NeuroNEXT Network

Standard Operating Procedure (SOP)
Conflict of Interest and Financial Disclosure Requirements
For Clinical Study Sites
Version 1.0
SOP NN GA 104

Originators: NeuroNEXT CCC and DCC Personnel

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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.: 1.0
Effective Date: [insert]

CONFLICT OF INTEREST AND
FINANCIAL DISCLOSURE
REQUIREMENTS FOR CLINICAL
STUDY SITES

Supercedes
Document: N/A

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 regulations pertaining to objectivity in research, and with relevant requirements of the NeuroNEXT Central IRB (CIRB) 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 RESPONSIBILITIES 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 Clinical Coordinating Center/ d its policy 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 shall
      a. Shall have certified in its Master Clinical Trial Agreement 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 shall:
      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 shall:
      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 PPIs who are IND/IDE sponsors with their implementation of these requirements.

C. PROVISION OF COI INFORMATION TO THE NeuroNEXT CENTRAL IRB:
Each CSS will be responsible for providing to the NeuroNEXT Central 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
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

**CIRB**
NeuroNEXT Central Institutional Review Board

**CSS**
Clinical Study Site that conducts research for a particular NeuroNEXT protocol

**CSS PI**
Principal Investigator who is responsible for implementing and conducting a specific NeuroNEXT protocol at a Clinical Study Site

**DCC**
NeuroNEXT Data Coordinating Center at The University of Iowa

**FCOI**
Financial Conflict of Interest

**FDA**
US Food and Drug Administration

**GCP**
Good Clinical Practice

**ICH**
International Conference on Harmonization

**IND/IDE**
Investigational New Drug Application/ Investigational Device Exemption

**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

**Protocol Institution**
Institution awarded grant for a specific NeuroNEXT protocol/study

8. SPECIFIC PROCEDURES

**A. Certification and Reporting**

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<th>Who</th>
<th>Task</th>
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<tbody>
<tr>
<td>1.</td>
<td>Protocol Institution</td>
<td>Certify to NINDS its compliance with Regulations in grant application</td>
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<tr>
<td>2.</td>
<td>Protocol Institution</td>
<td>Report to NINDS each of its identified FCOIs, in accordance with Regulations</td>
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</table>
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
Certify to Protocol Institution, compliance with Regulations prior to grant application
that is not Protocol Institution, but has policy that complies with Regulations

7. Non-Network CSS
Enter into agreement with CCC as required under Regulations
that is not Protocol Institution, but has policy that complies with Regulations

8. Non-Network CSS
Report to CCC each of its identified FCOIs, in accordance with Regulations
that is not Protocol Institution, but has policy that complies with Regulations

9. Non-Network CSS
Notify the CCC during negotiation of the subcontract between the non-Network CSS and the CCC
that is not Protocol Institution, and does NOT have a policy that complies with Regulations

10. Non-Network CSS
Agree to comply with such policy as the CCC, together with Committee on Conflicts of Interest, shall determine is applicable to the policy
that is not Protocol Institution, and does NOT have a policy that complies with Regulations

11. Non-Network CSS
Enter into agreement with relevant institution as required under Regulations
that is not Protocol Institution, and does NOT have a policy that complies with 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

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<tr>
<td>1.</td>
<td>Each CSS</td>
<td>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</td>
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### C. Provision of COI Information to the Central IRB

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<tbody>
<tr>
<td>1.</td>
<td>Each CSS</td>
<td>Provide NeuroNEXT CIRB, via the CCC, information regarding its investigator conflict of interest analysis, for each NeuroNEXT Network study, as required by the Reliance Agreement</td>
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