



## Biweekly Update 15-January 2021

### StrokeNet Enrollment Update

|             |          |            |           |
|-------------|----------|------------|-----------|
| ARCADIA     | 565/1100 | TRANSPORT2 | 22/129    |
| ARCADIA-CSI | 130/500  | I-ACQUIRE  | 39/240    |
| Sleep SMART | 395/3062 | MOST       | 123/1200  |
| SATURN      | 46/1456  | CREST H    | 172/500   |
| ASPIRE      | 12/700   | CREST 2    | 1761/2480 |

\*Enrollment as of 15-January 2021

## StrokeNet Trial Updates



Happy New Year and thank you for your continued dedication to Sleep SMART. We truly appreciate all your hard work.

As of January 13, 2021, 1163 subjects have been enrolled and 394 subjects have been randomized.

Congratulations to the following sites for January randomizations:

1. Brooks Rehabilitation Hospital, Jacksonville, FL
2. Memorial Hermann Texas Medical Center, Houston, TX
3. Wake Forest Baptist Medical Center, Winston-Salem, NC
4. North Shore University Hospital, Manhasset, NY
5. University of Chicago, Chicago, IL

### PLEASE NOTICE:

**Corrective Action Plan (CAP):** After one additional out of window or missed 3-month or 6-month visit, a CAP will need to be completed by your site. If an additional visit is missed while a CAP is ongoing, site probation will be triggered. Please try your best to obtain these critical outcome assessments.

### IMPORTANT INFORMATION THAT MAY HAVE BEEN FORGOTTEN:

The 3-month mRS is a primary outcome for Sleep SMART. Please complete all 3-month assessments within window. These can be done by phone, if needed and should be completed by a blinded assessor if possible.

A "warm transition" for intervention (CPAP) subjects should be completed sometime prior to discharge. This contact between intervention subjects and the FusionHealth Care Team helps facilitate CPAP adherence post-discharge.

**End of Study (EOS):** If you have a subject who moved to EOS, please document in WebDCU™ as soon as possible. Completing this CRF lets FusionHealth know the subject has completed participation. If not completed, you will likely receive emails from NDMC, Kayla, and the FusionHealth team asking about the subject's status.

Don't forget to ask each subject (or LAR) who is eligible for randomization based on a CPAP run-in night, if he/she agrees to randomization (may not wish to be randomized to CPAP if had unfavorable experience or may not wish to be randomized to control arm if had very favorable experience).

**Re-Opening:** If your site is ready to be re-released to enroll please email Kayla or Joelle for further instructions.

### KEEP AN EYE OUT:

Quarterly reports will be coming out soon from NDMC.



## **ARCADIA: New Year, New Sites, Let's Celebrate our Achievements!**

Happy New Year, Arcadians! We reached several important milestones over the past few weeks!

1. We reached 50% of our target recruitment! Congratulations to Cheryl Bushnell, PI, and Krystal Schmidt, Study Coordinator, of Wake Forest Baptist Medical Center in Winston-Salem, NC for bringing us to this point.
2. Our 1<sup>st</sup> Canadian enrollment! Congratulations to Dr. Ng and the study team at Hamilton General Hospital.
3. We now have 134 active sites, as we did prior to the COVID pause on enrollment. Thanks to the 119 sites who have restarted and the 15 NEW sites released to enroll after the enrollment pause was lifted.
4. We have consented 432 subjects and randomized 125 since the enrollment pause was lifted despite the incredible challenges facing each site.

We understand that this winter COVID surge may continue to rise and impact our enrollment—through all your clinical and research efforts, our wish is that you all remain safe and healthy during these difficult times.

You have randomized a total of 565 participants, an increase of 19 since the last update. A special thanks to the 18 teams that provided the last randomizations since early December: Baylor College of Medicine Medical Center, Houston, TX; Emory University Hospital, Atlanta, GA; Greenville Hospital System, Greenville, SC; Houston Methodist Hospital, Houston, TX; Medical University of South Carolina University Hospital, Charleston, SC; Mercy St. Vincent Medical Center, Toledo, OH; Methodist University Hospital, Memphis, TN; OU Medical Center, Oklahoma City, OK; Rhode Island Hospital, Providence, RI; University of Kentucky Hospital, Lexington, KY; University of Mississippi Medical Center, Jackson, MS; University of Nebraska Medical Center, Omaha, NE; University of Texas Health Science Center San Antonio, San Antonio, TX; UPMC Presbyterian Hospital, Pittsburgh, PA and Wake Forest Baptist Medical Center, Winston-Salem, NC – what a magnificent group!

The teams at Sanford Medical Center Fargo, Fargo, ND; St. John's Hospital, Springfield, IL and UC Irvine Medical Center, Orange, CA randomized their first participant in the last few weeks! Some firsts took a while and others came right away, but now keep the momentum going and thank you for reaching this goal despite the circumstances.

We still have a pool of 38 subjects eligible and pending randomization. We understand that not all can be randomized immediately; however, please continue to conduct randomization visits safely and per protocol.

We are currently at 2142 subjects enrolled/consented, an increase of 83 during this period, thanks to 59 sites which means we have sites have enrolled multiple subjects during this period - thank you to all the teams making this possible! A special thanks to Tampa General Hospital, Tampa, FL for enrolling 4 and to UC Irvine Medical Center, Orange, CA and NYP Columbia University Medical Center, New York, NY for enrolling 3 each. Miami Valley Hospital, Dayton, OH, Hamilton General Hospital, Hamilton, ON, Canada and UC Irvine Medical Center enrolled their 1st subjects during this period. We understand the level of commitment it takes to get this done – great job everyone!

We want to welcome the following site teams to the ARCADIA family: Allegheny General Hospital, Pittsburgh, PA; Cooper University Hospital, Camden, NJ; Saint Luke's Hospital of Kansas City, Kansas City, MO; Boca Raton Regional Hospital, Boca Raton, FL and Memorial Hermann - Woodlands Hospital, The Woodlands, TX as they were just released to enroll since the last BWS.

Let us know if you know of a good site that would like to participate in ARCADIA. We hope to continue to re-start sites as per the ARCADIA re-start plan for the 8 sites still pending re-release to enroll. We understand some of the sites cannot yet re-start, but those that can re-start enrollment, even if only remotely, please reach out to Rebeca ([ra2356@cumc.columbia.edu](mailto:ra2356@cumc.columbia.edu)) to review any pending items needed for your re-release. PLEASE do not start enrolling new subjects until your site has been officially re-released to enroll.

We're looking forward to sharing information and hearing from you in our Virtual Investigator Meeting on Tuesday, January 26<sup>th</sup> from 1pm to 4pm EST. Look for the link to come soon by email. See you all there!

## **Site Startup and Enrollment Updates**

**Sites: 72/108      Subject Enrollment: 129/500**

Enrollment has been challenging in the wake of Covid19, however the use of eConsent has alleviated some of the burden. We look forward to working with sites to institute eConsent at most, if not all of our sites.

Congratulations to the following sites who are now released to enroll:

**University of Chicago Medical Center  
Lehigh Valley Hospital- Cedar Crest  
Cleveland Clinic**

**eConsent:** Please complete and return the Remote Implementation form for your site if you haven't done so already. This form lets us know if your site will need an eConsent database.

**Continuing Review:** The continuing review for CSI is now underway. Please send in your fCOI forms (PI only) and a completed CR form. Please let us know if you have any questions.

**Form 515:** We have several sites that have enrolled subjects into CSI but have not completed Form 515. The form is found in the ARCADIA database and must be completed within a few days of enrollment into the study. If the subject declines, you will still need to complete the form.

Please contact Tashia Harris, [herndotl@ucmail.uc.edu](mailto:herndotl@ucmail.uc.edu) or Stephanie Kemp, [skemp@stanford.edu](mailto:skemp@stanford.edu) with any questions.



**Happy New Year!!**

**Congratulations to the Cincinnati Site for being the first to randomize in 2021!**

We now have enrolled **39** study participants. Everyone's hard work is greatly appreciated!

- Ann Arbor, MI – **5** participants randomized
- Boston, MA – **12** participants randomized
- Cincinnati, OH – **4** participants randomized
- Columbus, OH – **5** participants randomized
- La Jolla, CA – **5** participants randomized
- New Haven, CT – **3** participants randomized
- Philadelphia, PA – **1** participant randomized
- Roanoke, VA – **4** participants randomized

**Save the dates:** Upcoming **2021** PI/Co-I/Coordinator Webinar:

- Thursday 11 February (12-1pm ET)
- Thursday 11 March (12-1pm ET)
- Thursday 22 April (12-1pm ET)
- Thursday 13 May (12-1pm ET)
- Thursday 10 June (12-1pm ET)



**CREST-H****Site Startup and Enrollment Updates:** sites: **56**; enrollments: **172/350**

Enrollment is a challenge with the COVID surge due to restrictions on elective surgery, but continues with a total of 172, **49%** of our target. We are hoping all are CREST-H sites will remain active as possible, and we look forward to the inclusion of several additional sites in the onboarding pipeline. CREST-2 has <720 patients left to recruit. We need 176 them for CREST-H. Let's continue the pace to meet our target. Keep an eye out for asymptomatic carotid patients and let's keep the enrollment going!

Enrollment tip, although signed consent for CREST-H must take place after CREST-2 randomization occurs, you can minimize the number of visits for your patients by verbally consenting the patient for CREST-H at the time of the discussion of CREST-2 imaging. Then, schedule the MR or CT scan and have them sign the consent form when they come in for the scan.

Interested in becoming a CREST- site? Contact Randy Marshall [rsm2@columbia.edu](mailto:rsm2@columbia.edu), Ron Lazar [rlazar@uabmc.edu](mailto:rlazar@uabmc.edu), Jaya Vijayan [vijayan.jaya@mayo.edu](mailto:vijayan.jaya@mayo.edu), or Kevin Slane [KJS4@columbia.edu](mailto:KJS4@columbia.edu) with any questions.

**From the CREST-2 Clinical Coordinating Center:****17562 Overall****928 CEA****834 CAS**

**2021: THE YEAR OF RECRUITMENT!** **Happy New Year!** With the start of the new year, the CREST-2 CCC is focused on increasing monthly enrollment to meet our target goal of 2,480 by the end of 2022. As a reminder, we have many resources that include patient brochure, video brochures, clinical study apps, and more to aid in recruitment — with new tactics coming soon! We need YOUR help to accomplish this — let us know what we can do to increase enrollment in your site. We appreciate all that you've done thus far! On another note, it is with mixed emotions that both Ewa Szymkiewicz, CREST-2 Site Manager, and Rosalean Rock Ruby (Rose), CREST-2 Monitor, have accepted new positions at Mayo Clinic outside of CREST-2. Ewa's last day is January 26<sup>th</sup> and Rose's last day is January 29<sup>th</sup>. We wish them both the best of luck with their future endeavors! With that we would like to introduce our new CREST-2 Site Managers, Celine Ginsburg and Stephanie Gilles! Celine started January 11<sup>th</sup> and Stephanie will start February 1<sup>st</sup>. We are so excited for their abundance of research experience and knowledge that they will bring to CREST-2.

## MOST Enrollment Update:

Total randomizations: **123**

Randomizations between 16Dec2020 and 23Dec2020 (**Enrollment Suspension**): **1**

Sites released to enroll with at least one subject consented: **36**

There are now **71** sites that have been released to enroll, **61** of which are actively recruiting!

According to the protocol the **24-hour NIH Stroke Scale (NIHSS) assessment should be performed by a blinded assessor**. If it is performed by an unblinded assessor, an Unanticipated Event Report (UAE) should be entered into WebDCU™ under Project Management □ StrokeNet Unanticipated Event-PD Report.

The **30 and 90-day modified Rankin Scale (mRS)** outcomes assessments should also be blinded. Although this will not require a UAE, **we strongly encourage all outcomes for MOST to be blinded**.

The **MOST Trial Investigator Meeting** was held on Tuesday, 12Jan2021. The following items were discussed:

- Root causes and corrective actions regarding recurrent issues with the administration of study drug that led to a CIRB-imposed enrollment suspension.
- Study drug administration retraining.
- Major changes to Protocol Version 5.1 dated 08Dec2020 including the addition of tenecteplase as a standard of care thrombolytic therapy and inclusion/exclusion criteria updates.
- Best practice for switching from alteplase to tenecteplase.
- Rankin Focused Assessment should be used to conduct structured mRS interviews according to the DSMB's recommendation.

The Investigator Meeting presentation slides have been provided to the sites via email. The slides have also been uploaded in the Toolbox within WebDCU™. The clean protocol, protocol signature page, CIRB Prime approval letter for Protocol Version 5.1 and the Rankin Focused Assessment have also been uploaded in the Toolbox within WebDCU™.

An email was sent by Iris Deeds following the meeting to Principal Investigators, Primary Study Coordinators and Regulatory Coordinators with instructions on restarting enrollment after study drug administration retraining, processing the protocol amendment and opting to use tenecteplase.

The **PI Hotline** is available 24/7 for any questions: **1-833-229-MOST**.



FASTEST wishes you a Happy New Year! We are excited to continue study start-up! We would like to thank you for your continued efforts and hard work getting FASTEST ready to launch.

Our next webinar will be **Wednesday, January 20<sup>th</sup> at 2:00 pm ET**. Prior presentations and slides are available on the StrokeNet website, <https://www.nihstrokenet.org/fastest/webinars>.

The ABC/2 and IVH Score Imaging Training is available, <http://fasteststudy.com>. Team members will need to register for an account, which can take up to 24 hours to activate.

Approved EFIC community-facing template materials, English and Spanish, are available on WebDCU™, in the Toolbox under Project Documents. The Spanish version of the central REDCap survey is also available now.

A few helpful reminders:

- If you have not submitted an EFIC plan for review, please reach out to the NCC with an update on your site's progress. We would like to hear from sites, even if your site is still developing a plan.
- When you are ready to initiate your EFIC plan, update your DOA log with your EFIC team.
- Reach out if you plan to use the central REDCap survey and need access.

Congratulations, we now have **21** sites that have submitted EFIC plans to Advarra and are taking next steps to implement them! Since the last update -- **Kaiser Permanente Los Angeles Medical Center, Toledo Hospital (ProMedica), Mills-Peninsula Medical Center, University of Tennessee/Methodist University Hospital!**

Upcoming Advarra EFIC Panel meeting dates -- January 25<sup>th</sup>, February 8<sup>th</sup> and 22<sup>nd</sup>, March 8<sup>th</sup> and 22<sup>nd</sup>

Please contact Pooja Khanolkar (Prime Project Manager), [khanolpa@ucmail.uc.edu](mailto:khanolpa@ucmail.uc.edu) or Julie Denlinger (NCC Project Manager), [denlinjk@ucmail.uc.edu](mailto:denlinjk@ucmail.uc.edu) with any questions.



## ASPIRE

### ENROLLMENT:

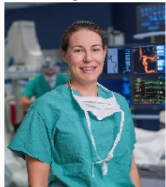
Congratulations to our sites that **enrolled participants in 2020!**

**UNIVERSITY OF IOWA – Top ASPIRE enroller with 3 participants!**

|                           |
|---------------------------|
| HARBORVIEW                |
| MAYO CLINIC, JACKSONVILLE |
| OREGON HEALTH & SCIENCE   |
| OSF ST. FRANCIS           |
| UNIVERSITY OF UTAH        |
| UPMC PRESBYTERIAN         |
| WAKE FOREST               |
| YALE                      |

And special thanks to **Stacey Wolfe** (PI) and **Wendy Jenkins** (CRC) at **Wake Forest** for their **2<sup>nd</sup> enrollment** and our **1st participant of 2021!**

Stacey Wolfe, PI



Wendy Jenkins, CRC



In addition to our 12 study participants, there are 3 consented subjects who are pending randomization at **University of Utah, Cedars-Sinai and Prisma Health.**

Thanks to all our active sites for **screening ICH patients** for the study. We know a majority will rule-out for ASPIRE, but the enrolling sites have shown that eligible patients are out there! A few suggestions and tips we have learned:

- If you find a patient with an eligible ICH event and non-valvular AF, you should track them during their hospital stay and consent in-hospital if possible. If they ultimately don't get randomized, that's okay.
- ICH patients with atrial fibrillation are often elderly and frail. That's okay! That is the population of interest and exactly who we want to enroll.
- If you find that a patient is able to participate, we recommend you **consent the patient (or LAR) prior to hospital discharge** and work out the logistics of randomizing the patient within the 14-120 day post-ICH window.

We appreciate all the effort that went into screening and enrolling study participants in our first year and look forward to working with our sites to make 2021 a very productive one for ASPIRE.

### STUDY NETWORK

**88 sites** have been activated (of these, **83** are currently released to enroll) and **41 sites** are pending activation.

**ASPIRE is looking to add new motivated sites.** Please contact [ASPIRE@yale.edu](mailto:ASPIRE@yale.edu) if your site would like more information about participating in the ASPIRE Trial.

### CONTINUING REVIEW

Continuing review was approved December 9, 2020. New approval letter and informed consent documents were distributed the week of December 14, 2020. If not already done, please upload your site's new approval letter and informed consent documents to WebDCU™. eConsent REDCap Projects have been updated with newly approved informed consent documents

**Our next Webinar** is January 27, 2021 3:00p-4:00p EDT. Please join us for a discussion of Atrial Fibrillation – a Field Guide.





Our next PI and Coordinator call will be on **Monday, 2/1/2021 at 11am ET**. If anyone has topics they would like to discuss during the call, please send them to Kristina Balderson ([Kristina.balderson@duke.edu](mailto:Kristina.balderson@duke.edu)) or Julia Gonzalez, ([Julia.jackson@duke.edu](mailto:Julia.jackson@duke.edu)).

12 sites have reopened to enrollment! Congratulations to MUSC, Burke, Baystate, Medstar, UAB, USC, Kentucky, Houston, Cincinnati, Moss, Emory, and Duke for being re-open to enrollment amidst the COVID-19 restrictions. Cleveland VA has received IRB approval and UPMC is finalizing study start-up activities. We are hopeful that our two pending sites will open in the next month. There are 22 subjects randomized in the trial, 15 have completed the study and we have several subjects we are hoping to randomize this month.

A new protocol amendment has been approved through the CIRB as of 12/10/2020. Changes include a clarified schema and schedule of activities, allowing sites to use video for prescreening, and an increase of the number of training subjects for more efficient site training.



SATURN has 90 sites open for enrollment and has randomized 46 patients! We want to thank everyone for their efforts to screen recruit and randomize! We ask that sites continue to screen every ICH daily!

Reminder: it is important to communicate the subject's randomization assignment to the clinical team once randomization is completed to ensure the patient will be discharged with the proper medications and instructions.

SATURN held the monthly PI/Coordinator webinar 12/17/2020. Please find the recording here: <https://www.nihstrokenet.org/saturn-trial/webinars>

#### **Topics Covered:**

- Enrollment experience, COVID-19 Impact Assessment Forms, updated Screen Failure CRF, Lab Kit Requests, Biobank Reminders, Biobank Shipping

The next monthly SATURN PI/Coordinator webinar will be held 1/28/2021 at 12:30pm EST

SATURN is actively looking to **add sites**; please reach out for further details.

SATURN has received approval for central REDCap eConsent and **Remote Implementation and eConsent Forms** were distributed to all US Sites for completion. **Please complete and return these forms as soon as possible**. The site-specific eICF templates are pending one final CIRB approval and then they will begin to be distributed next week.

SATURN has received approval on a recruitment video. The video may be viewed here: <https://www.nihstrokenet.org/saturn-trial/home>

Sites will receive a communication with all available links to the SATURN Video as well as the regulatory approval documents.

If you have any questions regarding SATURN and reopening enrollment at your site please contact:

- Kimberlee Bernstein NCC Project Manager [gammk@ucmail.uc.edu](mailto:gammk@ucmail.uc.edu)
- Sarah Marchina Prime Project Manager (BIDMC) [smarchin@bidmc.harvard.edu](mailto:smarchin@bidmc.harvard.edu)

#### **IMPORTANT STAUrn CONTACTS:**

- **Questions regarding eligibility or protocol implementation**
    - Email: [SATURN@bidmc.harvard.edu](mailto:SATURN@bidmc.harvard.edu)
  - **SATURN Clinical Hotline**
    - Call 617-667-7000 and ask to page beeper #39636.
- \*\*\*Please tell the operator that you are calling about the SATURN trial.

## NIH StrokeNet RCC Manager Reminder

All NIH StrokeNet Trial Sites are required to collect a StrokeNet fCOI form initially for all study team members and any new investigators. Sites are to file the initial fCOI forms for all study team members in their site files to be made available for monitors/auditors when requested for the length of the trial. Please refer to your local policy/requirement for annual renewal of the fCOI form. During the Annual Continuing Review, sites will be asked to verify that there has not been changes to any study team member's fCOI that is submitted to the cIRB. Sites should always disclose any positive COI as soon as it is presented so the information can be submitted to the cIRB. Disclosures will be stored in WebDCU™ along with the PI fCOI form in the [Site Documents] section.

## NIH StrokeNet Coordinator Webinar

*Coordinator Webinars are a requirement for the NIH StrokeNet RCC Coordinators/Managers however, all are welcome to attend*

**Wednesday, January 27, 2021  
1:30 pm ET**

Topic: Mastering the StrokeNet Master Trial Folder – Updates and Reminders

Presenters: Jen Golan, MS, NCC Regulatory Specialist  
Aaron Perlmutter, MPH, MSW, NDMC Trial Site Monitoring Manager

Moderator: Dave Haney, CWRU

As always, please bring your questions for all StrokeNet trial Project Managers!

To join the meeting: <https://nihstrokenet.adobeconnect.com/coordinator/>

Please enter as a guest, then your email address or your first and last name.

Please forward this calendar invitation to your satellites.

Please log into the meeting room 15 minutes prior to start time

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

## Steering Committee Call

*Steering Committee Calls are a requirement for all NIH StrokeNet RCCs; Please invite satellite sites to attend*

The next Steering Committee call is scheduled for **Wednesday, 10-February, 2021, at 11:00 am ET.**

**\*Please note that the NIH StrokeNet Spring Network Webinar is scheduled for Wednesday, 14-April, 2021, from 12 noon – 3:00 pm ET.**



## Grand Rounds

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

**Thursday, January 28, 2021**

**4:00 pm ET**

Topic: Stroke Transitional Care and How it Fits into The Continuum of All Stroke Trials, Both Acute, Prevention and Rehab/Recovery

Presenter: Cheryl Bushnell, MD, Wake Forest University

Moderator: Shyam Prabhakaran, MD

To join the meeting: <https://nihstrokenet.adobeconnect.com/grandrounds/>. 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. (877) 621-0220 Passcode: 190825**

## Professional Development Webinar

*Professional Development Webinars are a requirement for the NIH StrokeNet Trainees*

**The next PDW is TBD. We will keep you posted.**

## NIH StrokeNet Employment Opportunities

### University of Chicago Department of Neurology Neurohospitalist Faculty Position

The University of Chicago's Department of Neurology is searching for a full-time faculty member at any rank who will provide direct patient care managing hospitalized patients with complex neurological subspecialty needs. This position will be a mix of community hospital and academic medical center practice beginning initially at UCM's Ingalls Memorial Hospital but with effort at other community hospitals and at UCM's Hyde Park hospital as the group of neurohospitalists grows to a dedicated section in the department. This position will also encompass academic effort, including providing education and oversight to medical students, residents and fellows.

We especially welcome applicants with training in vascular neurology or neurohospitalist fellowships. Academic rank and compensation (including a generous package of fringe benefits) are dependent upon qualifications.

Prior to the start of employment, qualified applicants must: 1) have a medical doctorate or equivalent, 2) hold or be eligible for medical licensure in the State of Illinois, and 3) be Board certified or eligible in Neurology or equivalent.

To be considered, those interested must apply through The University of Chicago, Academic Recruitment job board, which uses Interfolio to accept applications: <http://apply.interfolio.com/82306>. Applicants must upload: CV including bibliography and a cover letter. Review of applications ends when the position is filled.

For instructions on the Interfolio application process, please visit <http://tiny.cc/InterfolioHelp>.

### **Beth Israel Deaconess Medical Center and Harvard Medical School Interventional Neurology Position**

The Divisions of Stroke and Endovascular Neurosurgery at Beth Israel Deaconess Medical Center (BIDMC) and Harvard Medical School are searching for an interventional neurologist with academic interests. Applicants must have completed fellowship training in interventional endovascular neurology, radiology or neurosurgery, be proficient in endovascular neurological/neurosurgical procedures, and be ABPN Board-eligible or certified. Additional fellowship training and certification in Neurocritical Care or Vascular Neurology is desirable but not required. Successful candidates are expected to perform interventional neurology/endovascular neurosurgery procedures and participate in call coverage with a team of 3 endovascular neurosurgeons. They will also be expected to perform other clinical activities consistent with their training, and to be involved in various research, outreach, and teaching activities within the BIDMC Comprehensive Stroke Center. Salary and academic rank will be commensurate with experience, training and achievements.

Please send a letter of intent indicating career goals and academic interests and Curriculum Vitae to Dr. Christopher Ogilvy, Director of Endovascular and Operative Neurovascular Surgery and BIDMC Brain Aneurysm Institute at ([cogilvy@bidmc.harvard.edu](mailto:cogilvy@bidmc.harvard.edu)) and Magdy Selim, Chief of the Stroke Division at BIDMC at ([mselim@bidmc.harvard.edu](mailto:mselim@bidmc.harvard.edu)).

Harvard Medical Faculty Physicians at BIDMC is an equal opportunity employer and all qualified applicants will receive consideration for employment without regard to race, color, religion, sex, sexual orientation, gender identity, national origin, disability status, protected veteran status, or any other characteristic protected by law.

### **Clinical Research Coordinator, Neuro Critical Care Research Yale University**

#### **StrokeNET Program Manager**

Reporting to the Principal Investigator of StrokeNET and the Clinical Research Manager-Neurocritical Care and Neurovascular, the StrokeNET Program Manager oversees research participant activities for a variety of StrokeNET studies at Yale. StrokeNet is a NIH funded stroke trials network in which Yale is a collaborative site with Brown University and Hartford Hospital to create SPIRIT (Southern New England Partnership In Stroke Research, Innovation and Treatment) <https://nihstrokenet.org/>. SPIRIT is one of only 25 nationally funded regional coordinating centers within StrokeNet in the country. StrokeNet was developed to promote and conduct high-quality, multi-site clinical trials focused on key interventions in stroke prevention, treatment and recovery. It is designed to serve as an infrastructure and pipeline for exciting new potential treatments for patients with stroke and those at risk for stroke.

As the StrokeNET Program Manager the primary duties of this position include: study start up, oversight of recruitment and trial activities, collaborating with other satellite and clinical performing sites, planning meetings, scheduling calls and setting agendas for network related events, quarterly matrix and reporting, serve as liaison between StrokeNet program/Yale site/Affiliated Programs, quality control review of study activity, SOP development and implementation, and regulatory updates for all StrokeNET studies at Yale site. May include direct patient activities for certain studies as determined by staffing needs.

#### Essential Duties

1. Compares protocols and sponsored projects to confirm consistency between funding proposals/awards and approved protocols. 2. Documents established congruency between funding proposals and approved protocols. 3. Facilitates and/or assists with resolution of any inconsistencies between funding proposals and approved protocols. 4. Serves as a liaison between the Grants and Contracts offices, investigators, and business managers to resolve congruency issues in a timely manner. 5. Attends meetings and presents issues when necessary that were identified during congruency review. 6. Serves as a resource and provides technical assistance to investigators and their staff. 7. Provides analytical and technical support related to establishing and recording protocol/grant congruency, as needed. 8. Monitors federal and state regulations for new guidance, updates, or policies. Maintains a high degree of knowledge on these requirements to determine actions and follow directives that may be required to ensure University compliance with congruency review and reporting requirements. 9. Develops, implements, and manages internal practices that ensure compliance with federal requirements. 10. May perform other duties as assigned.

#### Required Education and Experience

Bachelor's degree in a relevant academic/scientific field and a minimum of 3 years of related research support experience; or the equivalent combination of education or experience.

Required Skill/Ability 1: Strong clinical and research skills, including a thorough knowledge of medical and research terminology, along with an ability to train and provide guidance to research assistants on clinical trials.

Required Skill/Ability 2: Flexibility and capability to work as a team player. Excellent interpersonal and communication skills, including ability to effectively present and work with a wide variety of stakeholders.

Required Skill/Ability 3: Proven problem-solving skills including an ability to independently prioritize tasks with competing deadlines and priorities.

Required Skill/Ability 4: Demonstrated skilled knowledge of Good Clinical Practice along with University clinical research guidelines. Proven ability interpreting federal, state, University and sponsor policies and regulations. Demonstrated ability with interpreting clinical trial protocols and federal, state, local guidelines.

Required Skill/Ability 5: Exemplary time and attendance, including being able to be flexible in schedule to attend to project needs and subject recruitment including a rotation for 24x7 on call schedule for the Stroke/Neuro Critical Care Research Units.

Preferred Education, Experience and Skills:

Master's degree in health or research related discipline and two years of related work experience in a similar job family.

Preferred Skill 1: Familiarity with neurological clinical research strongly preferred, especially with a focus on inpatient research and/or stroke.

Preferred Skill 2: Experience in EPIC and OnCore systems and IRB submissions.

Preferred Licenses or Certifications:

Certified Clinical Research Professional (CCRP) or equivalent.

Weekend Hours Required? Occasional

Evening Hours Required? Occasional

Contact:

**Sara Jasak, BSN, CCRP**

Yale University-Department of Neurology

Stroke and Neurology Critical Care

Clinical Research Nurse Manager

(offsite)

[sara.jasak@yale.edu](mailto:sara.jasak@yale.edu)

(413)896-3429- cell

*For more information about StrokeNet employment opportunities, please visit*

*<http://nihstrokenet.org/education/employment-opportunities>*

**Please share your satellites and study teams!**

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