SOP Number: GCP 02
SOP NAME: Qualified Investigative Personnel and Sites
Effective Date: 4-Jan-2016

1. Policy

The purpose of this Standard Operating Procedure (SOP) is to define and clarify the responsibilities of the NIH StrokeNet Regional Coordinating Centers (RCCs), the National Coordinating Center (NCC), and the National Data Management Center (NDMC) in the management of clinical trial performance sites (CTPS). The Protocol Principal Investigator (PPI) and/or designate is considered by the US FDA to be the trials "investigator sponsor" should such a role be required for the protocol, this role includes the responsibility for the identification of qualified clinical trial performance sites (inside or outside of the NIH StrokeNet network) and qualified site personnel.

2. Definitions and Abbreviations

GCP	Good Clinical Practice
HSP	Human Subjects Protection
NCC	National Coordinating Center – located at the University of Cincinnati
NDMC	National Data Management Center – located at the Medical University of South Carolina
RCC	NIH StrokeNet Regional Coordinating Center
NCC-PI	NIH StrokeNet Principal Investigator
NCC-PM	StrokeNet Project Manager – coordinator of StrokeNet site, who is responsible for providing and or verifying training and general oversight for NIH StrokeNet projects conducted at the Clinical Trial Performance Site
PPI	Protocol Principal Investigator – Principal Investigator who is awarded the NIH StrokeNet site grant and has oversight of NIH StrokeNet projects conducted at the Clinical Trial Performance Sites
CPM	Clinical Project Manager- coordinator associated with the funded protocol who is responsible for developing and providing personnel training in collaboration with the NCC PM and the PPI.
RCC-PI	RCC Principal Investigator who provides oversite to trials executed in the RCCs network
RCC-NC	RCC Coordinator who provides oversite to trials executed in the RCCs network
CTPS	Clinical Trial Performance Site - clinical location that serves as execution site for a clinical trial

CTPS-PI	Clinical Trial Performance Site Principal Investigator

3. Scope

This SOP has been developed to ensure compliance with Federal regulations and Good Clinical Practice (GCP) guidelines, as set forth in the 1996 ICH E6 Consolidated Guidance manual. The policies and procedures in this SOP apply to parties involved with NIH StrokeNet research, including the National Coordinating Center (NCC), the National Data Management Center (NDMC) and all NIH StrokeNet Regional Coordinating Centers (RCC) and all Clinical Trial Performance Sites (CTPS). For purposes of this SOP, a site is any institution engaged in research. The scope of this policy applies to the process of delegation by the NCC PI and PPI in the performance of such a project at a site.

4. Procedures

The NIH StrokeNet NCC Principal Investigator (NCC-PI) and NIH StrokeNet NCC Project Manager (NCC-PM) provide general oversight for each NIH StrokeNet Trials conducted in the network. Any direction is done in collaboration with the particular funded trial PPI.

A. Responsibilities of the NCC-PI, PPI, and NCC-PM and CPM regarding Qualified Investigative personnel and sites.

Identify qualified sites with appropriate personnel, necessary equipment and sufficient patient volume to successfully recruit and execute the clinical trial from inside the network CTPS and outside the network.

Identify any required training and credentialing necessary for CTPS research staff for the funded clinical trial.

Provide CTPS staff with access to the identified training and credentialing required. Verify all required training and credentialing have completed and maintained all required training.

Provide assistance and oversight to each regional network site to facilitate and ensure the RCC CTPS' research staff receive the required training for particular protocols.

Provide assistance and oversight to CTPS that are NOT directly affiliated with a specific network RCC to facilitate and ensure the RCC CTPS' research staff receives the required training for particular protocols.

B. Responsibilities of the RCC-PI and RCC-NC regarding Qualified Investigative personnel and sites.

Facilitate and ensure all RCC network CTPS Research Staff receive the required training for particular protocols.

C. Responsibilities of the CTPS-PIs and CTPS-SC

CTPS-PIs are the lead investigators for various approved NIH StrokeNet trials at the selected sites. The site is responsible for confirming that each staff member is qualified to perform study specific tasks that have been delegated to her/him, and documenting staff training and qualifications on the study specific Delegation of Authority Log for the purposes of ICH, FDA and CIRB requirements.. They are also responsible for updating this log throughout the study as needed, as well as documenting his or her supervision and involvement in the ongoing conduct of the study. The CTPS-PI will actively prepare for, and allow the research staff time to participate in, monitoring visits and audits.

The Clinical Trial Performance Site Coordinator (CTPS-SC) is responsible for coordinating activities for the CTPS Research Staff. Before beginning direct involvement in NIH StrokeNet study activities, all CTPS Research Staff will complete training in Human Subjects Protection (HSP) and GCP, as well as other trainings and certifications that are required under the study protocol.

The CTPS-PI or designate is responsible for maintaining a record that each research staff member has completed the required trainings.

5. Applicable Regulations and Guidelines

Code of Federal Regulations. General responsibilities of investigators: 21 CFR Parts 11, 50, 54, 56, 312 & 314. March 31, 2008.

International Conference on Harmonization Guidelines. Good Clinical Practice: Consolidated Guidelines E6; Safety E2A; General Considerations E8. March 31, 2008.

Guidelines for the Monitoring of Clinical Investigations. January 1988

FDA Compliance Program Guidance Manual Program 7348.811. Chapter 48-Bioresearch. February 21, 2001.

6. References to Other Applicable SOPs

NIH StrokeNet GCP #12 Regulatory and Clinical Data Storage

7. Attachments and References

General FDA information:

- The FDA Home Page

- Good Clinical Practice in FDA-Regulated Clinical Trials: Includes useful guidance documents and information sheets.
- The Drug Approval Application Process

Specific FDA information:

- Information for Clinical Investigators

8. Document History

Version	Description of Modification	Justification for Modification	Completion Date	Issue Date	Effective Date
1.0	Final		21-Dec-2015	21-Dec-2015	4-Jan-2016