SOP Number: ADM 09
SOP NAME: RCC Management of Satellites and Performance Sites
Effective Date: 3-Jun-2014

1. POLICY

The purpose of this Standard Operating Procedure (SOP) is to define the expectations for Regional Coordinating Centers (RCCs), the National Coordinating Center (NCC) and the National Data Management Center (NDMC) in the management of Satellite Sites (SS) and Performance Sites (PS). The RCC Principal Investigator (PI) (or her/his delegate) is responsible for the identification and management of any RCC affiliated Satellites or PS. This responsibility is inclusive of all aspects of clinical trial performance and NIH StrokeNet Network activities, including but not limited to: 1) execution of Master Trial Agreements and Clinical Trial Agreements with the National Coordinating Center (NCC), execution of Reliance Agreements with a Central Institutional Review Board (CIRB), and the maintenance of required documents in WebDCU™.

2. DEFINITIONS AND ABBREVIATIONS

Abbreviations:

CIRB	Central Institutional Review Board (StrokeNet CIRB or Commercial CIRB)
CPS/PS	Clinical Performance Site/Performance Site
CTA	Clinical Trial Agreement
MTA	Master Trial Agreement (RCCs only)
NCC	National Coordinating Center, University of Cincinnati
NDMC	National Data Management Center, Medical University of South Carolina
NIH	The National Institutes of Health
NINDS	The National Institute of Neurological Disorders and Stroke
OON	StrokeNet Out-of-Network Satellites and Clinical Performing Sites
PI	Principal Investigator
PPI	Protocol Primary Investigator
RA	Reliance Agreement
RCC	Regional Coordinating Centers with a NINDS U24 award
SS	Satellites Sites
SMART IRB	“Streamlined, Multisite, Accelerated Resource for Trials” IRB Reliance platform
SOP	Standard Operating Procedure

Definitions:

Central/Single Institutional Review Board (cIRB/sIRB): Use of a cIRB/sIRB for the US sites of the NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research is required by the NIH policy.

Performance Site, also known as Clinical Performance Site (PS/CPS): A clinical location that is engaged in research for a clinical trial.

Reliance Agreement: A formal, written document that provides a mechanism for an institution engaged in research to delegate institutional review board (IRB) review to the CIRB.

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

Satellite Site (SS): Regional Coordinating Centers Satellites sites -an institution that is not legally affiliated with the awarded RCC but named by an RCC as a branch of its regional network. SS may or may not be a site for a clinical trial for StrokeNet affiliated studies.

StrokeNet Out-of-Network Satellites and Clinical Performance Sites: Satellites and Clinical Performance Sites not in StrokeNet under an RCC but participates in a particular trial. The Prime Awardee for the trial acts in the "role of the RCC" for support and oversight. Can join a StrokeNet RCC after one year of trial participation and acceptance into a StrokeNet RCC network.

3. SCOPE

This policy applies to all Regional Coordinating Centers with infrastructure awards from the NIH.

4. PROCEDURES

A. RCC Rights and Responsibilities

1. The RCC, through the RCC Program Director/Principal Investigator (PD/PI) has primary authority and responsibility to develop, implement and maintain a Regional Coordinating Stroke Center (RCC) for the NINDS Stroke Trials Network ("Stroke Network").
2. The RCC has primary and lead responsibilities for recruiting satellite centers to participate in RCC supported trials and providing scientific leadership and regular communication to satellite centers regarding protocols and study progress and for providing administrative and budget support for protocol initiation.
3. RCC request to add Satellite and Satellite PS outside of their NINDS designated geographic area requires the approval of the StrokeNet Executive Committee.
4. The RCC has responsibility for providing leadership for the Stroke Network activities at the RCC, including implementation of studies, coordinating with the central/single Institutional Review Board (IRB), monitoring RCC performance and quality control, participating in the preparation of

publications and presentations, and collaborating with Stroke Network clinical investigators and interacting with non-Stroke Network investigators.

5. Exceptions or additions to such activities can be made by the Network Steering Committee.
6. The RCC will manage and conduct the proposed clinical trial (or "study") in compliance with all established DHHS, NIH, NINDS policies and procedures.
7. The RCC will be responsible for protecting patient safety and obtaining adequate patient recruitment to complete the study.
8. It is the RCC's responsibility (1) to ensure that all sites engaged in research involving human subjects have an appropriate OHRP-approved Assurance and an IRB approval of the research consistent with 45 CFR Part 46 and (2) to retain documentation of compliance with the requirements of 45 CFR Part 46.
9. It is the responsibility of the RCC to comply with FDA policies and regulations as relevant to clinical trials and as published at 21 CFR Parts 50 and 312.
10. The RCC or his/her designee will ensure that the RCC page in the [Regional Coordinating Center] tab is current in the WebDCU™ on a yearly basis or within 30 days of a change.
11. The RCC is responsible for acting as a resource for any local questions regarding ongoing NIH StrokeNet trials within the RCC.
12. The RCC is responsible for assessing the Satellite Site/PS to understand their infrastructure and processes that are in place. This meeting should include an overview of the NIH StrokeNet Network, the network website www.NIHStrokeNet.org/ , and a directory of key contact personnel at the RCC, NCC and NDMC.
13. Roles of the local pharmacies and the local IRBs must be assessed for ways to expedite clinical trial implementation for NIH StrokeNet trials.
14. Clinical trial metrics will be maintained in the WebDCU™ for all RCCs, SS, and PS. For the NIH StrokeNet Network metrics, refer to SOP ADM 08: Network Process for RCC Performance Review.

B. SS or a PS Rights and Responsibilities

1. SS must have current registration in SAM.gov.
2. The SS/PS must execute a RA with the CIRB of record.
3. The SS/PS must keep current and accurate information about study personnel updated in the WebDCU™.
4. PS will recruit into NIH StrokeNet trials under the same Clinical Trial Agreements (CTAs) as the participating RCC site.
5. SS will recruit into NIH StrokeNet trials under its own Clinical Trial Agreements.
6. SS/PS will provide quality data, documentation of conflict of interests, good clinical practice, human subject protection and protocol training for participating investigators.
7. All travel to RCC meetings or NIH StrokeNet meetings must be paid by the SS/PS except as covered for travel related to trials as a recruitment site. Any other coverage of travel expenses would be at the discretion of the RCC PI. Must provide a site representative to attend all required investigator meetings and trial conference calls.

8. The SS/PS must complete required enrollment documentation for any trial and complete payment milestone tasks prior to receiving payment.
9. Each Performance Site will be responsible for:
    a. Complying with all local, and federal requirements for the initiation and ongoing performance of a clinical trial per the principles of Good Clinical Practice as defined in ICH Consolidated Guidance (ICH E6) and Title 45 and part 46 Federal Policy for the Protections of Human Subjects "Common Rule"
    b. Complying with the trial investigational plan as defined in the protocol and approved by the StrokeNet CIRB and the NINDS appointed DSMB
    c. Obtaining appropriate central IRB and local IRB acknowledgement of CIRB review.
    d. Reporting of required adverse events to CIRB and to the WebDCU CTMS for central trial review in compliance with defined procedures
    e. Responsiveness of site PI or in his/her absence, another designated investigative team member, to email correspondence within 2 business days
    f. Completion of internal logistics necessary to execute the trial
    g. Assurance that standard medical care and management of adverse events will be provided for all subjects randomized
    h. Assuring that the expenses for research related procedures are not billed to the subject
    i. Receipt, storage and accountability of study provided supplies in compliance with defined procedures
    j. Handling and administration of study supplies to subjects in compliance with defined procedures
    k. Assurance of access to subject medical records for site monitoring visits per institutional and trial procedures.
    l. Data collection entered into WebDCU™ in a time frame consistent with the MOP
    m. Compliance with all study policies and procedures published in the trial MOP. MOP will be available under Project Documents in the WebDCU™ as maintained by the NCC and on the StrokeNet website: http://www.nihstrokenet.org/

C. NCC Rights and Responsibilities

1. The NCC will enter a CTA with each RCC and SS so that the per-patient cost associated with specific Stroke Network protocols can be efficiently administered.
    a. Direct costs for approved Stroke Network trials are supported by grants from NINDS or other funding sources.
    b. The NCC will distribute the per-patient cost to the Stroke Network sites as total fixed unit basis.
2. The NCC will be responsible for fiscal oversight for overall project finances and protocol specific funding.
    a. The NCC is responsible for providing payment directly to RCCs and Satellite Sites for dispersal to the appropriate PS. Payments will be determined by the per patient budget and available online in the trial MOP WebDCU™ and/or on the StrokeNet website. Payments will be conditional on data completion/quality criteria and may be withheld until all issues are resolved.

3. This SOP along with ADM SOP 7 specifies budgeting guidelines for Stroke Network studies (industry and non-industry trials) including reconciliation and reporting plans that incorporates the following guidelines:
    a. The RCC will enter a Master Trial Agreement (MTA) and CTA with the NCC, so that the per-patient cost associated with specific Stroke Network protocols can be efficiently administered.
4. Clinical Trial Site Selection
    a. The NDMC will disseminate Stroke Network proposals surveys to all RCCs to allow sites the option to participate in each Stroke Network-supported study.
    b. The RCC is responsible for ensuring the clinical sites follow approved protocols and maintain quality control of data and ensure participant safety.
    c. Any problems concerning the compliance of clinical sites in the protocol or quality control of data should be reported immediately to the Administrative Program Official.
    d. For those clinical trials supported by a Third Party (any non-academic, commercial, advocacy, or philanthropic entity), the RCC must obtain the written documentation or agreement from all participating sites that they will abide by the terms of the agreement between a Third Party and the NINDS, including but not limited to special publication procedures and data sharing as well as the intellectual property options.
    e. Collaborations with a Third Party may have unique conditions, so the RCC, as well as the satellite sites, should confirm the details of each collaboration with NINDS.
5. The NCC is responsible for assessing the SS/PS performance as part of the larger RCC performance measurement.
6. The NCC is responsible for crediting the RCC for all recruitment at the affiliated PS.
7. The NCC is responsible for providing a SS/PS start-up checklist to assist with initiation of new RCC/PS in an RCC (see Attachment A).

D. NIH Requirement for CIRB/Single IRB Use for Multi-site Studies

1. In collaboration with the NINDS, the NCC will implement all procedures required to establish and implement a C IRB for all Stroke Network trials.
2. This includes coordinating a CIRB of record and managing all required IRB communication and documentation including, but not limited to, tracking approval, maintaining regulatory documents, communicating with site IRBs, and handling adverse event reporting and notifications.
3. The RCC PI is responsible for complying with CIRB requests and implementing the approved protocol, including obtaining informed consent for all study participants at the clinical site.

E. NDMC Responsibilities

1. Is responsible for development of the regulatory document module for a trial, and the module will track missing and/or expired trial specific regulatory documents on behalf of the SS/PS and OON sites and the responsible RCC.
2. The NDMC is responsible for the management of data for a trial and will notify the site and the responsible RCC of data quality issues including but not limited to missing data, missed data entry timelines, protocol deviations and protocol violations and other criteria as defined by the network or PPI.

3. The NDMC will collaborate with the NCC in developing SS/PS start-up checklist to assist with initiation of new PS in a RCC.
4. The NDMC will develop a database for Site Management, including CTA and invoicing.

5. APPLICABLE REGULATIONS AND GUIDELINES

21 CRF 312.57	Recordkeeping and Record Retention
ICH E6, 2.13	The Principles of ICH GCP
ICH E6, 5.1	Quality Assurance and Quality Control
ICH E6, 5.5	Trial Management, Data Handling and Recordkeeping
RCC NOA	RCC Notice of Grant Awards (2013)
45 CFR Part 46	Protection of Human Subjects
21 CFR Parts 50	FDA Policy and Regulations
21 CFR 312	FDA Policy and Regulations

6. REFERENCES TO OTHER APPLICABLE SOPS

ADM 02	Process for Reporting Financial Conflict of Interest
ADM 06	Process for Documenting Essential Financial and Federal Compliance
ADM 07	Per Subject Payments and Development of Clinical Trial Budgets
ADM 10	Process for Inclusion of New Satellite Sites for RCC
ADM 11	Process for CIRB Reliance
ADM 12	Process for CIRB Reporting
ADM 13	Process for Medical and Safety Monitoring
ADM 15	Network Communications
ADM 16	Process for Trial “Master” and “Site” Regulatory file Management

7. ATTACHMENTS AND REFERENCES

8. DOCUMENT HISTORY

Version	Description of 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	16-Sep-2016		
2.0	Final	19-Dec-2016	19-Dec-2016	19-Dec-2016
3.0	Further define roles in site management	26-Sep-2018	4-Oct-2018	4-Oct-2018
4.0	Inclusive of past MTA language	20-Apr-2020	20-Apr-2020	20-Apr-2020

Attachment A
*Editable for site use

NIH StrokeNet Site Start-Up and Initiation

Section I – Network Organization

The network is organized with a National Clinical Coordinating Center at the University of Cincinnati (UC) and the National Data Coordinating Center at the Medical University of South Carolina (MUSC). There are two websites you will need to access for the network, the NIH StrokeNet website and the MUSC WebDCU™ website.

NIH StrokeNet Website
Public View – no password required: https://nihstrokenet.org

- Education, Presentations/Webinars and Resources: https://nihstrokenet.org/education

Private or Network View – Password required: https://nihstrokenet.org/intranet

- Biweekly Updates: https://nihstrokenet.org/intranet/updates
- Minutes/Presentations
  - Steering Committee: https://nihstrokenet.org/intranet/minutes/steering-committee
  - Working Groups: https://nihstrokenet.org/intranet/minutes/working-groups
  - Trial Proposal Presentations: https://nihstrokenet.org/intranet/minutes/trial-proposal-presentations

MUSC WebDCU™ Website:
Password Required: https://webdcu.musc.edu

Section II – Important Contacts

A. NIH StrokeNet National Clinical Coordinating Center (NCC) contacts:

University of Cincinnati
260 Stetson St. Suite 5221
PO Box 670525
Cincinnati, OH 45267-0525
Toll Free: 855-472-0072

Administrative Director, NCC:
Jamey Frasure, PhD, RN
513-558-1742
frasurjs@ucmail.uc.edu

Contracts Team, NCC:
Diane L. Sparks, RN, BS
513-558-3924
sparksdn@ucmail.uc.edu

Wren Hanson, MBA

513-558-6566
hansonwm@ucmail.uc.edu

Regulatory Team, NCC:
Emily Stinson, MS
513-558-3979
stinsoey@ucmail.uc.edu

Jen Golan, MS
513-558-3976
golanjl@ucmail.uc.edu

Lauren Stricker, MHA
513-558-2968
strickla@mail.uc.edu

UC Central IRB (CIRB) Liaison, NCC:
Susan Roll, RN, BSN, CCRP
513-558-6061
rollsn@ucmail.uc.edu

Finance Team, NCC:
Keri Davidson Pinger, MHA
513-558-3915
davidski@ucmail.uc.edu

Paula Sinclair, BS
513-558-3945
sinclapl@ucmail.uc.edu

Administrative Specialist, NCC:
Rose Beckmann, CCRP
513-558-3907
beckmare@ucmail.uc.edu

NIH StrokeNet Secure Website User Name and Password Requests:
Jeanne Sester, Educational Coordinator
513-558-5225
sesterrj@ucmail.uc.edu

List Study Project and Clinical Managers specific to the startup study.

_____Study Project Manager, NCC (insert name):
Name: _____
Contact Phone (Office) _____ and if applicable (Cell) _____
Contact email: _____

_____Study Clinical Manager, Prime Award Site (insert name):

Name: _____
Contact Phone (Office) _____ and if applicable (Cell) _____
Contact email: _____

B. MUSC StrokeNet National Data Coordinating Center (NDMC)

Data Coordination Unit
Department of Public Health Sciences
Medical University of South Carolina
135 Cannon Street, Suite 303
Charleston, SC 29425-8350
P: 843-876-1919
F: 843-876-1923

NIH StrokeNet Director of Trial Operations, NDMC
Jessica Griffin, MHA, CCRP
843-792-1677
simonsjl@musc.edu

NIH StrokeNet Project Manager, NDMC
Logan Sirline, MPH
843-876-1262
sirline@musc.edu

List Study Data Manager and Monitor Manager specific to the startup study.

Data Manager, NDMC (insert name):
Name: _____
Contact Phone (Office) _____ and if applicable (Cell) _____
Contact email: _____

Monitor Manager, NDMC (insert name):
Name: _____
Contact Phone (Office) _____ and if applicable (Cell) _____
Contact email: _____

Section III - Checklist for Ready to Enroll

A. Clinical Trial Agreement (CTA) (grant subawards)

NCC Study Project Manager provides:

a. The name of the trial specific medical facility PS, the name of the RCC or Satellite, the name, phone and email of the performance site PI; name, phone and email of the performance site trial primary coordinator to StrokeNet Contracting.
b. If the site is OON, the name, address, DUNS# and FWA of the Satellite, the name address, FWA of trial specific medical facility PS, the name, phone and email of the performance site PI; name, phone and email of the performance site trial primary coordinator to StrokeNet Contracting.

c. Registration in SAM.gov, an active OHRPP FWA and a StrokeNet CIRB Reliance Agreement/Advarra IRB Reliance Agreement/SMART IRB Agreement is required for issuance of a CTA

☐ **Complete and Return Clinical Trial Agreement**

CTA 3B data is required for issuance of the CTA the Administrative Contact, Financial Contact and Authorized Official sections.

- Administrative Contact - the person the NCC will send the Clinical Trial Agreement to and who will be responsible for obtaining the Authorized Official's signature.
- Financial Contact –contact in the post-award office in Sponsored Programs Grants and Contracts office. If we have questions regarding the receipt of the electronic payments, this person would be able to answer questions.
- Authorized Official - the person authorized to sign legal agreements on behalf of the institution.

Once StrokeNet Contracting has received the 3B data, the CTAs are prepared and sent out for signature by NCC Contracting or by a CRO (if part of a particular trial, usually foreign). The partially executed CTA is returned to StrokeNet Contracting for full execution. A fully executed CTA will be returned to the RCC or the Satellite or the OON site for their files.

Changes to the 3B must be updated and communicated to StrokeNet Contracting as soon as possible. The PI and site changes require prior Prime approval and amendments.

☐ **Complete and Return Electronic Funds Transfer Agreement**

Vendors

Payments in NIH StrokeNet NCC clinical trials are directed to the RCC or Satellite (in network or OON) named in the Clinical Trial Agreement (CTA), not to the PS. Payments will be made via direct deposit. NO checks will be issued.

RCCs and Satellites only

If an RCC or Satellite has not established an electronic form of deposit, please follow the instructions below.

Remittance Instructions

A University of Cincinnati Direct Deposit form is sent with the CTA. For audit purposes a W-9 is also required. The UC form is to be completed by RCCs and Satellites only. When returning the form please reference the UC vendor number which is the last 6 digits of the subaward number cited in the MTA and referenced in the CTA; e.g. 'StrokeNet vendor# 123456.'

Please print and complete the UC direct deposit form (it is not fillable) and return via encrypted email to Tina Huston (Asst Director Bus Affairs) hustontm@ucmail.uc.edu with a cc to the

StrokeNet Trial Payments mailbox strokenettrialpymts@uc.edu. For more detailed instructions please contact Tina at 513-556-6772.

If you do not have a direct deposit account, please ask Ms. Huston about the e-payables option.

Payment

A purchase order (PO) will be set up for each PS participating in a StrokeNet trial. NO payment can be made without an active PO. POs are updated annually. Authorization is established by completing a CTA Amendment (FEO) for the new performance period.

Only when this information is at the NCC can a purchase order (PO) be set up for the site. NO payment can be made without an active PO. POs are renewed annually.

B. Local Site Clinical Trial Agreement (CTA) Requirements (time from receiving to execution target is < 45 days)

☐ **Complete appropriate forms for your local research Sponsored Programs/Grants and Contracts Office following your performance site specific procedures prior to receiving the CTA. Some institutions require preapproval of the budget prior to deciding whether their institution can participate.**

Data required

- Performance Site PI
- Prime Award PI
- Per Patient Budget (includes projected trial enrollment) There is no site-specific enrollment target number.
- Contact information
  - Prime Award Site PI
  - NCC
  - RCC
  - Performance Site PI
- Project period
- Indirect rate is approved by the NINDS with the award per patient budget and is non-negotiable. The StrokeNet rate was increased in the 2019 grant submissions to align with other NIH-funded networks.
- Funding source and number

☐ **Determine if any other Agreements are required:**

- Data Use Agreements (DUA) with the data coordinating center and/or prime award site if applicable
- License Agreements/Contracts/Business Associate Agreement/DUAs with any vendors if applicable

C. CIRB Process (time from receiving packet to submission target is < 45 days)

All RCCs and Satellites, which includes clinical performance sites, have signed a Reliance Agreement prior to being trial eligible. Use of a CIRB is NIH-mandated.

Process overview will be determined by the use of the NIH StrokeNet CIRB or a commercial IRB.

Performance Site Submissions - Follow the study specific directions provided by the NCC Project Manager

☐ **Complete the Performance Site CIRB Application as needed**

☐ **Complete any requirements of the local performance site Human Research Protection Program (or equivalent office) for relying on another IRB. This could include, but may not be limited to, the following:**

- Entry into the local institutions IRB system for tracking of reliance protocols or any necessary **pre-approvals of materials** required by the IRB before submission to the CIRB.
- Complete local forms for research billing compliance:
  - Determination of research vs clinical care costs
  - Ensure that all charges will be covered by the subject payment
  - Notes about billing compliance: In order to comply with federal, state and institutional regulations and standards for clinical trial billing, the institution is responsible for establishing effective processes to ensure that all services for a study are billed properly. These processes can be complex because clinical trials often involve multiple entities that are responsible for costs incurred during the course of a trial. During a single visit a research participant may receive routine medical care in addition to services or procedures conducted purely for research purposes.
  - The purpose of the institutional Billing Coverage Analysis is to determine deemed and qualifying status as well as which routine care costs may be billed to Medicare or other insurers and which costs must be paid by the sponsor.
  - The StrokeNet Per subject Schedule of Events patient care costs were determined in compliance with the Centers for Medicare/Medicaid Services' (CMS) "Medicare Clinical Trial Policy". The study will only pay for items provided solely to satisfy trial data collection and analysis needs, and will not pay for routine costs for items typically provided absent of a clinical trial. The SOE flags the Prime Award PI's determination of SOC.
- Assess and provide local site approval/acknowledgment process with approval timelines
  - Will there be additional required local reviews pre- or post-CIRB approval?
  - Can the reviews take place in parallel with the CIRB review?
  - Inform the NCC if the local process will be >30 days.
  - The StrokeNet CIRB Chair and Liaison are available for consultation as needed for complex local IRB matters.

CTA Subaward

Some RCC and Satellites will not sign the CTA until CIRB approval has been obtained. Know the process of your institution prior to a trial and advise all involved parties (PI, site trial coordinator, NCC Project Manager, NCC Contracting) of the institution's procedures.

☐ **Upon receipt of the fully executed Subaward - Review budget and budget components**

☐ **Obtain a WebDCU™ User Account for the research office finance personnel.**

- Plan for assigning effort to grant account when activated.

- Pharmacy, lab and other charges that may be applicable to a particular study should be set up to be charged to the grant account.
- Internal rebudgeting is permitted.
- There is no invoicing for any StrokeNet trial. Start-up payments are generated by the fully executed CTA and verified completion of study specific start-up requirements (e.g., CIRB approval, posting of site and people documents in WebDCU™, etc.). Per subject enrollment payments as outlined in CTA are generated by data submitted into WebDCU™ and confirmed by NCC Financial Administrator.

D. WebDCU™ Process for Regulatory Documents

☐ **Obtain a WebDCU™ User Account to Upload Regulatory Documents**

If you are new to WebDCU™, you will receive an email from the NDMC with your login information. New team members need a WebDCU™ account to enter data and to upload and view documents in WebDCU™, the Clinical Trial Management Systems used for StrokeNet.

If you currently have WebDCU™ access for another project, you will see the Study icon appear upon logging in.

☐ **Upload Site Regulatory Documents to WebDCU™:**

- Regulatory documents will vary by study.
- The regulatory document parameters will be sent to the primary coordinator and site principal investigator at the start of each study. It contains instructions specific for compiling and posting study required documents (e.g., CV, medical license, etc.).
- Trial specific regulatory documents, study CRFs, data collection guidelines, MOP, etc. can be found in the study toolbox.
- Delay in completing this step delays submission to the CIRB or triggers amendments to the CIRB.

☐ **Create the WebDCU™ Delegation of Authority Log (DOA)**

- List your Study Team and their roles and study responsibilities
- Identifies level of privileges required and documentation needed
  - Notes: The delegation of authority log records all study team members study related duties. The purpose is to ensure that the individuals performing study-related tasks/procedures are appropriately trained and authorized by the investigator/study project managers to perform the tasks/procedures. This form should be completed prior to the initiation of any study-related tasks/procedures and should be updated as necessary due to changes in study staff, roles, or responsibilities.
- Once the WebDCU™ generated DOA log is accepted by the study specific NCC Project Manager, the required documents for each study team member are posted

- Required trial specific regulatory documents can be found in the study toolbox.

☐ **Attend Clinical Trial Training Session (held by overall Trial PI and NCC). If unable to attend in-person protocol training, view the on-line protocol training and acknowledge on the attestation form.**

☐ **Set up Study Processes or Work-flow at site**

- Diagram process flow for study team

- Set up Site specific workflow and create a step-by-step guide, detailing enrollment process screening through follow-up
- Prepare local study sample CRF Binder-CRFs are available and downloadable from WebDCU™
    - NOTE: Study specific Regulatory and CRF binders will not be provided
- Develop order sets (if needed).
- Initiate a research recruitment notification (if needed)
    - REMEMBER: all methods and materials aimed at recruiting participants into a research study (e.g., printed advertisements, scripts, web sites, phone calls) must be reviewed and approved by the CIRB prior to use.
- Develop lab/specimen collection/storage procedures (if needed). Study specific SOPs will be provided in the MOP and available in WebDCU™
- Finalize local study CRF Binder
- Identify location of binder

☐ **Site Initiation Visit scheduling, if applicable**

Checklist for Site Initiation (will vary by study)

Regulatory / CTA	**Training / Certification**
☐ DOA approval	☐ Protocol (Everyone)
☐ Regulatory Documents uploaded to WebDCU™	☐ Training for study specific measures such as NIHSS, mRS
☐ Regulatory Documents approved	☐ Other training per protocol requirements
☐ Performance Site CIRB approval	☐ WebDCU™ (Everyone)
☐ Clinical Trial Agreement	☐ Credentialing

☐ **Roll out Study at Site**

Training/education

- Clinical team
- Nurses
- Lab
- Pharmacy
- Other ancillary personnel
- Mock enrollment with team

Local/Regional Marketing to promote study – All material presented to or viewable by the public or potential participants must be CIRB approved before use.

Site Activation to Begin Enrolling

WebDCU™ will send notification authorizing the site's release to enroll.

A special thanks to Sherry Goldfarb, MPH, at the University of Michigan for authoring this helpful document

NIH StrokeNet
PREVENTION | TREATMENT | RECOVERY

NIH StrokeNet Network

Standard Operating Procedure (SOP)

RCC Management of Satellites and Performance Sites

Version 4

ADM 09

Originators: NIH StrokeNet NCC Personnel

Reviewed and Approved by:

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