SOP Number: ADM 14
SOP NAME: Development of Study Materials and Investigational Site Training
Effective Date: 3-Jun-2014 (rev 11-May-2023)

1. POLICY

All studies conducted within NIH StrokeNet (StrokeNet) will receive assistance from the National Coordinating Center (NCC), National Data Management Center (NDMC) and StrokeNet working groups on the development of the trial specific materials. The study team led by Protocol Principal Investigator (PPI) or his/her designee will decide what materials are needed to facilitate conduct of the trial. The identified study specific materials might include a Manual of Operations (MOP), source document templates, training programs, and other essential items. For all StrokeNet studies, each participating Regional Coordinating Center (RCC), Satellite Sites (SS) and Performance Sites (PS) will receive initial training on all aspects of the study protocol. Re-training will be provided as needed throughout the course of the clinical investigation. New staff will be trained before they are permitted to engage in any study-related tasks. The PPI, NCC, and NDMC will maintain records of training and certifications.

2. DEFINITIONS AND ABBREVIATIONS

Abbreviations:

CIRB	Central Institutional Review Board
MOP	Manual of Procedures
NCC	National Coordinating Center at the University of Cincinnati
NDMC	National Data Management Center at the Medical University of South Carolina
NINDS	National Institute of Neurological Disorders and Stroke
PS	Performance Sites
PPI	Protocol Principal Investigator
RCC	Regional Coordinating Centers
SS	Satellites Sites

Definitions:

Manual of Procedures: A document that describes how a study will be managed by the PPI, NCC, NDMC and subsequently by the RCCs, SS and PS. The MOP will give study specific information on trial logistics, the trial's safety monitoring plan, directions for specimen collection, storage and shipping, study

supplies, investigational product, contact information for the study management team, and any important study-specific operational information.

3. SCOPE

This SOP applies to the Protocol Principal Investigator, NCC, NDMC, and to all StrokeNet investigators, staff, or other entities associated with the Network who manage, oversee, and conduct research.

4. PROCEDURES

A. Protocol Principal Investigator

1. The PPI or designee with assistance from the NCC and NDMC is responsible for developing the study MOP, any necessary protocol specific training modules, study documents and templates. The PPI will conduct investigational site training on the protocol and study procedures.

2. The PPI with guidance from the NCC Trial Budget and Operations Planning Liaison will determine what is standard of care versus what is a research procedure based on published best practice guidelines.

3. The PPI in collaboration with the NCC and NDMC is responsible for incorporating protocol modifications based upon comments from the Extramural Scientific Committee (ESC) and the NINDS, and the FDA as needed.

4. The PPI is responsible for providing the final protocol to the CIRB with assistance from the NCC Administrative Co-Director or study-specific Project Manager (if hired).

5. The PPI and his/her designee in collaboration with the NCC and NDMC will determine what regulatory documents are required for participating sites and study individuals prior to the initiation of the clinical trial and throughout the duration of the study. This may include assessment tool certifications and research or protocol related training.

B. National Coordinating Center Services

1. The NCC will assist the PPI or his/her designee with the development of the study MOP, training modules and study documents.
2. The NCC will assist the PPI with investigational site training through webinars, study meetings and study site initiation visits.

3. The NCC will provide on-site or web-based training as outlined in the MOP, or 'for cause' as warranted.
4. The NCC and NDMC will facilitate standard training and certification in common stroke related assessment tools.
5. The NCC will manage the regulatory documents stored in WebDCU™. The study-specific Project Managers will report lapses in certifications to the PPI, and follow-up with the site to ensure that criteria for certification are re-established or to initiate procedures for re-certification.

C. National Data Management Center Services

1. The NDMC will assist the PPI with the development of study case report forms in the WebDCU™.
2. The NDMC will assist the PPI or designee with the development of the study MOP, training modules and study documents.
3. The NDMC with the NCC will assist the PI with investigational site training through webinars, study meetings and study site initiation visits.
4. The NDMC will provide a repository for storage of site study specific regulatory documents and personnel training/certification for each StrokeNet recruitment site in the WebDCU™.

D. Regional Coordinating Centers

1. The RCCs are responsible for overseeing the maintenance of documentation (electronic preferred) of RCC, SS and PS personnel training; and study specific regulatory documents in the WebDCU™.

5. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.50 General Responsibilities of Sponsors

ICH E6 The Principles of ICH GCP

6. REFERENCES TO OTHER APPLICABLE SOPS

ADM 05 Process for Solicitation, Review and Development of Clinical Trials

7. ATTACHMENTS AND REFERENCES

8. DOCUMENT HISTORY

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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	20-Sep-2016		
2.0	Final	19-Dec-16	19-Dec-2016	19-Dec-2016
3.0	Review with administrative changes	11-May-23	30-May-2023	30-May-2023

NIH StrokeNet Network

Standard Operating Procedure (SOP)

StrokeNet SOP Process for the Development of Study Materials and Investigational Site Training

Version 1

ADM #14

Originators: NIH StrokeNet NCC Personnel

Reviewed and Approved by:

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6/3/14

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3 June 2014

NINDS/NIH Representative

May 30, 2014

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