

NIH StrokeNet Network Standard Operating Procedure

SOP Number: ADM06

SOP NAME: Essential Financial and Compliance Documentation

Effective: 3-Jun-2014 (rev 26-Jun-2023)

1. POLICY

Essential Financial and Compliance Documents will be maintained on the University of Cincinnati (UC) server (OSP and Neurology drives) and the UC SharePoint database. Access to documents will be limited to NCC staff with set permissions.

2. DEFINITIONS AND ABBREVIATIONS

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

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

SS: Satellite Sites are 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 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

RA: 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 which is designated by the NCC.

FCOI-The NIH definition of Financial Conflict of Interest applies to this SOP and can be located in 42 CFR Part 50.603-subpart F.

CIRB: Central Institutional Review Board

Certificates of Confidentiality - a certificate issued by the Secretary of Health and Human Services (Secretary) to protect the privacy of individuals who are the subjects of research.

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

CTA: Clinical Trial Agreement

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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 SS or PS, and 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 folders.
- B. **Preferred Document Naming Convention** - documents maintained on the UC servers 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 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 the StrokeNet 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. Maintain fully executed original (FEO) agreements (RAs and CTAs) established with each RCC or SS-PS on UC servers.
 - c. 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. **RCC responsibilities-** In agreement with the NCC the RCC will:
 - 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. Maintain, at the intervals stated below, any PS affiliation agreements, and “links” or website that provides the institution’s COI reporting policy and the FWA terms documents.

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F. Document Maintenance Responsibilities Schedule of Events:

Documents	Frequency of Posting/confirmation of content	NCC	RCC	Satellites Sites	Trial Sponsor
FEO CTA & 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 3 rd Party Agreements & Amendments (All-RCC and RCC-SS)	As finalized	X			
RCC-PS Affiliation agreements	As finalized		X		
RCC-PS 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		
Signed Trial specific Certificate of Confidentiality (investigator and Institutional official)	Per Trial Agreement		X		X
FDP Institutional Clearinghouse for PHS FCOI (Provide link) https://nrc59.nas.edu/pub/fcoi-home.html	Annually (Jan1 +/- 30 days)		X	X	

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

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1.1	Biannual review with minor administrative changes	23-Aug-2016		
2.0	Final	15-Sep-2016	15-Sep-2016	15-Sep-2016
3.0	Content revision	26-Jun-2023	29-Jun-2023	29-Jun-2023



NIH StrokeNet Network

Standard Operating Procedure (SOP)

Essential Financial and Compliance Documentation

Standard Operation Procedures

Version 3.0

ADM #6

Reviewed and Approved by:

A handwritten signature in black ink that reads "Pooja Khatri".

Pooja Khatri, MD, (StrokeNet NCC Principal Investigator)

A handwritten signature in black ink that reads "Jordan J. Elm".

Jordan Elm, PhD, (StrokeNet NDMC Principal Investigator)

A handwritten signature in black ink that reads "Scott Janis".

Scott Janis, PhD, (NIH/NINDS Program Director)