

Monthly Update

2 -November 2018



REMINDER!

Monthly Coordinator Call

The next coordinator call is scheduled for **Monday, November 12th at 10:30am.**

Neuro Teleconference Line: USA Toll-Free: (877) 848-7030

Access Code: 3386580

Enrollment Update (as of 10/26/2018)

- CREST 2 – 1197/2480
- ARCADIA – 110/1100 randomized; 413/4400 consented/not randomized
- CREST-H – 25/500

StrokeNet Trial Updates



We had 1 more site green lighted in the last 2 weeks, bringing our total to 32 sites and **25 patients enrolled**. Welcome to University of Minnesota. Go Gophers! UPMC is leading recruitment with 5 enrollments, followed by U Iowa, Columbia, and Michigan Vascular with 3, Maine Medical and UF Shands with 2 each. Seven other sites have one each.



Please note: The new CREST-H protocol (V3.0) allows both MR perfusion and CT perfusion. (V2.0 was for MRP only.) If you are interested in using CTP as an alternative to MRP for CREST-H, you need to do the following:

1. **Upload a CTP test scan for approval.** Test scans can be either a volunteer undergoing the CREST-H imaging protocol or a recent clinical patient who had a CT brain perfusion scan. Upload the de-identified CTP to the Sharepoint site at U Maryland as you do for CREST-2 images. (See slides from the CREST-H training webinar for reference.)
2. **Get the V3.0 consent form approved.** You should have received a recent email communication with specific instructions on how to do this. If you are already enrolling in CREST-H, MRP can be used under V2.0 until you get V3.0 approved.

Note: We are asking that all sites be approved for both MRP and CTP if possible. CREST-H secondary aims depend on MRI information about silent infarcts, white matter hyperintensity volumes, microbleeds and cortical thickness. Some patients will have MRI exclusions, however, and we will have a number of sites that are doing CTP exclusively.

Contact Randy Marshall rsm2@columbia.edu, Jaya Vijayan vijayan.jaya@m Mayo.edu, or Kevin Slane at KJS4@columbia.edu with any questions. We are still recruiting additional sites. Thanks!

At the end, please find the latest bi-weekly StrokeNet newsletter and the dashboard.

RCC Contact Information

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FAX 608.263.1728

Monthly Update

4 - October 2018

StrokeNet Trial Updates



Please join us for the MOST – Sleep SMART CIRB Webinar
(All are welcome to attend)

When: Monday, November 5th, 2018 - 2:00 PM Eastern Standard Time

Location: <https://nihstrokenet.adobeconnect.com/trials/>

MOST Hosts: Teresa Murrell-Bohn, RN, CCRC Project Manager
Iris Deeds, CCRP Lead Trial Coordinator

Sleep SMART Hosts: Joelle Sickler, MSN, RN, CCRC, CCRA Project Manager
Kayla Gosselin, MPH, CCRP Project Manager

Presenters: Mike Linke, PhD, CIP NCC IRB Chair
Sue Roll, RN, BSN NCC CIRB Liaison

To join the meeting: <https://nihstrokenet.adobeconnect.com/trials/> - Enter as a guest, then your first and last name.

To take part in the conversation you MUST dial in. 1 (877) 621-0220 PassCode: 745694

From the CREST-2 Clinical Coordinating Center:



1197 Overall	
619 CEA	578 CAS
27 in October	
17 CEA	10 CAS

The new CREST-2 video brochure has been a great success! We have ordered 150 more that we are working on getting sent to all CREST-2 sites!



Grand Rounds

Grand Rounds are a requirement for the NIH StrokeNet Trainees, however all are welcome to participate.

When: **Thursday, November 29, 2018 - 4:00 PM ET**

Presentation: From Compensation to Recovery in Motor Function Following Stroke: a Never Ending Continuum – **John Krakauer, MD, Johns Hopkins University**

Moderator: Steve Wolf, PhD, Emory University

To join the meeting: <https://nihstrokenet.adobeconnect.com/grandrounds/> Please enter as a guest, then your email address or complete name. To take part in the conversation you must dial in, 1 (877) 621-0220 Passcode Number: 190825

Professional Development Webinar

Professional Development webinars are a requirement for the NIH StrokeNet Trainees, however all are welcome to participate.

When: **Tuesday, December 4, 2018 - 2:00 PM ET**

Presentation: When and How to Incorporate a Statistician in a Study

Presenter: **Yuko Palesch, PhD, Medical University of South Carolina**

To join the meeting, please go to: <https://nihstrokenet.adobeconnect.com/pdw/>

Please enter as a guest, then your email address or complete name. To take part in the conversation you MUST dial in. 1 (877) 621-0220 - Passcode Number: 190825

NIH StrokeNet Coordinator Webinar:

When: **November 28, 2018 – 1.30pm ET**

To join Coordinator Webinars: <https://nihstrokenet.adobeconnect.com/coordinator/> Please enter as a guest, then add your first and last name or email address. For Audio: Dial-In Number: (877) 621-0220 Passcode 434578.

Please send suggestions for future coordinator webinar ideas to beckmare@ucmail.uc.edu.

Project Name	Protocol PI	Prevention/ Acute/Recovery	Status Update
FASTEST	Joe Broderick, Jim Grotto, Jordan Elm	Acute	June 2018 submitted
PAST-TIME	Jason McMullan, Opeolu Adeoye, Nerses Sanossian	Acute	June 2018 submitted
ARCADIA -CSI	George Howard, PhD Maarten Lansberg, MD/PhD Ronald Lazar, PhD Kevin N. Sheth, MD David Tirschwell, MD	Acute	June 2018 submitted
IMPACT	Andrew Naidech	Acute	July 2018 submission
VERITAS II	Sepideh Amin-Hanjani	Prevention	July 2018 submission

Project Name	Protocol PI	Prevention/ Acute/Recovery	Status Update
IACQUIRE (formerly IRIS)	Warren Lo, Sharon Ramey	Recovery	August 2018 study section
ALISAH 2	Jose Suarez	Acute	August 2018 study section
ASPIRE (formerly SCORPION)	Kevin Sheth	Prevention	August 2018 study section
SPLASH	Jose Suarez, DaiWai Olson (contact PI)	Acute	October 2018 submission
CASH	Adnan Qureshi	Acute	October 2018 submission
I-WITNESS	Lee Schwamm, Ona Wu, Steve Warach, Larry Latour, Shlee Song	Acute	October 2018 resubmission A01
PreLIMBS II	Sebastian Koch, Nestor Gonzalez, Neeraj Chaudhary	Acute	October 2018 resubmission A01
CAPTIVA (CRISIS)	Brian Hoh	Prevention	November 2018 submission
FURRThER	Bernadette Boden-Albala	Prevention	November 2018 resubmission
Tempo-EMS	Nerses Sanossian, William Meurer, Jeffrey Saver, David Hess	Acute	Hold for now
MATRICES	Maarten Lansberg, Greg Albers, Albert Yoo, Sam Zaidat	Acute	In concept development (no CSP on file)
DEFUSE TNK	Maarten Lansberg	Acute	In concept development, archive after 1-June 2018
ETHER	Stephan Mayer	Acute	On hold for EVD platform

Project Name	Protocol PI	Prevention/ Acute/Recovery	Status Update
SERENE (ASSIST + SEACOAST)	Radoslav Raychev, Dimiter Arnaudov, David F. Kallmes, (Radiology) Alejandro Rabinstein, (Neurology) Jeffrey Pasternak, (Anesthesiology) Rickey Carter, (Biostatistics)	Acute	On hold for EVD platform
PRECISE MRI- T2	Natalia Rost, Shyam Prabhakaran, Rebecca Gottesman, Clinton Wright	Prevention	In concept development
NEPTUNE (ARCADIA ancillary study)	Ajay Gupta, Hooman Kamel	Prevention	In concept development
Claassen	Jan Claassen	Acute	In concept development
HEMERA	Italo Linfante, Raul Nogueira	Acute	On hold for EVT platform
ARCADIA ORACLE	Babak Navid, MD, MS	Prevention	Hold ARCADIA ancillary study
CIAT RCT	Jerzy Szaflarski, MD	Recovery	In concept development
TACOCAT (COAT)	Brett Cucchiaria, MD Scott Kasner, MD	Prevention	In concept development
SCOUT (Ancillary to Sleep Smart)	Sandeep P. Khot, Martha E. Billings	Recovery	In concept development 25-April 18: Extensive feedback in recent weeks. Now at point where they are connecting that feedback with NIH and with the primary study (Sleep Smart)
WISC-R	Matthew Durand, Robert Dempsey, Allison Hyngstrom, John McGuire	Recovery	In concept development
ERSIAS	Nestor Gonzalez, Jeff Saver	Prevention	In concept development
BLAST	James Meschia	Prevention	In concept development

Project Name	Protocol PI	Prevention/ Acute/Recovery	Status Update
FOCAS	Heather Fullerton, Mitch Elkind	Prevention	In concept development
CAVIS	Mark Harrigan	Prevention	In concept development
SPLIT	Andrew Naidech	Prevention	In concept development
RAFT	Truman Milling, Steve Warach	ACUTE	In concept development
START	Steve Warach, Truman Milling	Prevention	In concept development
URIC	Enrique Leira	Acute	In concept development
SUCCESS	E. Sander Connolly Jr., John D. Lambris, Jan Claasen	Acute	In concept development
BrainPulse	Kyle Walsh, Shakeel Chowdhry, Julian Bailes, Andrew Russman	Acute	In concept development
Hasan – Intracranial Stenosis	David Hasan	Prevention	In concept development



Biweekly Update 26-October 2018

<http://nihstrokenet.org/coming-events>

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ARCADIA

110 patients randomized (10% of target)!

101 sites released to enroll!

World Stroke Congress update: RE-SPECT ESUS and NAVIGATE ESUS results support the need to complete ARCADIA!

As of Oct. 26th, ARCADIA has 413 participants consented and 110 randomized! Thanks to all for getting us to this milestone.

The University of Iowa in Iowa City, IA and United Hospital in St. Paul MN continue to be tied for the lead for randomizations with 9. Oregon Health and Science University (OHSU) Hospital in Portland, OR is close behind with 8 subjects randomized.

In other big ARCADIA news, the RE-SPECT ESUS trial results were presented at the World Stroke Congress last week. This trial found that anticoagulation with dabigatran did not reduce the risk of recurrent stroke in unselected patients with ESUS. These results were similar to the earlier NAVIGATE ESUS trial, which found no benefit of anticoagulation with rivaroxaban in ESUS patients. Based on these two trials, there is no indication for anticoagulant therapy in **UNSELECTED** patients with ESUS. Also at the WSC, the NAVIGATE-ESUS investigators presented a secondary analysis that showed a benefit of rivaroxaban over aspirin in the subset of patients with left atrial enlargement. This finding directly supports the underlying hypothesis of ARCADIA, though these NAVIGATE findings are a secondary analysis of a subset of the trial subjects and need to be prospectively tested as the primary objective of a different trial (i.e., ARCADIA!).

We interpret these results as a very strong argument for the importance of ARCADIA and a reason to encourage participation and recruitment. The target populations of the two other ESUS trials probably include a heterogeneous group of patients, only some of whom have atrial cardiopathy. ARCADIA, however, targets only ESUS patients who **ALSO HAVE** evidence of atrial cardiopathy, as determined by having at least one of the three biomarkers: left atrial abnormality on ECG, left atrial enlargement on echocardiogram, and elevated NT-proBNP in serum. We continue to believe that ARCADIA's pathophysiology-informed, biomarker-driven approach (i.e., "Precision Stroke") is more likely to succeed. In other words, by focusing on those ESUS patients with atrial cardiopathy, we believe that we have chosen the group most likely to benefit from anticoagulation over aspirin.

We are more enthusiastic than ever about the importance of ARCADIA and its potential to answer the question of whether atrial cardiopathy is a target for differential treatment, specifically whether apixaban is more effective than aspirin for these patients. We thank you for your hard work and your continued efforts to make ARCADIA a success!

****IMPORTANT NOTICE ABOUT CONTINUING IRB RENEWAL: Documents due November 5!!****

Information went out 2 weeks ago about the ARCADIA CIRB annual continuing review. Due to changes in the data management system at the CIRB, the turnaround time for this has been moved up. We realize the turnaround time is short, but the documents must be back to the CIRB by Nov. 5th. The main issue will be getting in updated Conflict of Interest forms, since we'll need one from every PI, Sub-I and coordinator at each site. We are here to help if you need it. Please reach out to Sue Roll, the CIRB liaison @ ROLLSN@UCMAIL.UC.EDU or Emily Stinson the NCC research compliance specialist @ stinsoey@ucmail.uc.edu with any questions about the continuing review.

From the CREST-2 Clinical Coordinating Center:



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NINDS News and Resources

National Institutes of Neurological Disorders and Stroke (NINDS) Clinical Trials Methodology Course (CTMC)

This is the third in our Fall 2018 Webinar Series for the National Institutes of Neurological Disorders and Stroke (NINDS) Clinical Trials Methodology Course (CTMC). These webinars are open to all. Our course focuses on the design of early stage clinical trials for investigators focused on neurological illness and injury.

October 29th at noon EDT

Pragmatic Trials

Presented by Shaun Treweek, PhD

Objectives of the webinar series

1. Participants will improve their knowledge of the design and conduct of clinical trials in the neurosciences;
2. Analyze the information presented; and
3. Integrate relevant content into the design and conduct of clinical trials.

Core competencies

1. Medical knowledge
2. Professionalism
3. Systems-Based Practice

To join the Meeting:

<https://bluejeans.com/7342322138>

To join via Room System:

Video Conferencing System: bjn.vc -or- 199.48.152.152

Meeting ID: 7342322138

To join via phone:

- 1) Dial: +1.888.240.2560 - US Toll Free (see all numbers <http://bluejeans.com/numbers>)
- 2) Enter Conference ID: 7342322138

The NINDS Clinical Trials Methodology Course is supported by the NIH-NINDS: R25 NS088248 and is administered by the University of Michigan, the University of Iowa, and Los Angeles BioMed. Additional support is provided by the American Academy of Neurology.

Questions? Email NINDS-CTMC-Info@umich.edu

The National Initiative for Minority Involvement in Neurological Clinical Trials

NIMICT.com is an online toolkit for researchers to support recruitment and retention of women and underrepresented racial/ethnic minorities in neurological clinical trials. Online tools include videos, infographics, diagnostic quizzes and resource collections, which distill best practices from leading Principal Investigators and Clinical Research Coordinators on topics such as building community partnerships, recruitment and retention best practices, budget and trial mechanics and communication techniques. NIMICT was funded by the National Institutes of Health (NIH), National Institute on Minority Health and Health Disparities (NIMHD), and National Institute of Neurological Disorders and Stroke (NINDS) and is led by PI, Dr. Bernadette Boden-Albala.

Release of Restricted Year 1 Funds

Reminder to all RCCs: Don't forget to request the release of restricted Year 1 funds when you meet the Performance Milestone: ***Randomization of 5 new participants into an NIH StrokeNet study.***

Your Grant Application Questions Answered in New NIH Center for Scientific Review

Curious about how NIH grant applications are reviewed? Get a front row seat to the peer review process in this video:

(<https://www.youtube.com/watch?v=Gg2nppTaLUw&feature=youtu.be>). It was created by the NIH Center for Scientific Review (CSR). Investigators will get insights into how applications are reviewed so they can better enhance and advance their applications in the NIH peer review process.

Be sure to visit <https://public.csr.nih.gov/FAQs/Top10> where experts from the NIH CSR answer the top 10 peer review questions.

Trainee Information and Opportunities

Neurorehabilitation and Restorative Neuroscience Training Network (NRNTN) Fellowship

Please be aware an outstanding opportunity for your junior faculty: NIH salary funding to support early faculty research development in Neurorehabilitation. This is a national, 2-year, K-track opportunity for qualifying individuals; they will remain at your institution while receiving mentoring and support from the Neurorehabilitation and Restorative Neuroscience Training Network (NRNTN) program. We are recruiting for our next cohort of scholars. We have a two-stage application process. The next deadline for brief preliminary applications is November 15, 2018. For details, see <https://rehabmedicine.georgetown.edu/K12-webpage>

The Neurorehabilitation and Restorative Neuroscience Training Network (NRNTN) provides outstanding research training and mentorship for clinical scholars in Neurorehabilitation and prepares rehabilitation clinician investigators for sustained and productive academic careers in Neurorehabilitation. NRNTN is funded by the National Center for Medical Rehabilitation Research, NIH/NICHHD.

This early career development and mentorship program seeks to prepare individuals with advanced neurorehabilitation related degrees (MD, MD/PhD neurologists, neurosurgeons, geriatricians, physiatrists and other physicians interested in neurorehabilitation, physical therapists, occupational therapists, speech language pathologists and others) who will be in a position to define the mechanisms underlying neural plasticity and recovery of function following CNS injury, to identify and implement methods to enhance that recovery, and to influence health care and policy to benefit individuals with disabilities. The NRNTN brings together a regional network of 8 leading academic clinicians and scientists in Neurorehabilitation to provide mentored research training and career development for junior faculty level clinicians in Neurorehabilitation.

Our leadership team is composed of members from several clinical disciplines who are accomplished investigators:

- Georgetown University Medical Center
- MedStar National Rehabilitation Hospital
- Johns Hopkins University/Kennedy Krieger Institute
- Cornell University/Burke Neurologic Institute
- Massachusetts General Hospital Institute of Health Professions
- Harvard University
- Massachusetts Institute of Technology

If you or your junior faculty would like more information or would like to discuss the program and application process, please contact either of us.

Alexander Dromerick MD and Barbara Bregman PhD PT
Georgetown University Medical Center, MedStar National Rehabilitation Network

International Fellowship Funding Opportunities

For those of you who may be interested in an international fellowship, please visit the links below:

<https://www.fic.nih.gov/Funding/Pages/Fogarty-Funding-Opps.aspx>

<https://www.fic.nih.gov/Funding/NonNIH/Pages/health-professionals.aspx>

<https://www.fic.nih.gov/News/Pages/2012-global-health-fellows-scholars-support-centers.aspx#awards>

<https://www.einstein.yu.edu/administration/grant-support/international-collaborations.aspx>

The Roles of Fellows and Trainees in NIH Supported Clinical Trials

NIH encourages fellows supported on NIH NRSA Fellowship awards and trainees supported on NIH NRSA Training awards to receive training in clinical research, including in the conduct of clinical trials. Under a mentor's guidance, fellows and trainees can gain experience in the wide variety of research skills specific to clinical trials including, but not limited to: developing a clinical trial protocol; applying the principles of informed consent and requirements for human subjects research; learning about random assignment of participants to different intervention arms; analyzing trial endpoints; and/or implementing quality control standards.

NIH fellowships and training grants provide support for the individuals and, for the most part, do not provide sufficient funding to actually conduct an independent clinical trial. For this reason, NIH expects the individual receiving research funding for the clinical trial (i.e., the sponsor or mentor) to assume responsibility for and oversight of the trial and any activities that the trainee or fellow undertakes related to the trial (reporting, etc.). The fellow/trainee may absolutely participate with the sponsor or mentor in some or even all of the clinical trial activities as part of their training but cannot independently lead the study. For FAQs about clinical trial-specific FOAs, visit https://grants.nih.gov/grants/policy/faq_clinical_trial-specific_FOAs.htm

Steering Committee Call

*Steering Committee Calls are a requirement for all NIH StrokeNet RCCs
(One representative per RCC required)*

The next Steering Committee call is scheduled for **14-November, 2018 at 12 noon ET**.

Just a reminder, minutes from all Steering Committee calls can be accessed via the www.nihstrokenet.org website. After log in, click on the "Minutes" tab, then at the dropdown menu, select "Steering Committee".

Coordinator Webinar

*Coordinator Webinars are a requirement for the NIH StrokeNet RCC
Coordinators/Managers*

The next Coordinator webinar is scheduled for **28-November, 2018**
Please send suggestions for future coordinator webinar ideas to beckmare@ucmail.uc.edu.

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StrokeNet Network Meetings and Important Info

RCC Manager: Please submit lodging receipts to Rose along with the correct address for the two individuals being reimbursed from the 16-October meeting. Again, we will reimburse one night room and tax, up to \$250 for each person.

6-February, 2019: Tentative social gathering at the ISC in Honolulu, Hawaii. Details TBD.

NOTE: Going forward, the NIH StrokeNet will have one in-person network meeting per year, in the fall. In the spring, there will be a half day all-network webinar.

Global Opportunities

Call for Applications: WSO Brief Clinical Exchange Program

The WSO Brief Clinical Exchange Scholarships are designed to expose young stroke professionals from medical, nursing and allied health backgrounds to best practice clinical stroke care at international centers of excellence. Five scholarships are awarded annually with maximum reimbursement of 2,000 USD on presentation of receipts for travel and accommodation costs. The host institution would be expected to waive any observership fees. The duration of visit would generally be 1-2 weeks but could be longer.

Completed application forms should be sent no later than **30 November 2018** to: admin@world-stroke.org

For detailed application requirements and evaluation standards, please see the Application form attached to this BWU.

*For more information on these and other conferences and seminars, please see:

<http://nihstrokenet.org/in-the-news>

NIH StrokeNet Employment Opportunities

Two Full-time Neurologists Columbia University

Title: Assistant/Associate Professor of Neurology

Field of Specialization: Stroke

Link to Apply: <http://pa334.peopleadmin.com/postings/1605>

Job Description:

The Department of Neurology at Columbia University is seeking two full-time neurologists at the assistant or associate professor level specialized in the area of Stroke.

These neurologists will be participants in the Joint Commission certified Comprehensive Stroke Center at New York Presbyterian Hospital Columbia sites in Manhattan and Westchester County.

Requirements: must be board certified in neurology and have cerebrovascular fellowship training. Candidates should possess a demonstrated record as a clinician and should possess excellent patient care, teamwork, and interpersonal skills.

Position 1: Stroke faculty at New York Presbyterian Hospital – Columbia University Medical Center in Manhattan. This position will include inpatient and outpatient clinical practice, teaching fellows and residents, and may include work on clinical trials or research. Hospital duties include Quality Assurance participation in addition to attending on the inpatient stroke and consultation services.

Position 2: Stroke Director at New York Presbyterian Lawrence Hospital in Bronxville, Westchester County, New York. This position will include inpatient stroke consultations, development and updating of stroke policies and procedures, overseeing data analysis and quality improvement for this primary stroke center, part-time participation in general neurology inpatient and ED consultation, and working with ICU physician and nursing leadership to develop protocols for and enhance care of critically ill neurology patients.

Please apply by following this link: <http://pa334.peopleadmin.com/postings/1605>

Requirements:

- M.D.
- All applicants **MUST** meet these minimum qualifications to be considered for the position.
M.D. and board certified in Neurology is required. Faculty rank is expected to be at the Assistant or Associate Professor level, commensurate with experience and achievement.
- Must be able to meet New York Presbyterian and ColumbiaDoctors credentialing. Must be board certified in neurology and have cerebrovascular fellowship training. Candidates should possess a demonstrated record as a clinician and should possess excellent patient care, teamwork, and interpersonal skills.

Pre-doc / Post-doc Training Opportunity in Stroke Research at UTHealth

We are looking for driven, motivated and enthusiastic doctoral candidates and recent doctoral program graduates in epidemiology, bio-statistics or data science who have a strong quantitative background along with an understanding of research design and research methods. The UTHealth Institute for Stroke and Cerebrovascular Disease will provide support for the pre-doctoral / post-doctoral position at the NIH salary guidance levels for up to three years. The trainee will have a unique opportunity to apply their research and analytic skill set in epidemiological, population health, and clinical areas pertaining to stroke and cerebrovascular diseases. They will train with highly skilled and reputable clinical and research stroke faculty at the Stroke Institute of UTHealth. The program will be tailored to individual trainee's background and career goals. Benchmarks of success will be determined based on research productivity (abstracts, manuscripts, grant submissions). Support will be provided for further training and certifications. UTHealth in partnership with its clinical affiliate, Memorial Hermann, is one of the largest stroke care providers in the world and has a strong and well-established track record of research productivity and stroke training programs. Individuals interested in applying their skill set towards solving complex research questions in cerebrovascular disease are encouraged to apply.

This is a non-clinical training slot for folks who have Masters or PhDs in bio-statistics / epidemiology / bio-informatics or data science. Individuals will require a work authorization in the US. There are no citizenship or residency requirements.

Please forward:

1. CV
2. School Transcripts (Masters or PhD)
3. 2 letters of recommendation
4. Brief personal statement (not more than 1,000 words)

Email (Farhaan.vahidy@uth.tmc.edu) with application materials or for any questions.

**Please share this with your clinical performing and satellite sites! Contact: Jamey Frasure, PhD, RN,
Director | NIH StrokeNet Coordinating Center | frasurjs@ucmail.uc.edu | 513-558-1742 <https://www.nihstrokenet.org>**