(Generic) StrokeNet
Roadmap to "Ready to Enroll"

Draft Version 6/26/17

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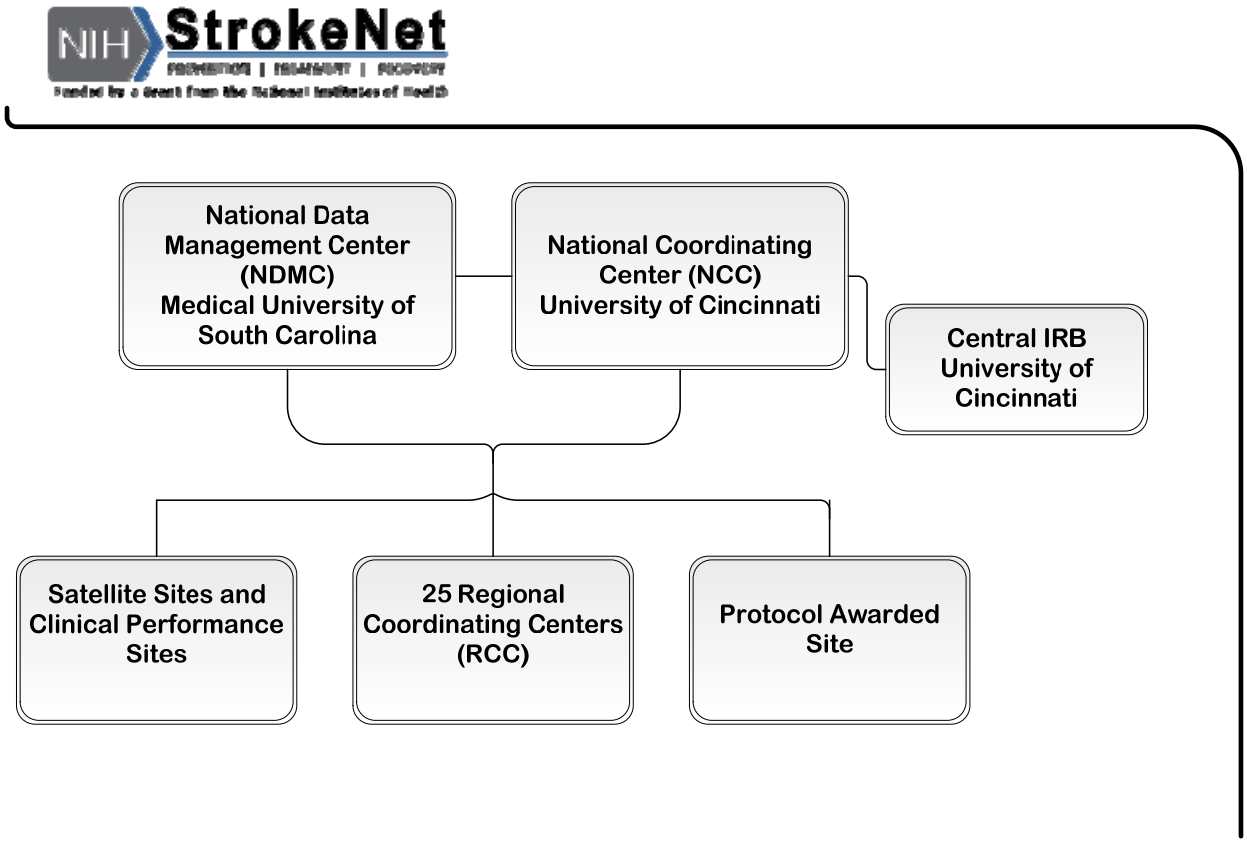
Section I – Network Organization

The network is organized with a National Clinical Coordinating Center (NCC) at the University of Cincinnati and a National Data Management Center (NDMC) at the Medical University of South Carolina (MUSC). All network trials utilize a central IRB (CIRB) which is housed at the University of Cincinnati. There are 25 Regional Coordinating Centers (RCC), each with satellite sites (SS) and clinical performance sites (CPS).



The NCC provides leadership for the network infrastructure including initiation of collaborative relationships, facilitation of the design, oversight, and management of network studies. Operationally, the NCC is the home for a Central Institutional Review Board (IRB) for NIH StrokeNet.

The NDMC is responsible for developing, implementing and maintaining the data management and statistical activities of the network.

Websites

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

Passwords are issued when your join a study team or the network

Section II – Important Contacts

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

NIH StrokeNet
University of Cincinnati
260 Stetson St. Room 5226
PO Box 670525
Cincinnati, OH 45267-0525
Toll Free: 855-472-0072

Administrative Directors, NCC:
Judith Spilker, RN, BSN
Administrative Director
513-558-5430
spilkeja@ucmail.uc.edu)

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

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

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

Finance, NCC:
Mary Ann Harty, Sr. Grant Administrator
Financial Manager
513-558-3915
hartyma@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
jeanne.sester@uc.edu
513-558-5225
sesterrj@ucmail.uc.edu

B. MUSC National Data Management Center (NDMC)

Data Coordination Unit
Department of Public Health Sciences
Medical University of South Carolina
135 Cannon Street, Suite 303
MSC 835
Charleston, SC 29425-8350
P: 843.876.1919
F: 843.876.1923

StrokeNet Director of Operations, NDMC
Catherine Dillon, MS
843-876-1942
rileycp@musc.edu

StrokeNet Data/Monitor Manager, NDMC
Jessica Griffin, CCRP
843-792-1677
simonsjl@musc.edu

NCC Study Specific Project and Clinical Managers

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

_____Study Clinical Manager, _____-Prime Award Site:
Name: _____
Contact Phone (Office) _____ and if applicable (Cell)_____
Contact email: _____

MUSC Study Specific Data Manager and Monitor Manager

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

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

Study Specific Prime Award Site

Principal Investigators:
Study Manager, if applicable

Regional Coordinating Center (RCC) Contacts

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

RCC Program Manager/Coordinator
Name: _____
Contact Phone (Office) _____ and if applicable (Cell)_____
Contact email: _____

Section III - Checklist for Ready to Enroll

Please keep in mind that many of these items will occur simultaneously and all tasks should be initiated as soon as possible to avoid delay in study start

A. Protocol Trial Agreement (PTA) (Grant Subawards)Process

The NCC Site Project Manager provides the following information to the NCC StrokeNet Contract Manager:

- Performance Site PI - name, address, phone and email
- Performance Site primary trial coordinator - name, phone and email
- Institutional name of the performance site

☐ **Complete and Return Protocol Trial Agreement (PTA)**

PTA 3B forms are sent to the performance site trial coordinator or RCC trial coordinator or PI to complete the administrative contact, financial contact and authorized official sections.

- Administrative Contact - the person the NCC will send the protocol 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 from the performance site primary coordinator, the PTAs are prepared and sent out for signature by the RCC or Satellite. The partially executed PTA is returned to StrokeNet Contracting for full execution.

☐ **Complete and Return Electronic Funds Transfer (EFT) Agreement**

In order to know to know where patient care funds should be directed (RCC or Satellite named in the Protocol Trial Agreement) it is necessary for the receiving institution provide this information. NO checks will be generated. Due to increased security procedures *vendors are no longer allowed to email the form unless it is "encrypted"*. The EFT information can be submitted:

- As electronically completed per the Website : https://www.uc.edu/af/controller/acctpayable.html
- The completed form can be returned to the person noted as **Finance Manager for the NCC** via email with the word **"ENCRYPTED"** in the subject line.

- Otherwise it must be returned through the US Postal Service. Mailing instructions can be found on page two of the pdf provided via the link.

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 Subaward Requirements and Process

☐ **Complete appropriate forms for your local research Sponsored Programs/Grants and Contracts Office following your performance site specific procedures**

Data required

- Performance Site PI
- Prime Award PI
- Per Patient Budget (includes projected trial enrollment) There is no site-specific enrollment number.
- Contact information
  - Prime Award Site PI
  - NCC
  - RCC
  - Performance Site PI
- Project period
- Indirect rate (Currently 42%, approved by NINDS with the award per patient budget, non-negotiable. The StrokeNet rate will be recalculated for Phase II of StrokeNet.)
- 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
- License Agreements/Contracts/Business Associate Agreement/DUAs with any vendors if applicable

☐ **Upon receipt of the fully executed Sub-award, review budget and budget components**

- 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 PTA 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 PTA are generated by data submitted into WebDCU™ and confirmed by NCC Financial Manager.

C. Central IRB (CIRB) Process

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

All Veteran Administration (VA) Non-profits and medical facilities have signed a Memorandum of Understanding with the VA CIRB, in lieu of the StrokeNet CIRB Reliance Agreement.

Process Overview

1) Prime Award Site PI will submit the protocol and informed consent form template (along with any other study-wide documents that need CIRB approval) to the CIRB Liaison for submission to the CIRB. All approved documents will then be available for distribution to the performance sites.
2) The prime award approval letter, protocol and informed consent template document will be distributed by the NCC Project Manager to performance sites along with the Local Site Context Form (to be completed in conjunction with the performance site's local Human Subjects Protection Program or equivalent office). The StrokeNet Conflict of Interest Forms and the ePAS Assurance Statement may have already been distributed to the performance site to obtain signatures.
3) The Performance Site CIRB Application Packet is submitted to and reviewed by the CIRB. The approval letter and approved documents are distributed to the performance site by the study specific NCC Project Manager.

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

☐ **Complete the Performance Site CIRB Application including:**

- Ancillary Reviews (to be done at performance sites as applicable):
  - Pharmacy (Initiate review by Investigational Drug Service, if required)
  - Lab
  - Others as applicable (e.g., radiation safety)
- StrokeNet Conflict of Interest Forms
- ePAS Assurance Statement
- Complete Informed Consent Sections:
  - Receive CIRB Consent template from the designated study NCC Project Manager
  - Review and follow the instructions for the Consent template (provided with the template). Remember the following sections may be modified per your performance site's requirements; however, NO OTHER CHANGES WILL BE ACCEPTED.
    - Please add the performance site's name, performance site principal investigator's name and a 24-hour emergency contact phone number on the template.

- Please add the performance site principal investigator's name and the performance site's name under WHO IS CONDUCTING THE RESEARCH STUDY?
- Please add the performance site principal investigator's name and a telephone number under WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?
- WHAT ARE THE FINANCIAL CONSIDERATIONS? –*The language that currently appears in this section is not modifiable; however, your institution might have other forms of compensation, incentive or reimbursement, if permitted under the trial, to add to this section and/or institutionally required language pertaining to payment of taxes that must be placed in this section.*
- WHAT COMPENSATION IS AVAILABLE IN CASE OF INJURY?
- AUTHORIZATION TO USE AND DISCLOSE HEALTH INFORMATION
  - *The Authorization section may be removed in its entirety (if using a stand-alone document) or modified as necessary to meet your site's requirements. Please note that if your institution requires a stand-alone HIPAA authorization document, it must be submitted to the CIRB for review and approval.*
  - If current language is retained, please add the performance site principal investigator's name and address at the end of the section referring to revoking or withdrawing from the research later.

- Complete the CIRB Performance Site Application Form
- If a Waiver of HIPAA Authorization for Screening Purposes is needed, please refer to the Local Site Context Form. If the response to Question 2c "Does the screening procedure at your institution require a Waiver of HIPAA Authorization?" has been marked "YES", complete the Request for a Partial HIPAA Waiver Form.

Please send the above documents, which represent the "CIRB Performance Site Application Packet" to the study specific NCC Project Manager.

CIRB Questions?

For **questions** regarding CIRB submissions, please contact: Susan Roll, StrokeNet CIRB Liaison (Phone: 513-558-6061, Email: rollsn@ucmail.uc.edu)

☐ **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 standard of care at each individual site determines which items on the protocol schedule of events will be paid for by the study.

☐ **Upon CIRB approval of the performance site the NCC PM will send the CIRB approval letter and approved informed consent to the performance site study coordinator and request the Local IRB acknowledgement.**

When acknowledgement is obtained it is to be posted in WebDCU™. Not all IRBs will provide an acknowledgement statement. Any refusal to provide acknowledgements will be posted once and subsequent requirements for such acknowledgements will be waived by the NCC PM for the site.

Reminder: Upload all CIRB approvals into WebDCU™ as they are received

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 specific toolbox in WebDCU™.

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

- Who can enroll/view/treat etc.
- Identifies level of privileges required and documentation needed
  - 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

DOA amendments require CIRB approval and should be timely to remain accurate; however, be combined whenever possible.

Regulatory Document Questions?

For **questions** regarding regulatory document requirements or why a DOA or regulatory document was approved/rejected, please contact: the study Project Manager

E. WebDCU™ Toolbox

Each study will have a toolbox in WebDCU™. The tool box includes many helpful items including:

- Study Specific WebDCU™ user manual
- Regulatory document Parameters
- Study Manual of Procedures
- Training Guides
- Reference Guides
- Study Book
- Protocol
- FAQs
- and more

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

F. Training

☐ 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.

G. Local Study Work-Flow

☐ 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. (See Sample Work-Flow Document for DEFUSE 3 attached separately)
- Prepare local study sample Case Report Form (CRF) Binder-CRFs are available and downloadable from the study specific toolbox in WebDCU™

  NOTE: Study specific Regulatory and CRF binders will not be provided
- Develop order sets (if needed). Templates will be provided by the study specific Project Manager
- Initiate a research recruitment notification (if needed)

  REMEMBER: all materials aimed at recruiting participants into a research study (e.g., printed advertisements, scripts, web sites) must be reviewed and approved by the CIRB prior to use.
- Develop lab/specimen collection/storage procedures (if needed).
- Study specific Standard Operating Procedures (SOPs) will be provided in the MOP and available in WebDCU™
- Finalize local study CRF Binder
- Identify location of binder

H. Study Initiation Visit

☐ Site initiation visit scheduling, if applicable

Checklist for site initiation (will vary by study)

Regulatory / PTA	**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)
☐ Protocol 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
You will receive an email from the NCC Project Manager authorizing site release to enroll in WebDCU™ followed by an email confirmation from WebDCU™ with approval to enroll.

Enroll

Appendix 1 – Abbreviations and Definitions

CIRB	Central Institutional Review Board: Assumes the responsibility of approving, monitoring and reviewing biomedical and behavioral research involving humans.
CRF	Case Report Form
DOA	Delegation of Authority Log
DUA	Data Use Agreement: A DUA is a contractual document that outlines the terms and conditions of the transfer of data to an outside entity.
EFT	Electronic Funds Transfer – required for study payments
fCOI	Financial Conflict of Interest
fCOI-C	Financial Conflict of Interest Certification
GCP	Good Clinical Practice: Is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects.
MTA	Master Trial Agreements
NCC	National Coordinating Center at the University of Cincinnati
NDMC	National Data Management Center at the Medical University of South Carolina
PO	Purchase Order: Set up to pay sites for study enrollment
Prime Award Site	The Prime Award site is the institution of the study principal investigator who received the project award for the StrokeNet trial.
PM	Project Manager
PS	Performance Site: An institution that is not legally affiliated with an awarded RCC but which has agreed to serve and be wholly supervised by the RCC as a network trial recruitment site.
PTA	Protocol Trial Agreement
RA	Reliance Agreement: Agreement of performance site to cede review to the central IRB.
RCC	Regional Coordinating Center: An institution designed and directly funded by the NINDS/NIH to provide leadership for the NSN on a regional level.
SOP	Standard Operating Procedures
SS	Satellite Site: an institution named by an RCC as a part of its regional network that is not legally affiliated with the RCC but maybe

delegated (via RCC standard operating procedures (SOPs) certain leadership responsibilities.