SOP Number: ADM 02
SOP NAME: Reporting Conflict of Interest And Financial Disclosure
Effective Date: 3-Jun-2014

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 to do so. 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 COI Standard Operating Procedure (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

EC StrokeNet Executive Committee

fCOI Financial Conflict of Interest

fCOI-C Financial Conflict of Interest Certification statement reporting for NIH funding

fCOI-cIRB Trial specific financial disclosure and Conflict of Interest reporting for cIRB review

FDA Food and Drug Administration

FDI Financial Disclosure Information

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

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
RCC	Twenty-five Regional Coordinating Centers with a 2013 NINDS U10 award
RCC-CPS	Regional Coordinating Center Clinical performance site- an institution that is not legally affiliated with the awarded RCC which has agreed with the RCC to serve as a clinical trial performance site for StrokeNet affiliated studies. An RCC-CPS institution does not have a master trial agreement with the NCC to participate in StrokeNet trials/activities but functions under the direct leadership of the RCC.
RCC-SS	Regional Coordinating Centers Satellites site -an institution that is not legally affiliated with the awarded RCC but named by an RCC as a branch of its regional network. An RCC-SS may or may not be a performance site for a clinical trial for StrokeNet affiliated studies. An RCC-SS institution has executed a master trial agreement with the NCC to participate in StrokeNet trials/activities.
SOP	Standard Operating Procedure
SS/CPS	Regional Coordinating Center Satellite sites and Regional Coordinating Center Clinical Performance sites that serve as performance sites for a clinical trial.
StrokeNet	NIH StrokeNet Network
Sub I	Sub-investigator
UC	University of Cincinnati

3. SCOPE

This SOP applies to all personnel involved with the StrokeNet. This SOP is applicable to the NCC, the National Data Management Center (NDMC), the Regional Coordinating Centers (RCC) and all Regional Coordinating Center Satellite sites and Regional Coordinating Centers Clinical Performance sites (SS/CPS), non-network protocol awarded centers, and to all 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.

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- 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 collaborators or consultants.

2. StrokeNet Central IRB (cIRB) 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.

B. Where to report fCOI for DHHS/NIH/PHS funding?

As stipulated in the notice of grant award, 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. The StrokeNet policy for reporting fCOI in accordance with these NIH requirements is as follows:

1. Each RCC is responsible for its own FDI and fCOI reporting for PHS compliance as certified by entering into the StrokeNet Master Trial Agreement (MTA).
2. Each SS/CPS with a COI policy that conforms to all applicable regulations including, but not limited to, those set forth in regulations cited in the notice or award will be responsible for its own compliance reporting as certified by entering into the MTA agreement.
3. Any SS/CPS without a policy for PHS funding will be expected to comply with their affiliated RCC's training, policy and disclosure requirements for reporting COI on externally funded projects.
4. Any non-StrokeNet Protocol Awarded Performance Center using the StrokeNet infrastructure must have a COI policy that conforms to all applicable regulations including, but not limited to, those set forth in regulations cited in the notice or award and will be responsible for its own compliance reporting as certified by entering into the MTA agreement.

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

The StrokeNet requires mandatory assurance of compliance with the PHS reporting described above. The fCOI-C certification form is required to be completed annually by all investigators at each and every RCC and SS/CPS, as well as by all investigators and key personnel at the NCC and NDMC.

Completed forms must be uploaded to the appropriate RCC folder on the secure section of the NIHSTROKENET.org website. If there is a change in status affecting the reported information, all investigators and staff are expected to refile updated forms with their home institutions and with the NCC via the StrokeNet website within 30 days of the change. NCC administrative staff will review PHS fCOI Certification forms as described below.

D. What fCOI must be reported by cIRB participating trial investigators and staff?

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 and the NCC 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:

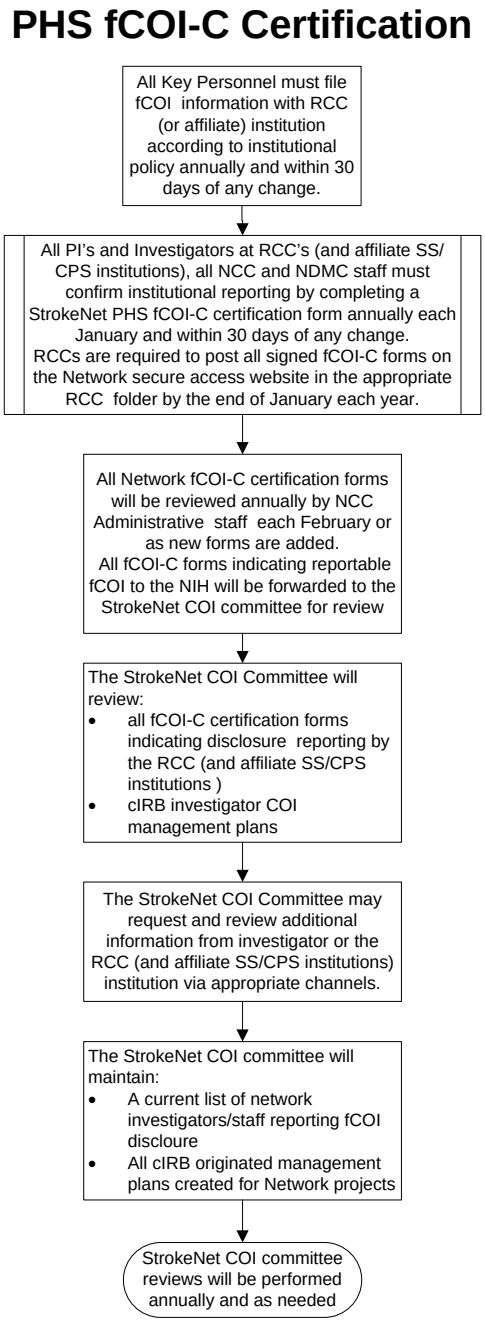
1. I or a member of my immediate family (spouse, children, parent, in-laws, and siblings) own(s) equity (stock ownership, stock options, convertible note(s), or other ownership interest in any amount) in the company or other legal entity whose drug, procedure, technique, device, or software I am testing (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 the fCOI-cIRB information be reported?

1. The cIRB will prompt the completion and renewal of trial specific financial disclosure forms (fCOI-cIRB) 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-cIRB form will be updated accordingly. All key 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-cIRB form. Every attempt will be made to remain current, but changes in corporate status can occur without notification.
3. All Investigators and staff (RCC and SS/CPS) are expected to notify the cIRB within 30 days *of any change* in their status and submit the appropriate updated form.

F. StrokeNet Assurance of PHS Compliance Procedures:

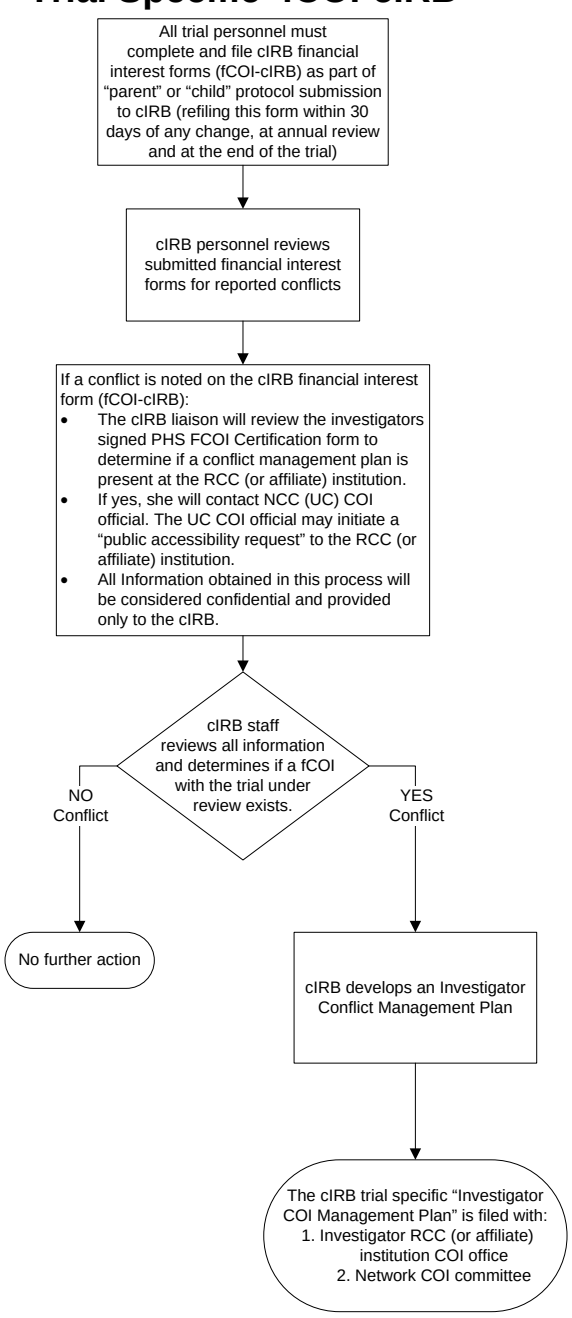
1. As noted previously, all RCCs (and SS/CPS) key personnel must file FDI and fCOI information annually (as defined by PHS requirements and institutional policy) with their institutions.
2. In *addition*, all StrokeNet PI's, investigators and other key personnel at the NCC, NDMC and all RCCs (and SS/CPS) must complete a PHS fCOI-C Certification Form annually (in January) and within 30 days of any change.
3. All completed PHS fCOI-C forms must be posted by the RCC (or SS/CPS) on the secure access section of the nihstrokenet.org website under the appropriate RCC folder.
4. All StrokeNet PHS fCOI-C forms will be reviewed at least annually by the NCC administrative staff (in February) and as new forms/staff are added.
5. All fCOI-C forms indicating a reportable fCOI to the NIH per PHS regulations will be forwarded to the StrokeNet COI Committee for review.
6. If the Strokenet COI Committee determines a need, additional information may be requested from the investigator or their institution per appropriate channels per the NCC (University of Cincinnati) COI officer.



7. A master file of all StrokeNet investigators and staff reporting fCOI will be maintained by NCC administrative staff.
8. Any information obtained for StrokeNet COI committee review will be considered confidential and maintained accordingly.

G. StrokeNet Trial Specific fCOI Review Procedures:

1. The fCOI-cIRB financial disclosure forms will be initially received and screened by the StrokeNet 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 will 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-C form indicates a reportable fCOI per PHS regulations, the liaison will contact the NCC (University of Cincinnati) COI officer who may execute a "public accessibility" request to the RCC (or SS/CPS) Institution.
4. All information collected will be kept confidential and submitted only to cIRB for evaluation.
5. If deemed necessary, the cIRB will work to develop a protocol specific management plan for the reported fCOI.
6. 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 RCC (or SS/CPS) Institution's COI office. The RCC (or SS/CPS) Institution can add to the individual's cIRB management plan but cannot remove any stipulations.



H. Document Management and Retention

All completed PHS fCOI-C 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-C statements will be blinded for the investigators name only; center/site affiliation will remain intact. The blinded fCOI-C forms will be scanned and stored on electronic storage medium for the life of the network plus five (5) years.

I. StrokeNet Review of COI Statements by StrokeNet COI Committee

The three-member StrokeNet COI committee will meet annually and as needed. Members will include the PI of the NCC, the UC COI official and a delegated Executive Committee (EC) member. The committee will review all fCOI-C forms indicating reportable fCOI and any cIRB management plans developed by the cIRB on behalf of a StrokeNet protocol. The committee will share the results of its review with the applicable RCC PI as deemed necessary/appropriate by the committee.

J. Publication and or public access to StrokeNet fCOI-C Forms

Procedure for Access to Network fCOI-C Statements:

1. Permission to review fCOI-C 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-C will be made by majority vote of the EC. If the EC has disbanded, the responsibility to grant this permission will rest with the network 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	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
45 CFR 94	Responsible Prospective Contractors

FDA Guideline Document 2011

9. REFERENCES TO OTHER APPLICABLE SOPS

10. ATTACHMENTS AND REFERENCES

A. PHS fCOI- C Form
B. fCOI- cIRB 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

Attachment A

NIH StrokeNet
PREVENTION | TREATMENT | RECOVERY
NATIONAL COORDINATING CENTER

Financial Conflict of Interest Policy Certification

This form is used to assure an investigators complinace with U.S. Public Health Services (PHS) Financial Conflict of Interest (FCOI) regulations (45 CFR Part 94 and 42 CFR Part 50). If information changes during the course of participation, please update within 30 days.

Check all that apply:		
□ Regionial Cood. Center PI	□ Investigator	□ Research Coordinator
□ NCC Staff	□ DMC staff	
□ Other_____		
Name:		
Email:		
Regional Coordinating Center Awardee Institution:		
RCC Number or RCC-SS or RCC-CPS Number:		

Please complete and post the signed form on the Essential Document Sharepopint in the appropriate RCC folder.

Statement Conflict of Interest Policy Certification

Please select that which applies:

☐ A. By signing this statement I am verifying that I have complied with my own institution's Financial Conflict of Interest policy. My institution has a conflict of interest policy which conforms to the requirements of all applicable regulations, including but not limited to those set forth in 45 CFR Part 94 and 42 CFR Part 50, Subpart F.

☐ B. My institution does not have a policy for PHS funding. By signing this statement I am verifying that I have complied with my Regional Coordinating Center's training, policy and disclosure requirements for reporting COI on Externally funded projects.

Please check one of the following that applies your filed report.

☐ A. The institution indicated above has reviewed my statement of financial interest and determined that there is no Financial Conflict of Interest or have indicated that there are no outside activities to review.

☐ B. The institution indicated above has reviewed the statement of financial interest and determined that there is a Financial Conflict of Interest that needs to be disclosed to the sponsor(s) and potentially reported to NINDS (if required by conditions set forth in 45 CFR Part 94 or 42 CFR Part 50 Subpart F). Should the NIH StrokeNet's Conflict of Interest Committee and/or the StrokeNet's cIRB need additional information; the NIH StrokeNet's Conflict of Interest Officer will contact the institution for the following information per public accessibility request:

- Name of investigator with the conflict,
- Investigators title and role with respect to the research project,
- Name of the entity in which the Significant Financial Interest is held,
- Nature of the Significant Financial Interest; and
- Approximate dollar value of the Significant Financial Interest.

Signature:
Printed Name:
Date of signature: day_____month_____year_____

3-Jun-2014 FINAL

NIH StrokeNet
PREVENTION | TREATMENT | RECOVERY

TRIAL SPECIFIC 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)

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 _____

Revised 09-May-2014