

NIH StrokeNet Network Standard Operating Procedure

SOP Number: ADM06

SOP NAME: Essential Financial and Compliance Documentation

Effective: 3-Jun-2014

1. POLICY

Essential Financial and Compliance Documents will be posted in the Essential Network Documents folder under each Regional Coordinating Center (RCC) main folder hosted on the National Coordinating Center (NCC) secure website. Access to documents will be limited to NCC staff and appropriate RCC Satellite Site (RCC-SS) personnel with set permissions.

2. DEFINITIONS AND ABBREVIATIONS

NCC: An institution designed and directly funded by NINDS/NIH to provide leadership for the StrokeNet on a national level.

RCC: Regional Coordinating Centers-Institutions designed and directly funded by NINDS/NIH to provide leadership for the Stroke Network on a regional level.

SS: Institutions named by an RCC as a part of its regional network that are not legally affiliated with the RCC.

PS: A performance site is an institution that is not legally affiliated with the awarded RCC but which has agreed to serve as a network trial recruitment site for an awarded RCC network. There are also SS-PS sites.

FEO: Fully Executed Original

DD: Due Diligence

MTA: Master Trial Agreements-(in the StrokeNet) is a bilateral agreement between the University of Cincinnati and the RCC or RCC-SS similar to a memorandum of understanding. This agreement expresses a convergence of will between the parties, indicating an intended common line of action.

RA: Reliance Agreement-A reliance agreement is a formal, written document that provides a mechanism for an institution engaged in research to delegate institutional review board (IRB) review to the cIRB of the NCC.

fCOI-C: Financial Conflict of Interest Certification Statement used for reporting under NIH funding regulations

cIRB: Central Institutional Review Board

Key Personnel: Personnel deemed key for the execution of a PHS funded research project or the execution of a trial at an investigative site

FDP Institutional Clearinghouse: certification of institutional compliance with public Health Service Financial Conflict of Interest Requirements

StrokeNet: NIH StrokeNet Network

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PTA: Protocol Trial Agreement

Annual Subrecipient Certification Form: a University of Cincinnati required form to collect use of F&A rate, fringe rate, small business designation, conflict of interest, debarment/suspension, human & animal assurances as well as copies of current federal rate and fringe agreements.

3. SCOPE

This policy applies to StrokeNet RCCs and their RCC-SS or RCC-PS, RCC-SS-PS that have written agreements with the University of Cincinnati

4. PROCEDURES

- A. **Website Access** - NCC website administrators will grant access and set permissions for designated RCC staff members to access to the NCC secure server via the www.NIHStrokeNet.org website. All RCCs will have access to StrokeNet common documents and access to their own RCC site directory and subdirectories. No RCC site or SS can view another RCC site's folders.
- B. **Preferred Document Naming Convention** - posted documents in RCC folders by the NCC will be labeled utilizing the RCC or RCC-SS or PS number, -short institutional name -type of document and date the document is considered effective.
- C. **Qualities of Information posted - The StrokeNet website and associated document repositories are hosted in a secure environment with restricted access but is not intended to be CFR 21 Part 11 compliant.** Documents posted on this website should *not* contain PHI as defined in the electronic guidelines. Posting by the NCC are considered "public" records but will still be handled confidentially by the NCC staff. RCCs are encouraged to use the website as a document repository to facilitate their network's communication but should not house trial data or regulatory documents.
- D. **NCC responsibilities** - In agreement with the RCC the NCC will:
 - a. Maintain content and administrative management of the website, <http://nihstrokenet.org/>
 - b. Post and maintain fully executed original (FEO) agreements (MTAs, RAs and PTAs) established with each RCC or SS-PS within the RCC folder or subfolder for each RCC.
 - c. Post the certified Site Information Sheet. Updates to the certified sheet will be maintained in the WebDCU™ system.
 - d. Post and maintain pertinent correspondence and payments managed by the NCC. All financial correspondence will be directed to personnel named on the site information sheet provided and maintained by each RCC.
 - e. Verify RCC and SS original signed agreements contained in each RCC site's essential document folder prior to initiating trial agreements.
- E. **RCC responsibilities-** In agreement with the NCC the RCC will:

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- a. Delegate key personnel for access privileges. RCCs are asked to limit access to the smallest number of individuals possible and to notify NCC staff if permissions need to be discontinued within 48 hours of departing the position.
- b. Post and maintain, at the intervals stated below, all PS affiliation agreements, completed fCOI-C forms and “links” or website that provides the institution’s COI reporting policy and the FWA terms documents.
- c. Changes and annual updates to the fCOI must be documented by completing the fCOI **Change Form** prior to uploading the new (or replacement) document to the fCOI folder.

F. Document Maintenance Responsibilities Schedule of Events:

Documents	Frequency of Posting/confirmation of content	NCC	RCC	Satellites Sites
FEO MTA & Amendments (All-RCC and RCC-SS)	As finalized	X		
FEO RA & Amendments (All-RCC and RCC-SS and RCC SS-PSs)	As finalized	X		
FEO Trial Protocol Agreements & Amendments (All-RCC and RCC-SS)	As finalized	X		
FEO 3 rd Party Agreements & Amendments (All-RCC and RCC-SS)	As finalized	X		
RCC CPS Affiliation agreements	As finalized		X	
RCC CPS IRB Affiliation Agreements and Institutional FWA Agreement Documents	As finalized		X	
Annual Certification Forms (including current federal rate agreement and fringe agreement)	Annually (Jan1 +/- 30 days)		X	
fCOI-C Personnel statement of compliance w PHS COI forms	Annually (Jan1 +/- 30 days)		X	
FDP Institutional Clearinghouse for PHS FCOI (Provide link) https://nrc59.nas.edu/pub/fcoi-home.html	Annually (Jan1 +/- 30 days)		X	X
Institutional FCOI Policy (Provide link)	Annually (Jan1 +/- 30 days)		X	X

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5. APPLICABLE REGULATIONS

42 CFR part 50.604-Resp of Institution Regarding Investigator fCOI

45 CFR Part 94 – Management and Reporting of fCOI

CRADA

21 CFR Part 11 Electronic Records

6. REFERENCES TO OTHER APPLICABLE SOPs

ADM 02 Reporting Conflicts of Interest and Financial Disclosure

7. ATTACHMENTS AND REFERENCES

NIH StrokeNet COI Certification Form- Non-UC Financial Conflict of Interest Policy Certification

8. DOCUMENT HISTORY

Version	Description of Modification Justification for Modification	Completion Date	Issue Date	Effective Date
1.0	Final	3-Jun-2014	3-Jun-2014	3-Jun-2014
1.1	Biannual Review with minor administrative changes	23-Aug-2016		
2.0	Final	15-Sep-2016	15-Sep-2016	15-Sep-2016



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Standard Operating Procedure (SOP)

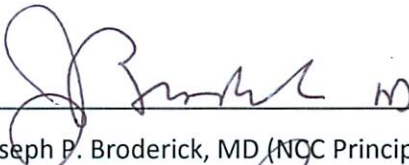
Documenting Essential Financial and Federal Compliance

Version 1

ADM #6

Originators: NIH StrokeNet NCC Personnel

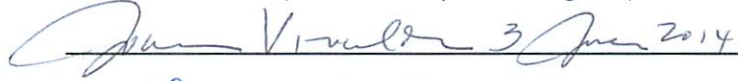
Reviewed and Approved by:



Joseph P. Broderick, MD (NCC Principal Investigator)


_____ 6/3/14

Yuko Palesch PhD (NDMC Principal Investigator)


_____ 3 June 2014

NINDS/NIH Representative


_____ May 23, 2014

Diane Sparks RN (NCC Contracts Manager, Legal Liaison)


_____ 23-May-2014

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