SOP Number: ADM 02
SOP NAME: Reporting Conflict of Interest and Financial Disclosures
Effective Date: 26-May-2017

1. PURPOSE

NIH StrokeNet (StrokeNet) investigators and staff at multiple institutions who participate in the network or a StrokeNet managed trial may receive both federal and industry funding. There is also the potential for a close association with the therapeutic products used to treat acute stroke "that ... while not intrinsically unacceptable, [may] raise the prospect that scientific advances will bring financial gain for the research scientist and his or her institution." (Conflict of Interest Workshop Executive Summary, National Institutes of Health (NIH), Bethesda MD September 30, 2002). As such, the potential for conflicts of interest (COI), of any kind and degree, is considerable. Documenting and maintaining records regarding the objectivity of investigators and administrative trial staff present a considerable challenge for the institutions involved, as well as the National Coordinating Center (NCC), but is a challenge that must be addressed both ethically and practically. Hence, the purpose of this SOP is to document the process by which the StrokeNet will assure compliance for trials managed under the network with Department of Health and Human Services (DHHS) financial Conflict of Interest (fCOI) regulatory requirements, including those of the National Institutes of Health (NIH) and the Food and Drug Administration (FDA).

2. DEFINITIONS AND ACRONYMS

cIRB StrokeNet Central Institutional Review Board at the University of Cincinnati

COI Conflict of Interest

DHHS Department of Health and Human Services

fCOI Financial Conflict of Interest

FDI Financial Disclosure Information

MTA **Master Trial Agreement**

NCC National Coordinating Center at the University of Cincinnati

NDMC National Data Management Center at Medical University of South Carolina

NIH National Institutes of Health

NINDS National Institute of Neurological Disorders and Stroke

Non-StrokeNet Protocol Awarded Performance Center Institutions operating within StrokeNet on behalf of specific protocols that are not RCCs nor are affiliated with RCCs

Pass-through Entity (PTE) **National Coordinating Center ("NCC")** – University of Cincinnati

PHS Public Health Service

PI Principal Investigator

Policy An overall plan to guide and determine present and future decisions

Procedures Established or prescribed methods to be followed routinely

PTA **Protocol Trial Agreement**

RCC	Twenty-five Regional Coordinating Centers with a NINDS NIH StrokeNet. The RCC has executed a MTA and a CIRB Reliance Agreement with the NCC to participate in StrokeNet trials/activities.
RCC PS	Performance site - an entity that has agreed with the RCC to serve as a clinical trial performance site for StrokeNet affiliated studies. The PS functions under the direct leadership of the RCC.
SS	Satellites site - an entity named by an RCC as part of its regional network. A SS may or may not be a performance site for a clinical trial for StrokeNet affiliated studies. The SS has executed a MTA and a CIRB Reliance Agreement with the NCC to participate in StrokeNet trials/activities.
SS PS	A SS may have multiple SS performance sites that may serve as a clinical trial performance site for StrokeNet affiliated studies.
SOP	Standard Operating Procedure
StrokeNet	NIH StrokeNet Network
Sub-I	Sub-investigator

3. SCOPE

This SOP applies to all personnel involved with the StrokeNet - investigators, staff, subcontractors, consultants or other entities associated with the StrokeNet who manage, oversee, and conduct research within the network regulated by the Public Health Service (PHS) and/or the FDA. This SOP is applicable to the NCC, the NDMC, the RCC, SS and PS, and all non-network protocol awarded centers.

4. STROKENET COI REPORTING POLICIES AND PROCEDURES

A. Who must complete financial disclosure information (FDI) and financial Conflict of Interest (fCOI) information?

There are two pertinent but different definitions of investigators used in specific reporting requirements. The term investigator is used in this SOP to define who is required to submit FDI and fCOI.

1. DHHS/PHS/NIH Definition of Investigator - a listed or identified investigator or sub-investigator who is directly involved in the treatment or evaluation of research subjects for a specific trial, as well as the spouse and each dependent child of the investigator. The term also includes all involved personnel who have access to the subject and or the data collected.

2. Strokenet Central IRB (cIRB) Definition of Investigator-Investigators are defined as the "project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants" (42 CFR Part 50.603)

B. Who has the responsibility for Reporting fCOI for DHHS/NIH/PHS funding In NIH StrokeNet?

As stipulated in NIH/NINDS notice of grant awards, all recipients *must* promote objectivity in research by establishing standards that provide reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's fCOI in accordance with the cited regulations.

42 CFR Part 50. 604 requires that institutions conducting PHS-funded research "Maintain an up-to-date, written, enforced policy on financial conflicts of interest." Further, "If the Institution carries out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), the Institution (awardee Institution) must take reasonable steps to ensure that any subrecipient Investigator complies with this subpart by incorporating as part of a written agreement with the subrecipient terms that establish whether the financial conflicts of interest policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators."

The NIH StrokeNet MTA and PTA documents contain the following language to identify which institution holds the responsibility for DHHS/NIH/PHS reporting of COI.

Each Subrecipient must designate herein whether the financial conflicts of interest policy of (check one)
___ Pass-through Entity Institution, or
___ Subrecipient Institution will apply.
If applying its own financial conflicts of interest policy, by execution of this Subaward Agreement, Subrecipient Institution certifies that its policy complies with 42 CFR Part 50 Subpart F.

Subrecipients complying with the pass-through entity's financial conflict of interest policy are required to complete the following four items prior to issuance of a subaward:

1) All individuals considered investigators must complete a FDI (FCOI) form;
2) Investigators must receive and review the pass-through entity's Financial Conflict of Interest (FCOI) Training;
3) Investigators must receive and review the pass-through entity's Conflict of Interest Policy;
4) Investigators must certify that they have received and understand the pass-through entity's Conflict of Interest Policy *(Conflict of Interest on Externally Funded Projects 1.3.2)* and FCOI Training, completed their disclosure honestly, and will update their disclosure within 30 days of any changes.

For sites wanting to use the pass-through entity's policy: Investigators are defined as the "project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants" (42 CFR Part 50.603).

C. What is required to be reported to the NCC for DHHS/NIH/PHS fCOI?

A subrecipient shall report any financial conflict of interest to Pass-through Entity's Administrative Representative, as designated on Attachment 3A of the MTA or PTA. Any financial conflicts of interest identified shall subsequently be reported to NIH. Such report shall be made before

expenditure of funds authorized in the Subaward Agreement and within 45 days of any subsequently identified financial conflict of interest.

D. What Trial Specific fCOI must be reported to the cIRB by participating trial investigators and staff?

A Trial Specific fCOI form (attachment A) will be used to identify any "company" or other entity that contributes in some way to the support of the trial. The FCOI form will be distributed by the Project Manager to the trial performance sites. The StrokeNet cIRB will use the criteria below to identify the investigator's financial interest(s). If the investigator indicates having any of the interests listed below, a separate explanation (including the amount of compensation received in the previous twelve months) will be requested from the investigator or staff completing the form. The cIRB will use this explanation to determine the presence of a trial specific fCOI. If there is a trial specific fCOI, the significance of any trial specific fCOI will also be assessed. All information provided will be treated as confidential to the extent permitted by law. The cIRB fCOI criteria are:

1. I or a member of my immediate family (spouse, children, parent, in-laws, and siblings) own(s) equity (stock ownership, stock options, convertible note(s), or other ownership interest in any amount) in the company or other legal entity whose drug, procedure, technique, device, or software I am testing (the "Company").
2. The Company holds patent rights to inventions created by me or a member of my immediate family.
3. I or a member of my immediate family hold(s) a position of senior management officer, or director of the Company.
4. I or a member of my immediate family am/is a scientific advisor, consultant, or speaker for the Company and receives payments from the Company (including direct or indirect payments, honoraria, and all other forms of compensation).
5. If a device, technique, software, or procedure involved in the research is marketed, I or a member of my immediate family may be entitled to royalty income or income from the sale of the product.
6. I or a member of my immediate family have any other financial interest that may appear to conflict with the protection of subjects or which should be disclosed to subjects in order to secure informed consent.

E. When will Trial Specific fCOI information be reported?

1. The cIRB will prompt the completion and renewal of trial specific financial disclosure forms (attachment A) for all personnel identified as associated with the trial at a site (per the FDA form 1572 or the delegation of authority log). This list could include clinical neurologists, emergency medicine physicians and operators who perform investigational procedures or use investigational products, as well as nurse practitioners, physician assistants, clinical coordinators and data handlers.
2. If new drugs or devices are added to an existing cIRB reviewed protocol or an industry sponsor of a study changes, the fCOI form will be updated accordingly. All personnel will be required to sign and submit the updated form. If existing products are acquired through a merger or purchased by a new corporate entity, trial participants may be required to sign a new fCOI

form. Every attempt will be made to remain current, but changes in corporate status can occur without notification.

3. All PS Investigators and staff are expected to notify the cIRB within 30 days *of any change* in their status and submit the appropriate updated form.

F. StrokeNet Trial Specific fCOI Review Procedures:

1. The trial Specific FCOI forms will be initially received and screened by the StrokeNet Project Manager and cIRB Liaison. Refiling will occur at annual intervals, within 30 days of a change and at the end of the trial.
2. If a financial interest is indicated, the StrokeNet cIRB liaison will contact the investigator to identify the particular circumstances of the interest and request a written explanation to determine the individual's role in the trial and the exact nature and extent of the interest if one was not provided.
3. If the Investigators StrokeNet fCOI form indicates a reportable fCOI per PHS regulations, the CIRB Liaison will contact the NCC (University of Cincinnati) COI officer who may execute a "public accessibility" request to the Investigator's home Institution.
4. All information collected will be kept confidential and submitted only to cIRB for evaluation. If deemed necessary, the cIRB will request the investigators institutional COI office to assist in the development of a protocol specific management plan for the reported fCOI. **In these instances, the NCC COI officer will work closely with the investigator's institution (COI office) to understand the terms of the management plan and to implement them accordingly. If the subrecipient institution has its own COI policy in compliance with 42 CFR Part 50, the cIRB defers to the investigator's institutional policy to identify and manage conflicts of interest; however, the cIRB may add additional protocol-specific safeguards to protect the welfare of subjects and the integrity of the research where appropriate.**
5. A copy of the protocol specific fCOI management plan will be archived with the cIRB regulatory files and a copy will be submitted to the PIs Institution's COI office. The PI's Institution can add to the individual's cIRB management plan but cannot remove any stipulations.

G. Document Management and Retention

All completed fCOI certification forms, explanations of disclosure documents, public accessibility reports, and cIRB management plans will be stored in a secure manner (for example, under lock and key or a stand-alone computer with no internet/network access) for the life of the network plus five (5) years. After that time this record maybe destroyed. More specifically, all fCOI statements will be blinded for the investigators name only; center/site affiliation will remain intact. The blinded fCOI-forms will be scanned and stored on electronic storage medium for the life of the network plus five (5) years.

H. Review of COI Statements by StrokeNet Leadership

The PI of the NCC is consulted on certain but not all cases of investigator/staff fCOI. The cIRB will share the final results of its review with the applicable PI as deemed necessary and with the RCC PI if the NCC PI makes the request.

I. Publication and or public access to StrokeNet fCOI Forms

Procedure for Access to Network fCOI Statements:

1. Permission to review fCOI statements for StrokeNet must be made in writing to the StrokeNet PI. The purpose of the review of this information must be clearly documented, signed, and dated by the requestor.
2. The decision to grant permission to view unblinded and later blinded fCOI will be made by majority vote of the EC. If the EC has disbanded, the responsibility to grant this permission will rest with the StrokeNet NCC PI alone.

5. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 54	Financial Disclosure by Clinical Investigators
21 CFR 812.43	Selecting Investigators and Monitors
21 CFR 312.53	Selecting Investigators and Monitors
42 CFR 50 Subpart F	Promoting Objectivity in Research
2 CFR 200	Uniform Administrative Requirements, Cost Principles, And Audit Requirements For Federal Awards
45 CFR 94	Responsible Prospective Contractors

FDA Guidance, Compliance & Regulatory Information (Drugs) https://www.fda.gov/Drugs/GuidancecomplianceRegulatoryInformation/Guidances/default.htm

FDA Standards and Guidances for Neurological Devices https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/NeurologicalDevices/ucm528789.htm

9. REFERENCES TO OTHER APPLICABLE SOPS

10. ATTACHMENTS AND REFERENCES

A. fCOI form

11. DOCUMENT HISTORY

Version	Description of Modification	Completion Date	Issue Date	Effective Date
1.0	Final	3-Jun-2014	3-Jun-2014	3-Jun-2014
2.0	May 2017 Revision Final	11-Apr-2017	26-May-2017	26-May-2017

Attachment A

NIH StrokeNet
PREVENTION | TREATMENT | RECOVERY

FINANCIAL CONFLICT OF INTEREST FORM

Please complete and return with any protocol submitted for initial and continuing review.

Study Title:

Study Sponsor Name:

For purposes of completing this form, a Sponsor is a party supporting a particular study at the time it was carried out. Typically, a trial is either an industry sponsored or investigator sponsored trial (if funded by a grant or award). If you are uncertain which to indicate consult the NCC CIRB liaison before submitting this form.

Name of Site PI: _____

Name of Person Completing Form: _____

Your Role in Study:_____

(for example, Investigator, Study Coordinator, Statistician, Research Nurse, data entry)

A "financial interest related to research "means a financial interest in the sponsor, product or service being tested. In order to protect participants from financial conflicts of interest the IRB requires that such potential conflicts during the past 12 months be disclosed. If the IRB determines that a conflict exists that could influence the research or jeopardize the well-being of participants, the IRB may require additional information about the conflict or may require that the conflict be resolved before the research is approved. In addition, it may require that the conflict be disclosed to the participant in the Informed Consent Statement.

Please indicate the following:

☐ Yes ☐ No I or a member of my immediate family own(s) equity (stock ownership, stock options, convertible note(s), or other ownership interest in any amount) in the company or other legal entity whose drug, procedure, technique, device, or

software I am testing (the "Company").

☐ Yes	☐ No	The Company holds patent rights to inventions created by me or a member of my immediate family (spouse, children, parent, in-laws, and siblings).
☐ Yes	☐ No	I or a member of my immediate family hold(s) a position of senior management officer, or director of the Company.
☐ Yes	☐ No	I or a member of my immediate family am/is a scientific advisor, consultant, or speaker for the Company and receive payments from the Company (including direct or indirect payments, honoraria, and all other forms of compensation).
☐ Yes	☐ No	If a device, technique, software, or procedure involved in the research is marketed, I or a member of my immediate family may be entitled to royalty income or income from the sale of the product.
☐ Yes	☐ No	I or a member of my immediate family have/has a financial interest that may appear to conflict with the protection of subjects or which should be disclosed to subjects in order to secure informed consent.

IF ANY BOX ABOVE IS CHECKED YES, INCLUDE ON A SEPARATE SHEET AN EXPLANATION OF THE CONFLICT (INCLUDING THE AMOUNT OF MONEY) FOR THE IRB'S CONSIDERATION. INFORMATION PROVIDED IS CONSIDERED CONFIDENTIAL.

My signature below is my representation that I have accurately completed this form to the best of my knowledge.

Signature	Date

If the investigator is disclosing a financial interest (i.e. checked "YES" in one of the boxes on the FCOI form), please provide the following information:

1. Identify the entity(s) of which the investigator has a financial relationship.

2. What is the amount of compensation received from that entity(s) in the past 12 months?

3. What is the amount of compensation expected from that entity(s) in the coming 12 months?

4. Please provide a description of the kind of service(s) provided to that entity(s) (e.g., consulting, speaking, proctoring, etc.)

5. Has your institution reviewed this financial disclosure in relation to the StrokeNet protocol?
   YES ☐ NO☐

   a. If yes, has your institution identified this as a conflict of interest requiring management?
      YES ☐ NO☐

   OR

   Did your institution review it and deem it not to be a conflict?

   YES ☐ NO☐

   b. If yes, please provide the conditions/stipulations of how your institution is managing the conflict (e.g., disclosure in informed consent, change in research role/responsibilities, etc.)

Signature Date

NIH StrokeNet
PREVENTION | TREATMENT | RECOVERY

NIH StrokeNet Network

Standard Operating Procedure (SOP)

Reporting Conflict of Interest
And
Financial Disclosures

Version **v2.0**

ADM #02

Originators: StrokeNet National Coordinating Center Personnel

Reviewed and Approved by:

_____ (Date) 5/8/17
Joseph P. Broderick, MD (StrokeNet NCC Principal Investigator)

_____ (Date) 5/15/17
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_____ (Date) _____
NIH/NINDS Representative

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