

NIH StrokeNet Coordinator Webinar

August 23, 2023

New This Funding Cycle: Clinical Research Professional (CRP) Education and Training Core

- **CALL FOR CHAIR APPLICANTS!** Funding for two chair positions to lead this new core starts **12/1/2023**
 - Open to RCC Managers and NCC Project Managers
- Contact Laura Benken osinsklr@ucmail.uc.edu with your resume and cover letter including experience in education and training in clinical research by **8/31/23**
- Two Chairs will be selected in September 2023 and asked to present an initial plan (20 minutes) during the StrokeNet Meeting in Toronto on **10/9/2023**

NIH StrokeNet Standard Operating Procedures (SOP) Webinar Series

https://www.nihstrokenet.org/sop_gcp

- Series to review all StrokeNet SOPs
- All **RCC PIs** and **RCC Managers** will be required to review and attest they have reviewed all StrokeNet SOPs

Attestation Form

NIH StrokeNet Standard Operating Procedures (SOPs), Administrative (ADM), and Good Clinical Practice (GCP)
*Note: after reviewing the SOPs please complete the review confirmation form.

Section One: Network Administration SOPs

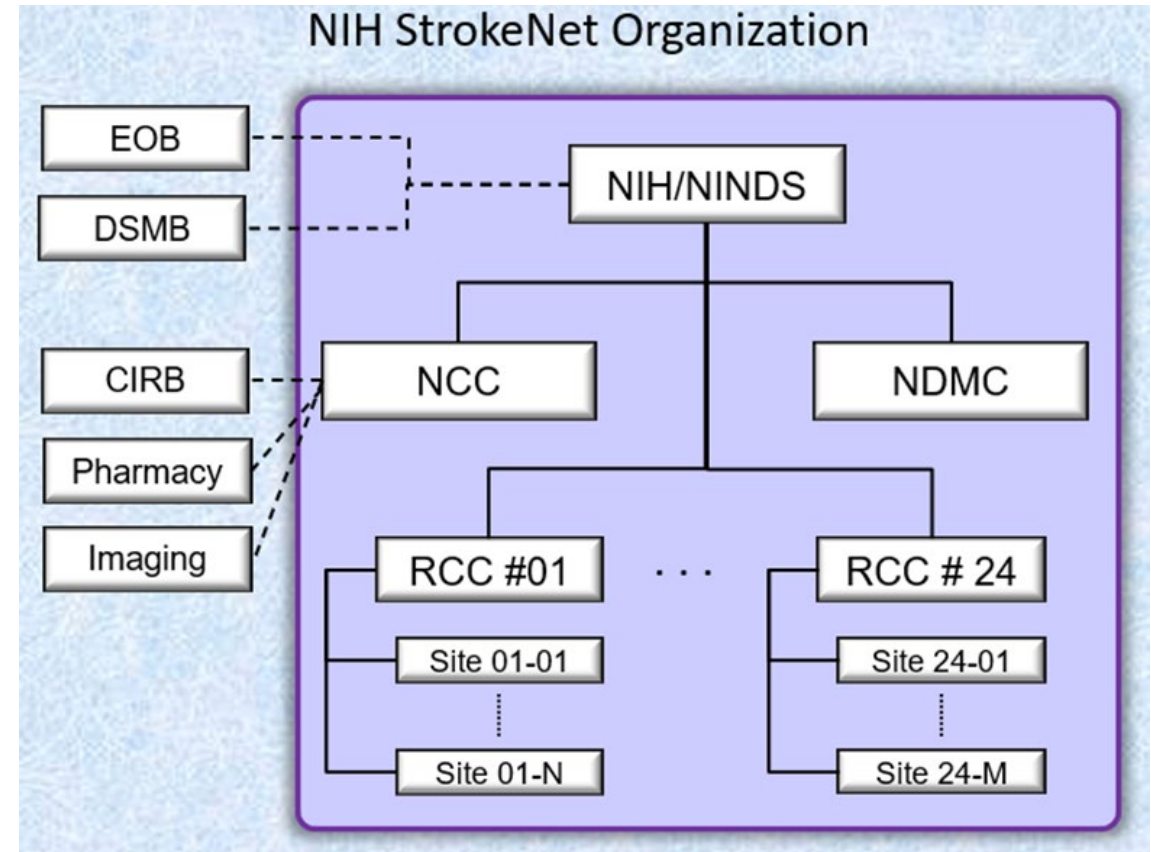
Administrative SOP Number	Adm. SOP Title	Status
ADM 1	Developing StrokeNet Standard Operating Procedures	Final - Reviewed January 2023
ADM 2	Site Performance Monitoring, Audits, and Inspections	Final - Reviewed February 2023
ADM 3	Network Publication Policy	Final - Reviewed July 2022
ADM 4	Network Data Sharing Policy	Final - Reviewed January 2023
ADM 5	Network Process for Solicitation, Review and Development of Clinical Trials	RETIRED
ADM 6	Essential Financial and Federal Compliance	Final - Reviewed June 2023
ADM 7	Per Subject Payments and Development of Clinical Trial Budgets	Final - Reviewed June 2023

SOP Review – How StrokeNet is Structured and Governance

SOP #	SOP Title
ADM 17	StrokeNet Organization and Governance
ADM 09	RCC Management for Satellites and Performance Sites
ADM 10	Inclusion of New Satellites and Performance Sites
ADM 15	Network Communications

ADM 17 – NIH StrokeNet Organization and Governance

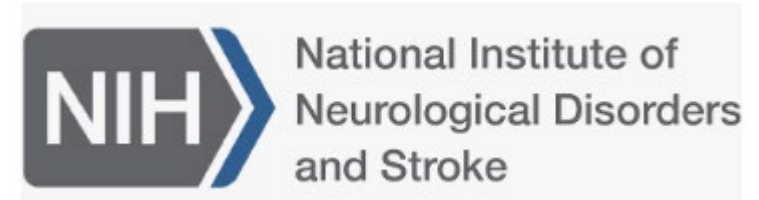
- **NIH/NINDS** funds the infrastructure in 5-year cycles:
 - **National Coordinating Center (NCC)** @ University of Cincinnati
 - **National Data Management Center (NDMC)** @ Medical University of South Carolina
 - **24-27 Regional Coordinating Centers (RCCs)**
 - Satellite Sites
 - Performance Sites



NIH/NINDS



Scott Janis, PhD
StrokeNet Program Scientist
janiss@ninds.nih.gov



- **National Institute of Neurological Disorders and Stroke (NINDS)** is the funding agency for the NIH StrokeNet Network. NINDS program staff are involved in the development of new StrokeNet proposals, as well as the management of funded proposals. StrokeNet Program Scientist provide scientific/administrative input.
- **External Oversight Board (EOB)** - oversees progress and advises its leadership on its overall direction.
- **Data and Safety Monitoring Board (DSMB)** - monitors study performance and participant safety.

NCC & NDMC: Main Responsibilities

- Provides leadership for the StrokeNet infrastructure to facilitate rapid development and implementation of NINDS-funded stroke trials.
- Overseeing from conception to analysis/publication the implementation of multi-center clinical trials, biomarker validation, and ancillary studies conducted in the network.
- Providing information necessary to potential investigators as they apply for funding by the NINDS:
 - reviewing protocol synopsis and schedule of activities, creating project work scope and timeline, ensuring the feasibility of the proposed projects by analyzing the numbers of potentially eligible participants at the proposed sites and by including patient representatives in the conceptual process.

NCC @ University of Cincinnati



The NCC provides the following services for funded trials

NCC Project Manager

Works closely with the Prime Principal Investigator(s) and Prime Project Manager for overall management of the trial and main point of contact for activities at the NCC

CIRB

StrokeNet CIRB

Trials < 50 sites

Advarra CIRB

Trials > 50 sites OR platform trials

Regulatory Specialists

Support staff assists NCC Project Managers and performance sites during start-up IRB approvals, modifications, and continuing review. Assists with review/management of the regulatory database in WebDCU

Contracting and Site Payments

Establish standard Clinical Trial Agreements (CTA)s with NIH StrokeNet RCCs and Satellites Sites for each trial

Pharmacy

Coordinates study drug management, drug and placebo acquisition, delivery plan for bulk drug, secondary packaging/labeling/distribution/storage, blindedness testing, coordinating stability testing, accommodating expiration timelines, and drug accountability

Imaging Management

Coordinating management of centrally stored neuroimages collected in NIH StrokeNet studies

NDMC @ MUSC



The NDMC provides the following services to funded trials

Data Management

Develop Case Report Forms (CRF's), finalize randomization scheme/process, data quality assurance and data monitoring plan. Provide efficient data management for trials. Promote standardization and harmonization of data collection across trials. Transfer data to statistician for interim analysis, after follow-up, cleaning, and closing-out the database.

Data Quality Assurance

Oversee data quality control, including but not limited to regular data queries and data monitoring and cleaning to assure data completeness and quality.

Data Sharing

Support and promote rigorous data sharing after trial completion by preparing a final data set, with limited personal or de-identified health information, in a format appropriate for data sharing, for submission to a secure data repository after publication of the primary study results.

Monitoring

Identify experienced clinical research monitors to conduct site visits to monitor the quality of record keeping, source documentation, and the accuracy of data entry.

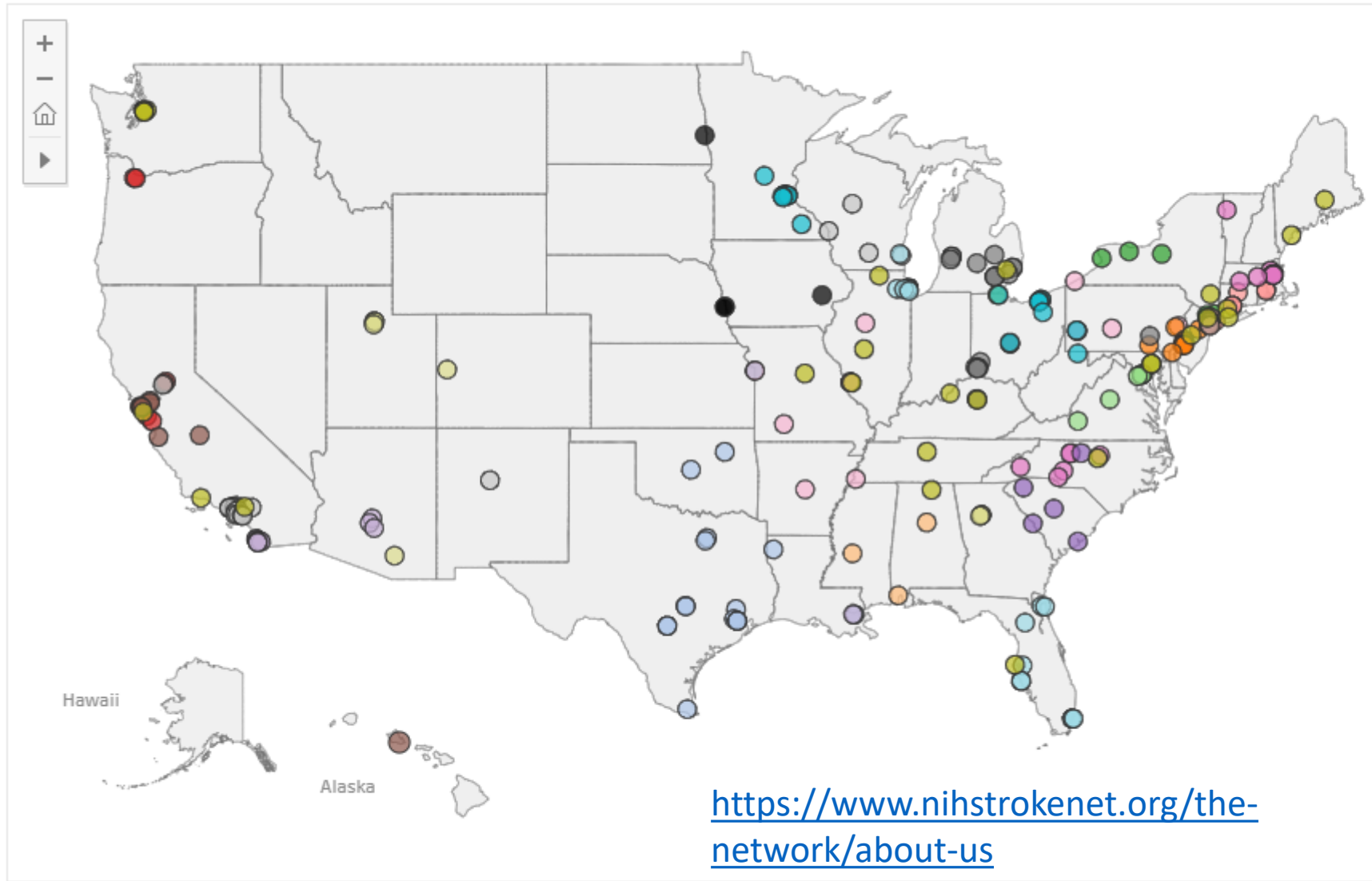
Statistical Support

Provide statistical input to network investigators or to potential network project applicants at the request of the NINDS during the conceptual, pre-submission phase. Collaborate with the clinical investigators and project study statisticians in the oversight of interim and final analyses per protocol and in preparation of presentations of primary and secondary publications. Provide additional analyses at the request of the DSMB, the FDA, or the NINDS.

StrokeNet Regional Coordinating Centers (RCC)s

- Have clinical science excellence and specialized expertise in stroke management, a strong background in stroke research, and a proven ability to recruit stroke patients that include patients from various racial and ethnic minority groups
- RCCs are expected to:
 - Propose, develop, and conduct protocols, recruit patients, and disseminate research findings.
 - Take part in multiple concurrent protocols and to recruit additional sites into their regional consortium as needed to enroll participants in a timely manner in NINDS-funded NIH StrokeNet trials.
 - Participate in a cooperative and interactive manner with one another and with the NCC/NDMC.
 - Providing scientific leadership and regular communication to satellite centers regarding protocols and study progress.

National and Regional Coordinating Centers and Performance Sites



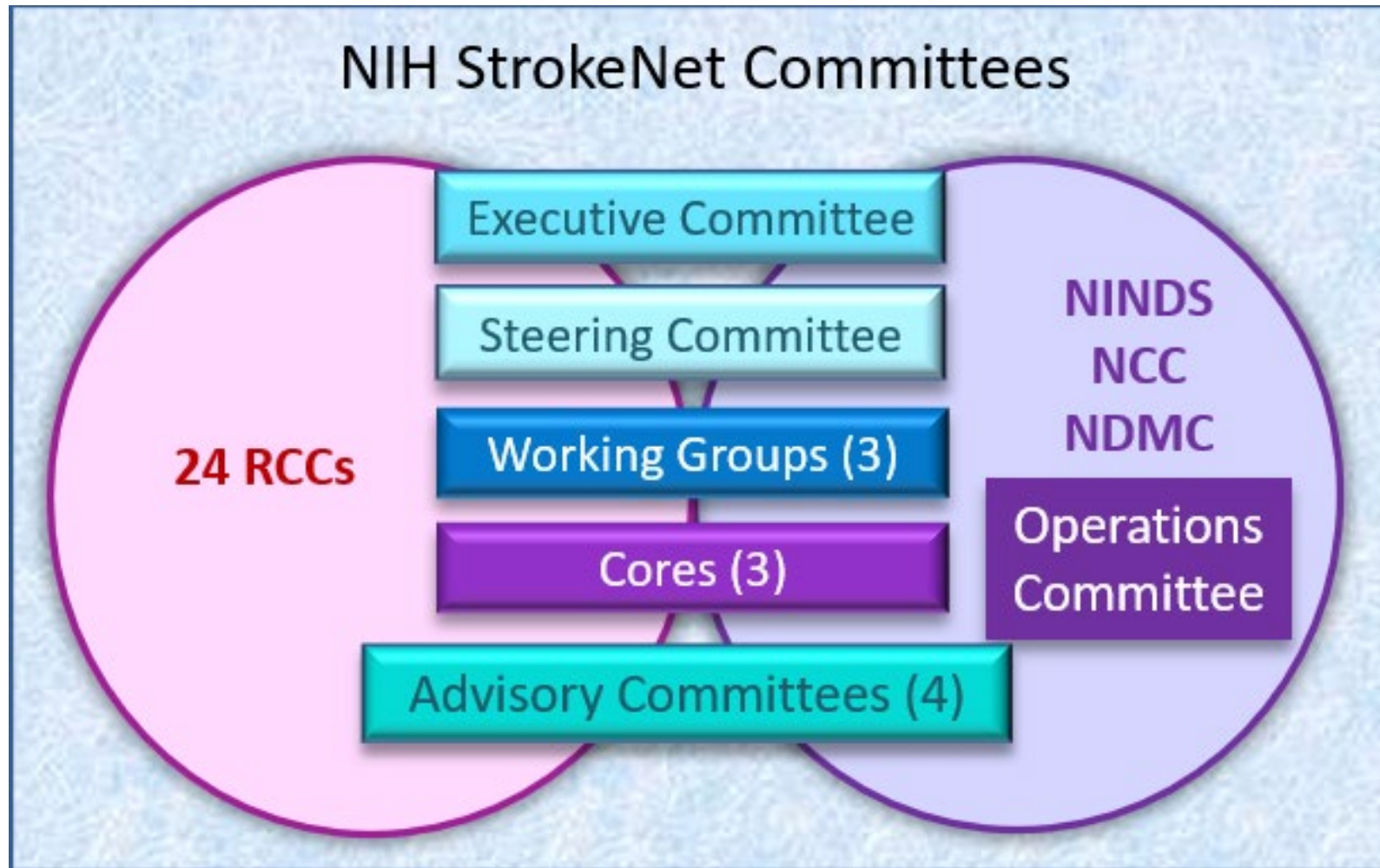
Network

- Chicago Stroke Trials Consortium
- Cleveland RCC
- Georgia StrokeNet
- Independent Performance Sites
- Los Angeles Southern California (LASC)
- Michigan StrokeNet
- Mid America RCC (MARCC)
- New England RCC (NERCC)
- New York City Collaborative RCC (NYCRCC)
- NorCal Research Coordinating Center
- San Diego Regional StrokeNet
- SE-CoAST Collaborative Alliance for Stroke Trials (SE-...)
- Southern New England Partnership in Stroke Researc...
- Stanford Stroke Center
- Stroke Central Atlantic Network for Research (SCANR)
- Stroke Trials Network of Columbia and Cornell
- StrokeBelt StrokeNet (SBSN)
- The Greater Philadelphia NIH StrokeNet (GPNSN)
- The Gulf Regional Area Stroke Programs
- University of Iowa RCC
- University of Miami RCC
- University of Minnesota RCC
- University of Utah StrokeNet
- University of Washington RCC
- University of Wisconsin Stroke Net
- Unvercity of Cincinnati RCC
- UPMC Stroke Institute
- Western NC StrokeNet

MAP TIPS:

- Zoom in and out using the toolbars Plus and Minus button, or mousewheel, or laptop trackpad.
- Return to default zoom level click the toolbar Home icon

NCC coordinates committee activities:



Executive Committee:

Oversees strategic StrokeNet leadership and overall network management (monitor site performance, extra and intra network collaborations, training, new study opportunities). Meets 2x per month virtually; 1x per year in person.

- **Members:**

NINDS:

Scott Janis, Project Scientist
Catherine Levy, Program Officer
Laura Kimberly, Program Officer

NCC:

Pooja Khatri, PI
Joseph Broderick, PI
Jamey Frasure, Adm. Director
Laura Benken, Adm. Director
Iris Davis, Adm. Director

NDMC:

Jordan Elm, PI
Wenle Zhao, PI
Catherine Dillon, PI
Jessica Griffin, Director
Jocelyn Craven, Program Manager

Working Group Chairs & Co-Chairs:

Karen Johnston, MD – Acute
Jeff Saver, MD – Acute
Marc Chimowitz, MD – Prevention
Hooman Kamel, MD – Prevention
Steve Cramer, MD – Recovery/Rehab
Steve Wolf, MD – Recovery/Rehab

Rotating Members of RCCs:

Scott Kasner, MD – U Penn PI
Cheryl Bushnell, MD – Wake Forest PI
J Macco, MD – Mount Sinai PI
Jose Romano, MD – U Miami PI
Eva Mistry, MD – U Cincinnati PI
Heena Olalde – U Iowa
Karen Rapp - UCSD

Steering Committee

- Main governing body of the StrokeNet's scientific operation and conduct. All major StrokeNet decisions will be determined by majority vote of this committee. Each RCC (24), the NCC, the NDMC will provide one vote each. All decisions must be concurred by NINDS leadership. Meets 1x per month virtually.



Operations Committee

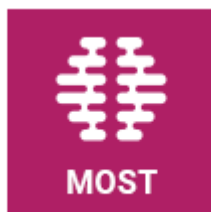
- a non-governing committee that oversees all StrokeNet activities, operational issues, and monitors network performance. Meets 1x per week; trial teams rotate.

- Members:

NINDS:
Scott Janis, Project Scientist
Catherine Levy, Program Officer
Laura Kimberly, Program Officer

NCC:
Pooja Khatri, PI
Joseph Broderick, PI
Jamey Frasure, Adm. Director
Laura Benken, Adm. Director
Iris Davis, Adm. Director

NDMC:
Jordan Elm, PI
Wenle Zhao, PI
Catherine Dillon, PI
Jessica Griffin, Director
Jocelyn Craven, Program Manager



Working Groups

– The primary function of the working groups is to critique, refine and to assist in determining feasibility for clinical concepts submitted to StrokeNet for review by NINDS or trial proposals developed by StrokeNet investigators.

& Co-Chairs

- 3 Working Groups:
 - Prevention
 - Acute Stroke Treatment
 - Recovery and Rehabilitation
- meetings on an as needed basis.

Working Group Chairs & Co-Chairs:

Karen Johnston, MD – Acute

Jeff Saver, MD – Acute

Marc Chimowitz, MD – Prevention

Hooman Kamel, MD – Prevention

Steve Cramer, MD – Recovery/Rehab

Steve Wolf, MD – Recovery/Rehab

Core Committees-

- **Fellow Education and Training Core** - Implements StrokeNet-wide educational activities and mentoring programs for Stroke Fellows.
 - Chairs: Devin Brown, MD; Randy Marshall, MD
- **(New) Clinical Research Professional (CRP) Training and Education Core** - dedicated to on-boarding, continuing education, and retention of CRPs.
 - Chairs TBD
- **(New) Diversity, Equity, and Inclusion Core** - Develop and implement a detailed patient recruitment, retention, and community engagement plan, with attention to adequate racial and ethnic minority recruitment.
 - Chairs: Bernadette Boden-Albala, MPH, PhD; Leslie Skolarus, MD

Advisory Committees

- Provide consultative expertise in areas needed to cover the spectrum of potential Clinical Stroke Trials.

- **(New) Patient Representative Advocacy – Chair TBD**
- **Pediatric Stroke – Heather Fullerton, MD**
- **Preclinical Science – Lauren Sansing, MD**
- **Telestroke – Chris Streib, MD**

ADM 09 - RCC Management for Satellites and Performance Sites

- Broadly details the rights and responsibilities of the RCC, Satellite Sites (SS), Performance Sites (PS), NCC, and NDMC.
- RCC Specifically:
 - Recruit SSs and PSs in regional area to participate in trials. If SS is outside regional area, requires StrokeNet NCC PI approval.
 - Provide leadership to their SS/PS
 - Each RCC will create a local RCC Management SOP to distribute to their SS/PS
 - Outlines roles, responsibilities, and operational expectations of the RCC to others in the StrokeNet network.

ADM 10 – Inclusion of New Satellite Sites and Performance Sites

- Review site criteria:
 - Not participating in another RCC
 - Demonstrates ability to recruit into stroke trials
 - Ability to execute clinical trial agreement (CTA), reliance agreement (RA), and all clinical research requirements including conflict of interest (COI) reporting.
- Process for adding site to RCC
 - RCC established relationship with SS/PS and executed any local service agreements
 - RCC must notify NCC of site addition to verify SS/PS is not linked to another RCC
 - NCC executes CTA for each trial and the IRB of record executes RA

ADM 15 – Network Communications

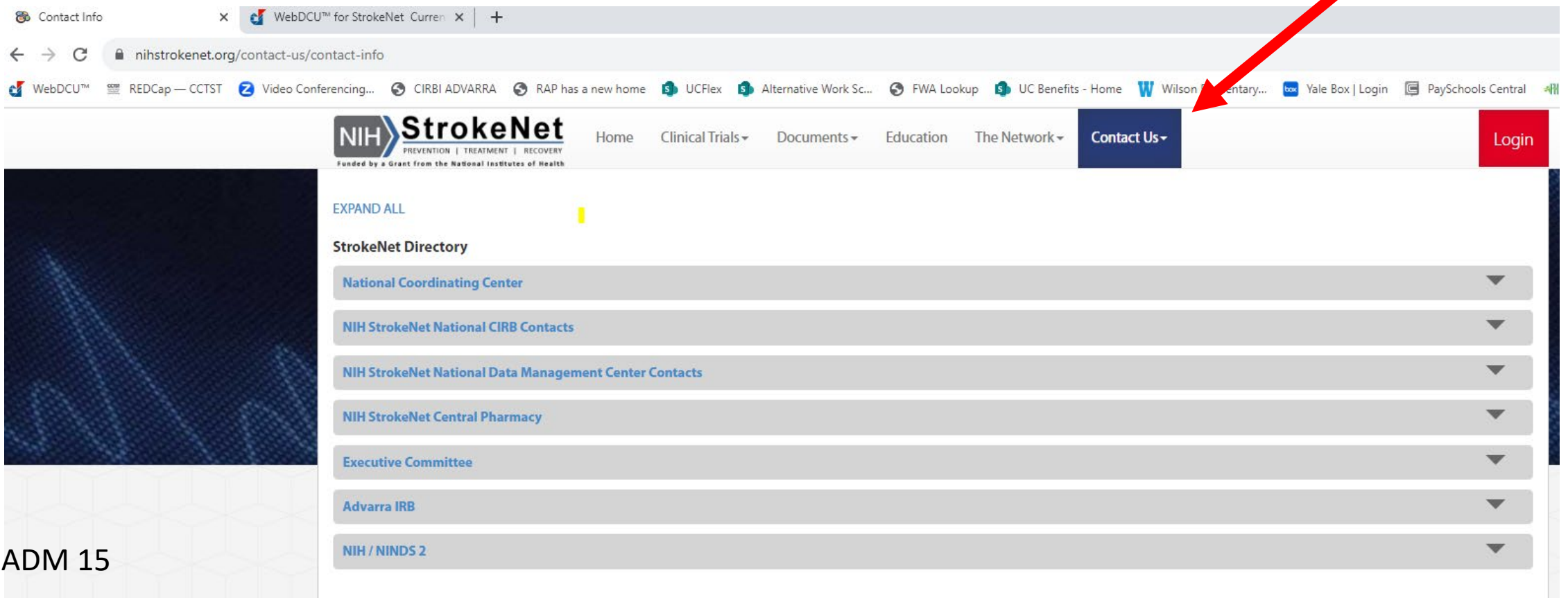
RCC Contact Information is stored electronically in WebDCU™ (Instructions on how to enter this information is in the **WebDCU User Manual** stores in the **Toolbox > Project Documents** of every StrokeNet trial).

No.	Item Description	Data										
1	WebDCU Center ID	1723										
1	RCC Code	R18										
3	RCC Name	Regents of the University of Minnesota										
2	RCC Short Name	U Minnesota										
4	Address	200 Oak St. SE										
5	City	Minneapolis										
6	State	MN										
7	Zip Code + 4	55455-2009										
RCC Principal Investigator Information												
8	PI Name	Kamakshi Lakshminarayan										
10	PI Telephone	6512085980										
11	PI Email	laksh004@umn.edu										
RCC Study Coordinator Information												
12	Study Coordinator	Abbey Staugaitis										
13	Study Coordinator Phone	(612) 624-8833										
14	Study Coordinator Email	staug002@umn.edu										
15	General Comments											
RCC Team Member												
No.	A. Role	B. First Name	C. Last name	D. Email	E. Phone	F. Fax	G. Street Address	H. City	I. State	J. Country	K. Zip	G. Note
4-1	Principal Investigator	Kamakshi	Lakshminarayan	laksh004@umn.edu	6512085980		420 Delaware Street , MMC 295	Minneapolis	Minnesota	USA	55455	
4-2	IRB Representative	Casey	Dahl	dahl0465@umn.edu	612-624-8745		420 Delaware Street Southeast, MMC 820	Minneapolis	Minnesota	USA	55455	
4-3	Contract Administrator	Tonya	Knutson	knuts055@umn.edu	612-624-7850	612-624-5599	200 Oak Street Southeast, Suite 474-3 McNamara Ctr	Minneapolis	Minnesota	USA	55455	
4-4	Institutional Authority	David	Hagen	awards@umn.edu	612-624-5599	612-624-4843	200 Oak Street Southeast, Suite 450	Minneapolis	Minnesota	USA	55455-2070	
4-5	Secondary Study Coordinator	Julie	Scherber	sche0245@umn.edu			717 Delaware St. SE 508J	Minneapolis	Minnesota	USA	55455	
4-6	Primary Study Coordinator	Abbey	Staugaitis	staug002@umn.edu			717 Delaware St. SE 508J	Minneapolis	Minnesota	USA	55414	

Contact information must be updated within **30 days** of change or annually each January!

Changes in RCC PI or key personnel must be approved by NINDS.

- General Correspondence with NCC/NDMC:
 - RCCs, their SS and PS are encouraged to ask questions as often as necessary. In an effort to maximize efficiency and facilitate correspondence archival,
 - **NCC** and **NDMC** request that all email correspondences include in the subject/topic line the RCC or site number and name and the topic of the email. <https://www.nihstrokenet.org/contact-us/contact-info>



The screenshot shows a web browser window with the URL [nihstrokenet.org/contact-us/contact-info](https://www.nihstrokenet.org/contact-us/contact-info). The page features the NIH StrokeNet logo and a navigation menu with items: Home, Clinical Trials, Documents, Education, The Network, Contact Us, and Login. A red arrow points to the 'Contact Us' menu item. Below the navigation, there is an 'EXPAND ALL' link and a 'StrokeNet Directory' section with a list of dropdown menus: National Coordinating Center, NIH StrokeNet National CIRB Contacts, NIH StrokeNet National Data Management Center Contacts, NIH StrokeNet Central Pharmacy, Executive Committee, Advarra IRB, and NIH / NINDS 2.

Trial Team Contact Information in WebDCU™

Toolbox > Project Contact List

webdcu.musc.edu/nett/ListRecord.asp?theFormID=1114

WebDCU™ REDCap — CCTST Video Conferencing... CIRBI ADVARRA RAP has a new home UCFlex Alternative Work Sc... FWA Lookup UC Benefits - Home Wilson Elementary... Yale Box | Login PaySchools Central Forest Hills School... Weekly Touch Base... Laura BENKEN Sign Out

List: Project Contact List

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#	Contact type	First name	Last name	Phone	Email	Notes
1	StrokeNet Central Pharmacy			513-584-3166	captivatrialrx@ucmail.uc.edu	Contact for questions related to study drug.
2	Site Monitoring Manager	Jama	Olsen	843-876-1914	olsen@musc.edu	Contact for monitoring and ICF related questions during working hours Eastern Standard Time.
3	CAPTIVA NCC Project Manager	Lesley	Butler	214-505-1275	butlelc@ucmail.uc.edu	Contact for CIRB and regulatory support.
4	CAPTIVA Project Manager	Stephanie	McLaren		CAPTIVA-Study@ufl.edu	Contact for adverse event reporting and protocol-related support.
5	CAPTIVA-MRI Project Manager	Amy	Sulken	513-258-1876	sulkenay@ucmail.uc.edu	Contact for regulatory support.
6	CAPTIVA-MRI Project Manager	Ka-ho	Wong	801-587-0173	ka-ho.wong@hsc.utah.edu	Contact for protocol-related support.
7	NDMC Data Manager	Farria	Khattak	984-221-0266	khattak@musc.edu	Contact for WebDCU issues and data entry questions during office hours (9:00-5:00 EST).
8	NDMC Data Manager	Mariana	Gould	843-792-4117	gouldma@musc.edu	Contact for WebDCU issues and data entry questions during office hours (9:00-5:00 EST).
9	Genotyping Core	Cheryl	Galloway		cdgallo@ufl.edu	Contact with questions regarding collection and sample shipment.

All information is generated based on data currently in the database. Data may not be verified or validated. The report is generated to assist in trial operations only, and is not valid to support any statistical analysis of study data. Unless noted, the Data Coordination Unit (DCU) assumes no responsibility for the use of this report. This report may contain protected health information covered by the Health Insurance Portability and Accountability Act (HIPAA). You are prohibited from disclosing this information without the specific written consent of the person to whom it pertains. Anyone using this data specifically assumes responsibility for maintaining the confidentiality of the protected data.

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List: Emergency Help

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#	Category	First name	Last name	Phone	Email	Notes
1	24/7 Clinical Emergency Hotline			1-888-351-7776		For clinical questions (i.e., questions pertaining to eligibility, safety, study intervention delivery, unblinding, etc.)
2	WebDCU Emergency Randomization Hotline			1-866-450-2016		For randomization questions associated with the WebDCU website
3	Data Management Support	Mariana	Gould	1-843-792-4117	gouldma@musc.edu	Contact for WebDCU issues and data entry questions during office hours (9:00-5:00 EST).
4	Data Management Support	Faria	Khattak	984-221-0266	khattak@musc.edu	Contact for WebDCU issues and data entry questions during office hours (9:00-5:00 EST).

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Network Communications and Meetings

- **StrokeNet Website** – www.NIHStrokeNet.org
- **NIH StrokeNet First Friday Updates** – sent from the NCC to RCC personnel. RCCs are responsible for distributing to SS/PS in their network
- **Trial Monthly Newsletter** – Sent from trial team to site PI/Sub-I/PSC/SSC
- **Urgent Network Updates** – Sent from NCC/NDMC to RCC. RCC responsible for distributing to SS/PS in their regional network
- **Regular Meetings**
 - StrokeNet Coordinator Monthly Webinar
 - Trial Monthly Webinars
 - Trial Monthly Coordinator Office Hours/Forum
 - Quarterly NCC/NDMC/RCC Managers Meeting

Next Time On – StrokeNet SOP Series

- ADM 11 Central Institutional Review Board Reliance and Approvals
- ADM 16 Network Process for Trial Master and Site Regulatory File Management
- ADM 21 Regulatory Document Maintenance and Storage
- ADM 02 Site Performance Monitoring, Audits, and Inspections
- ADM 13 Safety Monitoring and Reporting
- GCP 04 Safety Reporting