NEALS Northeast Amyotrophic Lateral Sclerosis Consortium

Standard Operating Procedure (SOP)

Conflict of Interest and Financial Disclosure Requirements for CIRB Pilot Study Sites

Version 1.0

SOP NEALS CIRB 100

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STANDARD OPERATING PROCEDURE FOR CONFLICT OF INTEREST AND FINANCIAL DISCLOSURE REQUIREMENTS FOR CIRB PILOT STUDY SITES

SOP NEALS CIRB 100 Version No.: 1.0 Effective Date:	CONFLICT OF INTEREST AND FINANCIAL DISCLOSURE REQUIREMENTS FOR CIRB PILOT STUDY SITES	Supercedes Document: N/A

1. POLICY

It is the Policy of the Northeast ALS (NEALS) Network that all entities and individuals participating in the CIRB Pilot Project 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 NEALS Central IRB (CIRB) Pilot regarding protection of human subjects.

2. SCOPE

The policies and procedures described in this SOP apply to the Neurological Clinical Research Institute (NCRI) Coordinating Center (CC) within the context of their oversight and advisory roles for the NEALS CIRB Pilot Project, and to all CIRB Clinical Study Sites (CSS), CIRB Pilot investigators, staff, subcontractors, or other entities associated with the NEALS CIRB Pilot Project who manage, oversee, conduct, or are otherwise engaged in research in the CIRB Pilot Project.

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 NEALS PILOT CIRB Project. The applicable regulations are 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 referred to "Regulations").

b. APPLICABLE POLICY AND IMPLEMENTATION:

i. Each CIRB 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. To the extent that a funding entity or funding individual has requirements in addition to those of the Regulations, any CSS that is proposed to receive funds through the NCRI CC from such funder shall have the right to decline to receive such funding if it does not accept such additional requirements, which acceptance shall not be unreasonably withheld. In the event a CSS declines to receive such funding, that CSS may not participate in research receiving such funding.

c. In the event that a CSS does not itself have a compliant policy, it shall so inform the NCRI CC prior to the CC agreeing to transfer funds to said CSS and the CC shall confer with the NEALS CIRB to determine the policy applicable to the otherwise non-compliant site.

d. 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"):

1. The CSS must be a member of the NEALS Network ("Network CSS"). In addition, it

   a. Shall have certified in its Master Clinical Trial Agreement (MCTA) with the NCRI CC its compliance status with the Regulations, and shall maintain its compliance status throughout its participation in the CIRB Pilot Project;

   b. Shall complete a specific task order for each study which will include information on the expected period of performance, payment details and a site investigator signature line.

   c. Shall report to the relevant institution at such time and with such information as required by the STA and in accordance with the Regulations, each of the CSS's FCOIs.

B. COMPLIANCE WITH FDA FINANCIAL DISCLOSURE REQUIREMENTS: The IND/IDE sponsor of a NEALS 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 NCRI CC may, upon request, assist Pilot Study Site PIs who are IND/IDE sponsors with their implementation of these requirements.

C. PROVISION OF COI INFORMATION TO THE NEALS CENTRAL IRB: Each CSS will be responsible for providing to the NEALS CIRB (via the NCRI CC), in connection with each Network study, the information regarding its investigator conflicts of interest analysis required by the NEALS CIRB Authorization Agreement (Reliance Agreement).

D. RESOURCES:

The NCRI CC shall be a resource available to each CSS involved in the CIRB Pilot Project and to any Investigator participating in a CIRB Pilot Project 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

Document History

7. TERMS AND ABBREVIATIONS

The following terms are used in this document:

CC	NCRI Clinical Coordinating Center at Massachusetts General Hospital
CFR	Code of Federal Regulations
CIRB	Central Institutional Review Board
CSS	Clinical Study Site that conducts research for a particular NEALS CIRB Pilot Project protocol and is a NEALS network member
CSS PI	Principal Investigator who is responsible for implementing and conducting a specific NEALS CIRB Pilot Project protocol at a Clinical Study Site
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
MCTA	Master Clinical Trial Agreement
NEALS CIRB Pilot PI	Principal Investigator who has been awarded a NEALS grant and has oversight over all NEALS CIRB Pilot Project at a Pilot Study Site
Protocol Institution	Institution awarded grant for a specific NEALS Pilot Project protocol/study

8. SPECIFIC PROCEDURES

A. Certification and Reporting

#	Who	Task	Attachment/ Reference	Related SOP
1.	CSS	Certify in STA with CC, compliance status with Regulations throughout participation in the NEALS Pilot Project		
2.	CSS	Report to CC each of its identified FCOIs, in accordance with Regulations		
3.	CSS	Certify to CC compliance with Regulations prior to participation in a given study.		

4.	CSS that does NOT have a policy that complies with Regulations	Notify the CC during negotiation of the subcontract between the CSS and the CC
5.	CSS that does NOT have a policy that complies with Regulations	Agree to comply with such policy as the CC, together with the CIRB shall determine is applicable to the policy
6.	CSS that does NOT have a policy that complies with Regulations	Enter into agreement with MGH as applicable
7.	CC	To the extent required by the funding entity, report funding identified FCOIs, in accordance with Regulations.

B. Compliance with FDA Financial Disclosure Requirements

#	*Who*	*Task*	*Attachment/ Reference*	*Related SOP*
1.	Each CSS	Provide CC 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 Central IRB

#	*Who*	*Task*	*Attachment/ Reference*	*Related SOP*
1.	Each CSS	Provide NEALS CIRB, via the CC, information regarding its investigator conflict of interest analysis, for each NEALS CIRB Pilot Project study, as required by the Reliance Agreement	Reliance Agreement	