

Monthly Update

10 – June 2019



REMINDER

Monthly Coordinator Call

The coordinator call is scheduled for June, 20th at 10.30am

Enrollment Update (as of 06/07/2019)

- CREST 2 – 1423/2480
- ARCADIA – 226/1100 randomized; 915/4400 consented/not randomized
- CREST-H – 74/500
- Sleep SMART – 2/3062
- TRANSPORT2 – 0/129

Reminder

Please remember to complete your PETITE feasibility survey and return to us.
The deadline is June 11th!

Heads Up

Incoming Site Clinical Profile Annual Survey!

We will be reaching out to you soon regarding the site clinical profile annual survey. This survey uses your data for site selection and participation in clinical trials for StrokeNet.

We will forward your previous completed survey as assistance with the new survey.

We are hoping to have this completed by the beginning of August.

RCC Contact Information

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Madison, WI 53792

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StrokeNet Trial Updates

ARCADIA Update

We can do this! Let's not lose momentum now!

As of June 6, 2019, ARCADIA has **915** participants consented and **226** randomized. Enrollment is at **20.5%** of the overall enrollment goal of 1,100 participants. This represents an increase of **20** consented patients and **6** randomized patients over the past 2 weeks! Please keep approaching potential subjects and don't lose momentum so that we can make this trial a success!

We truly appreciate the effort made by the **16** sites that have consented subjects in the last 2 weeks!

We congratulate Sharp Memorial Hospital, San Diego, CA for randomizing their first subject! Kudos also to the **5** other sites that randomized in the past two weeks: Mayo Clinic Saint Mary's Campus, Rochester, MN; MedStar Georgetown University Hospital, Washington, DC; OSU Wexner Medical Center, Columbus, OH; Montefiore Medical Center, Bronx, NY; and Kaiser Permanente Los Angeles Medical Center, Los Angeles, CA. Thank you!!!

The University of Cincinnati Medical Center and United Hospital St. Paul have both randomized 10 subjects! There is still a tie for 2nd place between the University of Iowa and OHSU with 9 apiece. Who will unseat the enrolling leaders? Maybe it will be a veteran site or one of the newer sites? These sites are neck-to-neck and we challenge you to be the site that randomizes more than they have!

ARCADIA cannot finish this race without you -- let's make a committed effort to be part of its success!

Our monthly per site randomization rate sits at **0.19** patients per site in those released to enroll. We have released to enroll **124** sites, with several more US sites to join the ARCADIA team, including more VA sites almost ready. There are **73** sites that have randomized at least one patient, and **51** waiting to randomize their first; **114** have now consented at least 1 patient, and **10** have not yet consented any (including 6 newer sites and 4 sites which are not active).

Vacation time is upon us, let's enjoy making sure that we have coverage so that we don't miss any potential subjects!

Webinar: Our next PI and coordinator webinar will be June 25th at 2 PM Eastern--save the date! We're asking that at least 1 person from each site attend the monthly webinar and pass the information along to their team. Also, please send suggestions for topics you'd like discussed.

If you miss out on a webinar, you will soon be able to find the slides on the StrokeNet website (<https://nihstrokenet.org/education>).



Currently, we have enrolled **76** subjects!!

PLEASE, remember to submit your test images for CT perfusion so CT can be used as a backup for MRP. Having CTP available as a backup will allow you to capture all potential CREST-H patients! Thank you!

If you are interested in becoming a CREST-H site, contact Randy Marshall rsm2@columbia.edu, Ron Lazar rlazar@uabmc.edu, or coordinators Jaya Vijayan vijayan.jaya@mayo.edu, or Kevin Slane KJS4@columbia.edu with any questions. Thanks!

Monthly Update

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Sleep SMART

We are pleased to announce that in May, the first TWO Sleep SMART subjects were randomized!!!

Congratulations

Barnes-Jewish Hospital, St. Louis, MO-Eric Landsness MD, William Holt, and Jill Newgent
First subject randomized on May 31, 2019

Prisma Health Midlands (Palmetto Health), Columbia, SC-Souvik Sen, MD and Jane Lim
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The following sites have also been released to enroll and we anticipate that we will see enrollment activity soon:

1. UCSD La Jolla, La Jolla, CA-Dawn Meyer, NP, PhD, Theresa McQuaid, and Karen Rapp
2. UCSD Medical Center Hillcrest Hospital, San Diego, CA- Dawn Meyer, NP, PhD, Theresa McQuaid, and Karen Rapp
3. Brooks Rehabilitation Hospital, Jacksonville, FL-Parag Shah, MD and Taisiya Matev

If your site readiness call has been completed and your site is not released to enroll please continue to work on those outstanding items preventing your site from being released to enroll. If your site has not yet completed the clinical trial agreement (CTA) and/or FusionHealth consent agreement or DUA please continue to work diligently with your contracts/legal teams to get them finalized. Also continue to work on CIRB submission, create and submit your DOA and upload people and regulatory documents. All of these will need to be finalized before your site can be released to enroll.



MUSC and the University of Kentucky are **RELEASED TO ENROLL!!!**

Reminder that our next PI and Coordinator call is scheduled for Monday June 10th at 11am EST. If anyone has topics they would like to discuss during the call, please send them to Kelly (kraieck@musc.edu).

If you already had your Readiness Call, please work to identify training subjects and schedule them for Rater & Trainer video certifications. This will be your last step to complete before your site is officially released to enroll. A few reminders:

- ✓ For mCMT and Outcome Assessment training, we ask that you please make every effort to use a training subject who has had a stroke and has some UE deficits for certification.
- ✓ Be sure to have someone operate the camera during recording to ensure nothing is blocking the participant's movements.
- ✓ Please review the grading rubric that Drs. Rowe and Fritz posted in BOX to ensure you are meeting all the requirements BEFORE you start recording.
- ✓ Raters – Don't forget to complete your self-assessment prior to informing Dr. Rowe that your videos are ready for review.

Please be sure to reach out to Kelly or any of the team members with any questions or updates regarding your site. If you feel you may need a refresher on any of the information covered during the Investigator Meeting, please reach out and we will be happy to schedule remote training sessions.

We look forward to enrolling our first subject soon!

From the CREST-2 Clinical Coordinating Center:

	CREST-2	CREST-2 StrokeNet
CEA	748	271
CAS	675	101
Total	1423	372

Recruitment: we would like to highlight the CREST-2 study team at Kaiser Permanente Division of Research and Medical University of South Carolina for randomizing in June! As a reminder, the NIH mandated milestone is 1700 randomizations by the end of February 2020. As we will need 278 more enrollments to meet this goal, our sites will need to randomize an average of **1.5 patients per day** for the next **183 working days**. StrokeNet sites have randomized 26% of CREST-2 patients to date.

New Continuing Review Meeting Date: As you may know, the CREST-2 study is currently under the continuing review for CIRB. The CIRB has had to reschedule the CREST-2 continuing review date from May 22nd to June 12th. We anticipate receiving the re-approval letters after this date. Please note that until the CIRB has reviewed and re-approved your site, you will **not** be able to submit any amendments (adding/removing study team members, updates to ICFs, new site submissions) to the CIRB. If you have any questions, please let us know.

Monthly Update

UW Health

10-June 2019



School of Medicine
and Public Health
UNIVERSITY OF WISCONSIN-MADISON



For those that were unable to attend any of the I-ACQUIRE specific webinars to date, please take the time to review them now. Recordings of the webinars can be found on the StrokeNet Website at the following link: <https://nihstrokenet.org/i-acquire/webinars>

All PIs, and Primary Study Coordinators received an e-mail from MUSC to access the WebDCU portal. With this access you can now begin adding other study team members, completing your electronic Delegation of Authority (DOA log), and uploading regulatory documents in WebDCU™. If there are others at your site who will be responsible for uploading regulatory documents or completing the DOA, please let Jessica Griffin (siminsil@musc.edu) at MUSC know so that she can give them access to the database. Study team members who are not involved in these specific tasks will be given WebDCU™ access closer to the start of enrollment.

For IRB questions please contact Sue Roll - ROLLSN@UCMAIL.UC.EDU

For regulatory compliance questions please contact Jennifer Golan (golanjl@ucmail.uc.edu) or Emily Stinson (stinoney@ucmail.uc.edu)



The MOST team would like to congratulate the following sites for completing their site readiness calls:

- St. Joseph's Hospital and Medical Center, Phoenix, AZ
- Greenville Hospital System, Greenville, SC
- Mercy Health Saint Mary's, Grand Rapids, MI
- Rhode Island Hospital, Providence, RI
- Mayo Clinic Hospital, Jacksonville, FL
- UCSD Health La Jolla, La Jolla, CA
- UCSD Medical Center - Hillcrest Hospital, San Diego, CA
- SUNY Upstate Medical University Hospital, Syracuse, NY
- Barnes-Jewish Hospital, St. Louis, MO
- Baylor University Medical Center at Dallas, Dallas, TX
- UPMC Presbyterian Hospital, Pittsburgh, PA
- UPMC Mercy Hospital, Pittsburgh, PA

Reminders:

Please make sure that your Institutional Pharmacy License is uploaded into WebDCU™ and enter your Pharmacy's physical shipping address as well. Remember, the addresses must match or you will need to provide an explanation as to why the addresses differ to strokenetcpharm@ucmail.uc.edu. Please continue to prepare your CIRB submissions and upload all required regulatory documents into WebDCU™. If you have any questions about preparing your site for start up, please contact Dana Acklin Winfrey, Project Manager at dana.acklin@uc.edu or call her at 513-558-3980.

- Trial Proposals status

Project Name	Protocol PI	Prevention/ Acute/Recovery	Status Update
PAST-TIME	Jason McMullan, Opeolu Adeoye, Nerses Sanossian	Acute	Review comments received; teams planning next steps
IMPACT	Andrew Naidech	Acute	Review comments received; teams planning next steps
VERITAS II	Sepideh Amin-Hanjani	Prevention	Review comments received; teams planning next steps
SPLASH	Jose Suarez, DaiWai Olson (contact PI)	Acute	October 2018 submission Planning next steps
CAPTIVA	Brian Hoh, PI, Marc Chimowitz, Co-I	Prevention	November 2018 resubmission Planning next steps
FURRTHER	Bernadette Boden-Albala	Prevention	November 2018 resubmission Waiting on summary statement
ALISAH 2	Jose Suarez	Acute	February 2019 submission
PreLIMBS II	Sebastian Koch, Nestor Gonzalez, Neeraj Chaudhary	Acute	February 2019 resubmission
TEST OF TIME	Schwamm, Wu, Urrutia, Barreto, Song, Warach	Acute	June 2019 submission
COASTAL	Adnan Qureshi	Acute	June 2019 submission
PETITE	Greg Albers	Acute	October 2019 submission
STEP-STONE	C. Meinzer, C. Derdeyn, P. Khatri	Acute	Possible October 2019 submission

Project Name	Protocol PI	Prevention/ Acute/Recovery	Status Update
eBOOST	Julius Fridriksson, Chris Rorden, Leo Bonilha, Jordan Elm, Mark George	Recovery	Possible October 2019 submission
VERIFY	Pooja Khatri, Steve Cramer, Cathy Sinear, Achala Vagal	Recovery	Pending ESC review
IMAGING U	David Hasan, Edgar Samaniego	Prevention	In concept development
ERSIAS	Nestor Gonzalez, Jeff Saver	Prevention	In concept development
FOCAS	Heather Fullerton, Mitch Elkind	Prevention	In concept development
TEACH2	Babak Navi, Scott Kasner, Mary Cushman, Mitch Elkind	Prevention	In concept development
SUCCESS	E. Sander Connolly Jr., John D. Lambris, Jan Claassen	Acute	In concept development
PRECISE MRI-T2	Natalia Rost, Shyam Prabhakaran, Rebecca Gottesman, Clinton Wright	Prevention	In concept development
Claassen	Jan Claassen	Acute	In concept development
CIAT RCT	Jerzy Szaflarski	Recovery	In concept development
COAT (TACOCAT)	Brett Cucchiara, Scott Kasner	Prevention	In concept development
SCOUTS (ancillary to Sleep Smart)	Sandeep P. Khot, Martha E. Billings	Recovery	In concept development
Durand	Matthew Durand Robert Dempsey Allison Hyngstrom John McGuire	Recovery	In concept development

Project Name	Protocol PI	Prevention/ Acute/Recovery	Status Update
GPAS	Pooja Khatry, Jin-Moo Lee, Jonathan Rosand, Steve Cramer	Acute + Recovery	In concept development
REMAKE	Sean Savitz, Larry Wechsler, Steve Cramer	Recovery	In concept development
THROTTLE	Kunal Agrawal, Brett Meyer, Steve Cramer	Recovery	In concept development
STARBURST	Stephen Page	Recovery	In concept development
BLAST	James Meschia	Prevention	In concept development
CAVIS	Mark Harrigan	Prevention	In concept development
SPLIT	Andrew Naidech	Prevention	In concept development
START	Steve Warach, Truman Milling	Prevention	In concept development
ICAS	David Hasan	Prevention	In concept development
PERFUSE-ICAS	S. Yaghi, P. Khatri, D. Liebeskind, S. Prabhakaran	Acute	In concept development
SIMVICH	C. Chen, A. Southerland, K. Johnston, B. Worrall, N. Naval, D. Ding	Acute	In concept development
SCORE	David Hasan	Acute	In concept development
IDDEAL	Syed Ali	Prevention	In concept development
ARCADIA-G	Dana Leifer	Prevention	In concept development
URIC	Enrique Leira	Acute	SPAN Initiative
MATRICES	Maarten Lansberg, Greg Albers, Albert Yoo, Sam Zaidat	Acute	On hold for EVT Platform
ETHER	Stephan Mayer	Acute	On hold for EVT Platform
SERENE (ASSIST +	Radoslav Raychev, Dimiter Arnaudov, David F. Kallmes, (Radiology) Alejandro Rabinstein, (Neurology)	Acute	On hold for EVT platform

Project Name	Protocol PI	Prevention/ Acute/Recovery	Status Update
SEACOAST)	Jeffrey Pasternak, (Anesthesiology) Rickey Carter, (Biostatistics)		
HEMERA	Italo Linfante, Raul Nogueira	Acute	On hold for EVT platform
NEPTUNE (ARCADIA ancillary study)	Ajay Gupta, Hooman Kamel	Prevention	In concept development
ARCADIA ORACLE	Babak Navi	Prevention	Hold ARCADIA ancillary study
RAFT	Truman Milling, Steve Warach	Acute	In concept development; gathering preliminary data for a future application



Biweekly Update 7-June 2019

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

StrokeNet Enrollment Update

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CREST 2 – 1423/2480

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StrokeNet Trial Updates

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@crest2strokestudy



@CREST2_Study



@crest2stroke



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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 **12-June, 2019, at 12 noon ET. Teleconference details: 1-877-621-0220, passcode 434578.**

At 12:30 pm, Greg Albers and Sarah Lee will present the proposed study, "PETITE: Pediatric Endovascular Therapy after Imaging in acuTe stroke", by *teleconference only*. RCCs received the feasibility survey for PETITE on 24-May, and it is due 17-June.

This is *NOT* a webinar presentation. Please follow along **via the PDF document attached to this email.**

NDMC News

PETITE Feasibility Survey

A feasibility survey for PETITE was sent out to the RCCs on 24-May. Please note that this is due by **17-June!**

Site Clinical Profile Annual Survey

The Site Clinical Profile Annual Survey for 2018 is now ready for data entry in WebDCU! RCCs – Please start working on completing this survey for each of the sites under your RCC. As a reminder, the data entered on these surveys are used for feasibility and site selection purposes. The data entered on these surveys should be for the 2018 calendar year. The 2016 survey is still available for viewing in WebDCU in case you need to refer back to what was entered for a site that year. We would appreciate completion by **1-August.**

Instructions for completing surveys in WebDCU:

- From the StrokeNet main menu page in WebDCU, click on [Project Management] and then [Site Clinical Profile Annual Survey]
- Click on the blue # link in the left hand column of the site and year (2018) that you want
- Once on the survey page, click [Edit Record] in the upper right hand corner of the screen
- Complete the survey and click [Save Record]. You are not required to enter all data at once.

If you have any questions or issues, please contact Jessica Griffin at simonsjl@musc.edu.

NINDS Clinical Trials Methodology Course

The CTMC is organized by the University of Michigan, in collaboration with the University of Iowa and Los Angeles BioMed

Upcoming webinar courses:

11-June 2019
25-June 2019
2-July 2019
16-July 2019

Biomarkers
Partnering with Industry
Data and Safety, IMM, AE Reporting
Rare Disease Trials

James, Berry, MD
Jeff Saver, MD
Roger Lewis, MD
Melanie Quintana

Unless otherwise specified webinars will generally be held on Tuesdays at 12PM ET: <https://bluejeans.com/7342322138>

For more information on fall webinar courses, please visit <https://nett.umich.edu/training/ctmc/ctmc-webinars>

StrokeNet Meetings/Webinars

Fall Network Meeting:

Tuesday, 29-October, Atlanta, Georgia. We anticipate up to **four** seats per RCC, with extra seats opening up after RSVPs are in, as in the past. There will NOT be a trainee meeting. Please send your RSVPs to Rose by **6-September**. On 9-September, we will open up the available seats on a first come-first served basis.

Coordinator Webinar

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

When: **Wednesday, June 26, 2019 - 1:30 PM ET**

Presenters: **Cheryl Grant**, Medical University of South Carolina
Preethy Feit, Medstar Health Research Institute

Topic: Manager's Survey Results

Moderator: **Dave Haney**, Case Western Reserve University

To join the meeting: <https://nihstrokenet.adobeconnect.com/coordinator/>. Please enter as a guest, then your email address or your first and last name.

To take part in the conversation you **MUST** dial in. 1 (877) 621-0220 Passcode: 434578

Professional Development Webinar

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

The next Professional Development webinar is TBD. Look for more information

Grand Rounds

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

The next Grand Rounds is TBD. We will keep you posted!

Seminars and Conferences

2nd Annual Aspen Conference on Pediatric Cerebrovascular Disease and Stroke

July 15-19, 2019

Viceroy Snowmass Hotel
Snowmass Village
Aspen Colorado

Online registration for this conference is required.

Please visit <http://www.cincinnatichildrens.org/AspenNeuro> to register.

StrokeNet Employment Opportunities

For more information on additional StrokeNet employment opportunities, please visit:
<http://www.nihstrokenet.org/education/employment-opportunities>

Full-time Vascular Neurology Faculty Position, Spectrum Health Medical Group

Title: Attending Vascular Neurologist

Field of Specialization: Stroke

Link to apply:

https://careers.peopleclick.com/careerscp/client_spectrumhealth/external/gateway/viewFromLink.html?jobPostId=123983&localeCode=en-us

Job Description: Spectrum Health's Department of Neurological Health is seeking to add a full-time vascular neurologist to their five board-certified vascular neurologist team. This new addition will participate in the Joint Commission certified Comprehensive Stroke Center at Butterworth Hospital in Grand Rapids, Michigan and support outreach to our surrounding regional hospitals. In addition to research opportunities, the position includes neurology residency and medical school teaching with faculty appointments through Michigan State University.

Spectrum Health Butterworth Hospital is a hub for regional stroke network in West Michigan.

Annual Stroke Volume: 1500+

Annual intravenous thrombolysis Volume: 150+

Annual Thrombectomy Volume: 150+

Requirements: MD or DO, BC/BE, ACGME-approved Vascular Neurology Fellowship
Contact: Christine Powers, Christine.powers@spectrumhealth.org

Full-time Neurocritical Care Faculty Position, Spectrum Health Medical Group

Title: Attending Critical Care Neurologist
Field of Specialization: Neurocritical Care

Link to **apply:**
https://careers.peopleclick.com/careerscp/client_spectrumhealth/external/gateway/viewFromLink.html?jobPostId=117639&localeCode=en-us

Job Description: Spectrum Health's Department of Clinical Neurosciences is seeking to add a full-time critical care neurologist to their fellowship-trained physician care team. This faculty member will participate in the Joint Commission certified Comprehensive Stroke Center and Level I Trauma Center at Butterworth Hospital in Grand Rapids, Michigan. In addition to research opportunities, the position includes neurology residency and medical school teaching with faculty appointments through Michigan State University. Robust Grand Round opportunities are available for CME/MOC and a Vascular Neurology Fellowship is also under development.

Leadership opportunity potential.

Spectrum Health Butterworth Hospital is a hub for regional stroke and trauma network in West Michigan.

Neuro ICU: 14 beds and growing

Annual Stroke Volume: 1500+

Annual intravenous thrombolysis Volume: 150+

Annual Thrombectomy Volume: 150+

Annual SAH Volume: 50+

Annual TBI Volume: 880

Requirements: MD or DO, BC/BE, Neurocritical Care Fellowship training

Contact: Christine Powers, Christine.powers@spectrumhealth.org



Lewis Katz School of Medicine

Department of Neurology
Lewis Katz School of Medicine at Temple University
Philadelphia, Pennsylvania
www.temple.edu/medicine

Summary of Opportunity

The Department of Neurology at the Lewis Katz School of Medicine at Temple University, is seeking applicants at the /Associate or Professor level to lead Temple's Stroke Division. The successful applicant will have completed a stroke fellowship and be BC/BE in neurology. The

Stroke Medical Director, reporting to the Chair, will oversee the clinical, academic and research operations within the Temple Stroke Center.

The Temple University Stroke Center is a Joint Commission Comprehensive Stroke Center. The Stroke Service sees 800-1000 cerebrovascular related admissions per year. The program includes 2 neurointerventional faculty, and a 20 bed Neuroscience Intensive Care Unit staffed by stroke neurologists and neurointensivists. The program participates in the "Get with The Guideline's" Stroke Program and has consistently achieved Gold Plus and Target Stroke Honor Roll status. There is an active program of clinical trials through the StrokeNet Network (NINDS funded), a formal stroke prevention clinic utilizing evidenced based guidelines for risk factor modification. We are actively building our Stroke Telestroke/Telemedicine network for acute stroke to neighboring community and rural hospitals.

In collaboration with the Department Chair and the organization's leadership, the successful applicant will be responsible for quality, safety and care provided on the stroke service and actively involved in performance improvement and cost containment initiatives. The Stroke Medical Director will provide leadership for regulatory and accreditation compliance and will co-direct the Temple Stroke Committee. The Director will be responsible for overseeing the residents for acute stroke care, share in the attending teaching schedule and help develop the stroke and acute care curriculum. He/she will maintain an outpatient practice and conduct research in one's area of interest. Stroke Telemedicine call has no in house obligations and will be shared with other attendings.

The Neurosciences Center at Temple University Hospital is one of the Philadelphia region's best facilities for the treatment of neurological disorders. A highly skilled and compassionate neurology and neurosurgery staff plus a state-of-the-art diagnostic center means access to advanced treatment options for patients with neurological disorders. Several of our physicians have been consistently selected by their peers as "Top Doctors," both locally and nationally. Working together, our neurologists and neurosurgeons use the latest protocols and state-of-the-art equipment, including the Leksell Gamma Knife® 4C, the Neuroblate® Laser Ablation System and the Elekta Synergy® S, to diagnose and develop individualized treatment plans for the full range of neurological problems.

Temple Health, one of Philadelphia's leading academic medical centers, is home to more than 1,000 physicians and scientists who share the mission of bringing innovative treatments to patients.

Giving our patients access to some of the world's most advanced therapies — and helping them achieve outcomes once thought impossible — is the driving force for all our clinical care, research, and medical education.

Procedure for Candidacy

Interested candidates should submit a current curriculum vita and complete contact information to the following address: <https://bit.ly/2HexEz4>

Please address all applications to: Paul M. Katz, M.D., Director, Temple Stroke Program, C/O Michael Lester, Senior Director, Physician/Faculty Recruitment & Retention, Temple University School of Medicine, 3420 N. Broad Street, MRB 101, Philadelphia, PA, 19140, Email: michael.lester@tuhs.temple.edu

The University is especially interested in qualified candidates who can contribute through their

research, teaching, and/or service to the diversity and excellence of the academic community. Lewis Katz School of Medicine at Temple University is an Affirmative Action/Equal Opportunity Employer and strongly encourages applications from women, minorities, veterans, and persons with disabilities.

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>