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

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 StrokeNet Organization
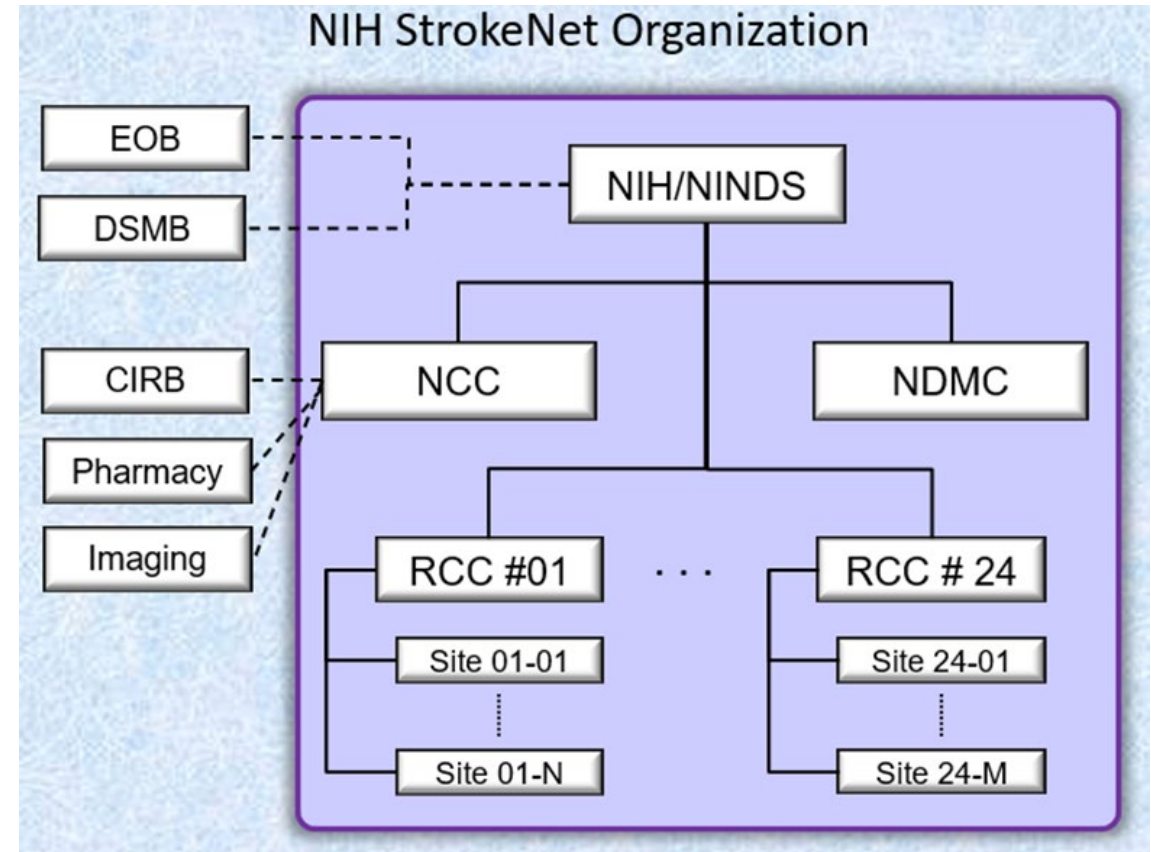
NIH/NINDS

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

National Institute of
Neurological Disorders
and Stroke
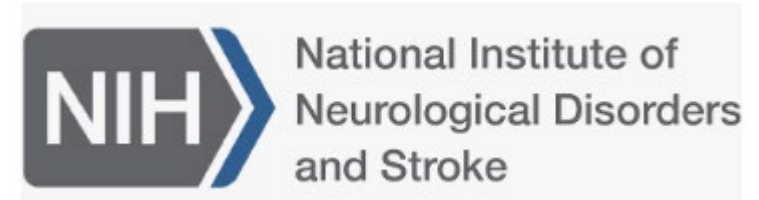
- **National Institute of Neurological Disorders and Stroke (NINDS)** is the funding agency for the NIH StrokeNet Network. NINDS program staff are involved in the development of new StrokeNet proposals, as well as the management of funded proposals. StrokeNet Program Scientist provide scientific/administrative 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.

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NCC @ University of Cincinnati

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

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NDMC @ MUSC

MUSC Medical University of South Carolina

WebDCU™ Data → Information → Knowledge

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.

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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
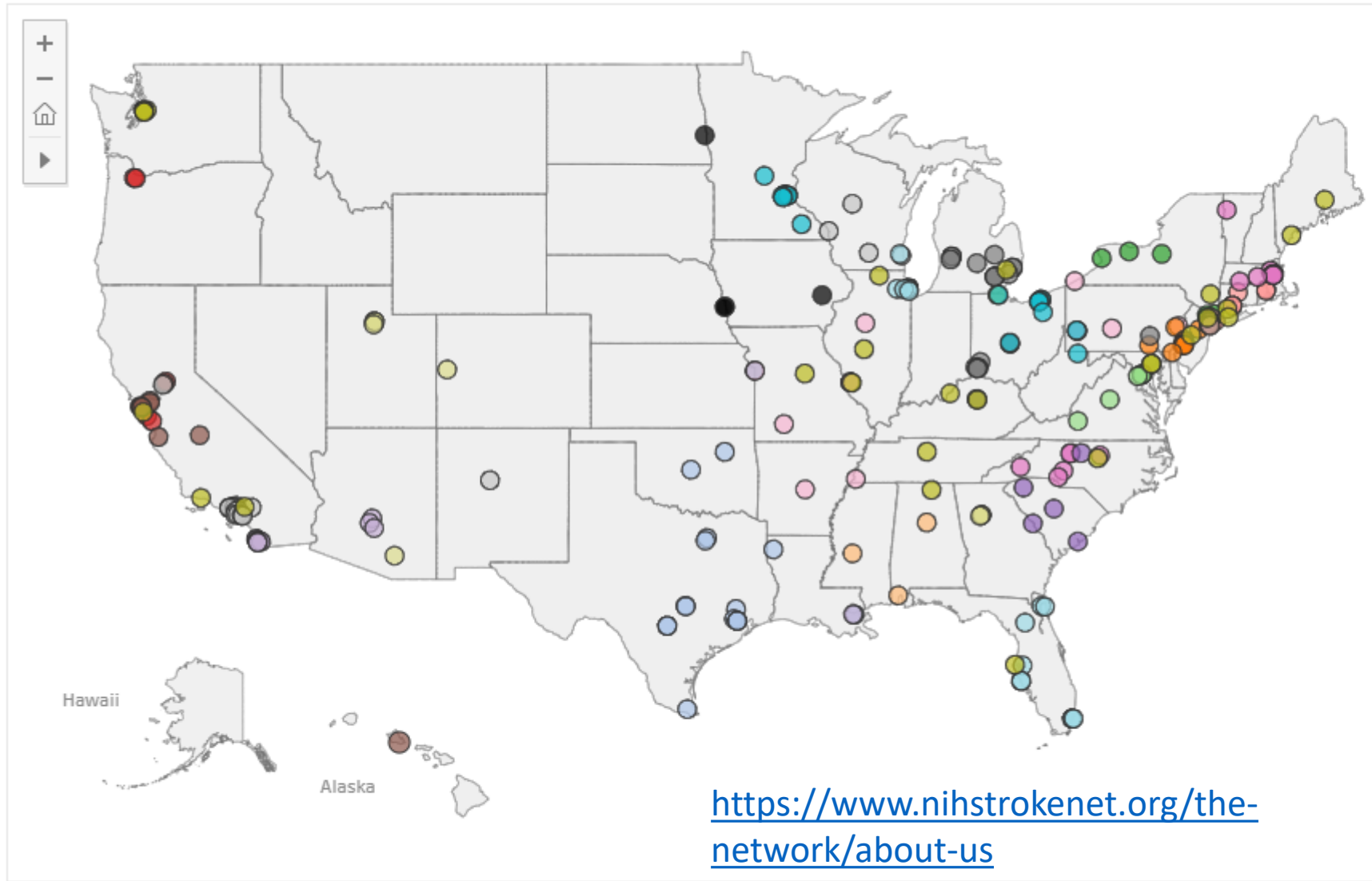
Network
- Chicago Stroke Trials Consortium
- Cleveland RCC
- Georgia StrokeNet
- Independent Performance Sites
- Los Angeles Southern California (LASC)
- Michigan StrokeNet
- Mid America RCC (MARCC)
- New England RCC (NERCC)
- New York City Collaborative RCC (NYCRCC)
- NorCal Research Coordinating Center
- 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

https://www.nihstrokenet.org/the-network/about-us

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

SOP ADM 17

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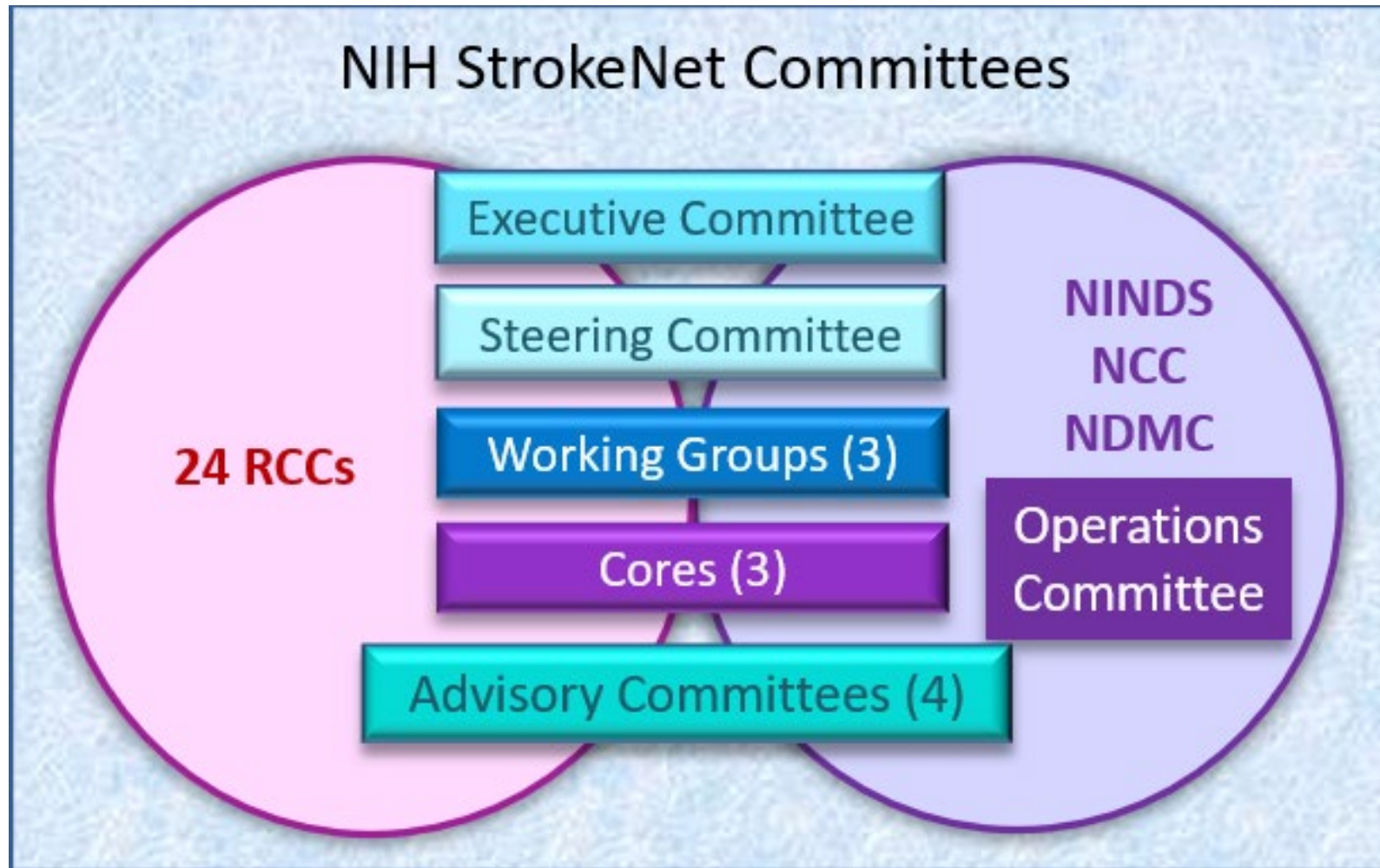
Executive Committee: Oversees strategic StrokeNet leadership and overall network management (monitor site performance, extra and intra network collaborations, training, new study opportunities). Meets 2x per month virtually; 1x per year in person.

- 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

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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.

Coordinating Center

Renewal RCC   New RCC   Legacy RCC

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

ARCADIA   MOST   TRANSPORT2   Sleep SMART   CAPTIVA   RHAPSODY-2   FOCAS
ASPIRE   SATURN   I-ACQUIRE   ARCADIA-CSI   FASTEST   VERIFY
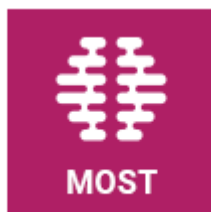
Working Groups – The primary function of the working groups is to critique, refine and to assist in determining feasibility for clinical concepts submitted to StrokeNet for review by NINDS or trial proposals developed by StrokeNet investigators.

- 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

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Core Committees-

- **<u>Fellow Education and Training Core</u>** - Implements StrokeNet-wide educational activities and mentoring programs for Stroke Fellows.
  - Chairs: Devin Brown, MD; Randy Marshall, MD

- **(New) <u>Clinical Research Professional (CRP) Training and Education Core</u>** - dedicated to on-boarding, continuing education, and retention of CRPs.
  - Chairs TBD

- **(New) <u>Diversity, Equity, and Inclusion Core</u>** - 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**

SOP ADM 17

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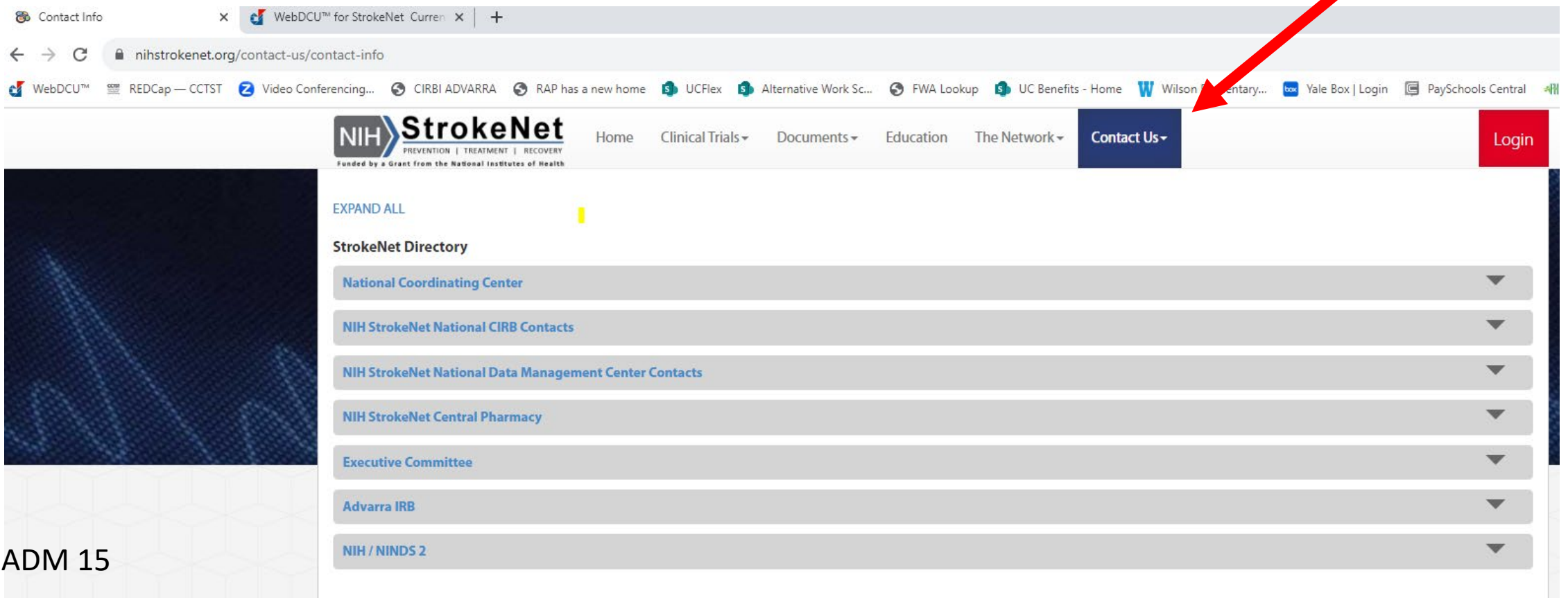
RCC Contact Information is stored electronically in WebDCU™ (Instructions on how to enter this information is in the ***WebDCU User Manual*** stores in the ***Toolbox > Project Documents*** of every StrokeNet trial).

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

SOP ADM 15

Trial Team Contact Information in WebDCU™
Toolbox > Project Contact List

SOP ADM 15

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