viewed by cudkowicz.merit@mgh.harvard.edu

2024-02-22 - 6:50:19 PM GMT

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2024-02-22 - 6:50:47 PM GMT

Signer cudkowicz.merit@mgh.harvard.edu entered name at signing as Merit Cudkowicz

2024-02-22 - 6:51:02 PM GMT

Document e-signed by Merit Cudkowicz (cudkowicz.merit@mgh.harvard.edu)

Signing reason: I approve this document

Signature Date: 2024-02-22 - 6:51:04 PM GMT - Time Source: server

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2024-02-22 - 6:51:54 PM GMT

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Signature Date: 2024-02-22 - 6:52:04 PM GMT - Time Source: server

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2024-02-22 - 7:55:15 PM GMT

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

2024-02-23 - 7:05:30 PM GMT

Document emailed to ecklundd@uiowa.edu for signature

2024-02-23 - 7:05:30 PM GMT

Tania Leeder (tleeder@mgb.org) added alternate signer cscoffey@iowa.uiowa.edu. The original signer christopher-coffey@uiowa.edu can still sign.

2024-02-23 - 7:05:40 PM GMT

Document emailed to cscoffey@iowa.uiowa.edu for signature

2024-02-23 - 7:05:41 PM GMT

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2024-02-23 - 7:14:13 PM GMT

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2024-02-23 - 7:47:56 PM GMT

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2024-02-23 - 7:48:11 PM GMT

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Signature Date: 2024-02-23 - 7:48:14 PM GMT - Time Source: server

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2024-02-24 - 11:02:06 PM GMT

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Challenge: The user opened the agreement.

2024-02-24 - 11:02:19 PM GMT

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2024-02-24 - 11:02:37 PM GMT

Document e-signed by Dixie Ecklund (ecklundd@uiowa.edu)

Signing reason: I approve this document

Signature Date: 2024-02-24 - 11:02:40 PM GMT - Time Source: server

Email viewed by ohayonj@ninds.nih.gov

2024-03-11 - 1:39:45 PM GMT- IP address: 104.47.64.254

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Challenge: The user opened the agreement.

2024-03-11 - 1:39:53 PM GMT

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2024-03-11 - 1:40:10 PM GMT- IP address: 72.83.187.43

Document e-signed by Joan Ohayon (ohayonj@ninds.nih.gov)

Signing reason: I approve this document

Signature Date: 2024-03-11 - 1:40:12 PM GMT - Time Source: server- IP address: 72.83.187.43

Agreement completed.

2024-03-11 - 1:40:12 PM GMT