# Biweekly Update
# 12-February 2021

**StrokeNet Enrollment Update**

| | | | |
|---|---|---|---|
| ARCADIA | 582/1100 | TRANSPORT2 | 26/129 |
| ARCADIA-CSI | 139/500 | I-ACQUIRE | 44/240 |
| Sleep SMART | 425/3062 | MOST | 127/1200 |
| SATURN | 56/1456 | CREST H | 178/500 |
| ASPIRE | 14/700 | CREST 2 | 1777/2480 |

*Enrollment as of 11-Feb 2021

## StrokeNet Trial Updates

ARCADIA•CSI
Cognition & Silent Infarcts

**Site Startup and Enrollment Updates**

**Sites: 73/108** **Subject Enrollment: 139/500**

Welcome to the new sites who have agreed to join CSI: **Rush Medical Center**
**Boca Raton**

**Important Updates:**

**Protocol vs. MOP**

We recently discovered a discrepancy between the ARCADIA CSI protocol version 2 and the Manual of Procedures version 2 in the guidelines on the timing of obtaining informed consent. The protocol states that consent should not be obtained until the subject is at least 3 months post stroke which does not match the guidance provided in the MOP and on readiness calls. After an internal review, ARCADIA CSI leadership has determined that the Manual of Procedures will require modification in order to be consistent with the protocol. The revised Manual of Procedures will be posted to WebDCU™ as soon as possible.

**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 in RedCAP.

**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 or Stephanie Kemp, skemp@standford.edu with any questions.

ARCADIA

# ARCADIA: Checking in with the Team!

We appreciate all the sites that have been working so hard since the holidays to screen, approach, enroll and randomize participants -- we thank you for that! Your consenting has increased in the last few weeks and we hope this will soon bear fruit in randomizations. Please remember to reach out to Pam or Rebeca if there is anything we can do to help you get through these challenges.

ARCADIANs have randomized a total of 582 participants since the study started, an increase of 11 in less than two weeks. A special thanks to the eleven teams that provided the last randomizations during this period: Chandler Regional Medical Center, Chandler, AZ; Hartford Hospital, Hartford, CT; Hospital of the University of Pennsylvania, Philadelphia, PA; Los Alamitos Medical Center, Los Alamitos, CA; Memorial Hermann Texas Medical Center, Houston, TX; North Shore University Hospital, Manhasset, NY; St. Mary's Medical Center, Grand Junction, CO; Swedish Medical Center - Cherry Hill Campus, Seattle, WA; UC Irvine Medical Center, Orange, CA; University of Kentucky Hospital, Lexington, KY and the University of Nebraska Medical Center, Omaha, NE – great job everyone!

We still have a pool of 44 subjects eligible and pending randomization --please continue to conduct randomization visits safely and as per protocol.

We are currently at 2,214 subjects enrolled/consented, an increase of 33 in less than 2 weeks, thanks to 26 sites. This also means we have sites that have enrolled multiple subjects over the past 2 weeks - thank you to all the teams making each enrollment possible! A special thanks to the following teams for enrolling multiple subjects during this period:

- Enrolling 3 participants:
  - Massachusetts General Hospital, Boston, MA
- Enrolling 2 participants each:
  - Greenville Hospital System, Greenville, SC; Massachusetts General Hospital, Boston, MA; Moses H. Cone Memorial Hospital, Greensboro, NC; Swedish Medical Center - Cherry Hill Campus, Seattle, WA; University of Mississippi Medical Center, Jackson, MS and Vanderbilt University Hospital, Nashville, TN,

We would also like to welcome a new site to the ARCADIA family – we're happy to have the team at UPMC Altoona, PA join us!

Besides enrollment, we want to remind sites that retention and conducting visits within the scheduled follow-up time window are also important. If a subject's window is closing, then please do the f/u window via EMR review and edit later if the subject returns your phone calls by noting the date they reached out in the f/u comment section so that you can obtain the rest of the f/u data. We understand that subjects do not always promptly return our calls; however, having the protocol ability to conduct the f/u via EMR means there is no excuse for an out of window visit (OOW). Remember that all OOW visits need to be reported as a UAE.

Please continue to 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 6 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) 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.

**Webinar**: Our next PI and coordinator webinar will be February 23rd 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://www.nihstrokenet.org/intranet/minutes/trial-webinars

ASPIRE

Anticoagulation in Intracerebral Hemorrhage Survivors for Stroke Prevention and Recovery

## ENROLLMENT:

14 Subjects have been randomized in ASPIRE!

Congratulations to **Dr. Sanjeev Sivakumar**, **Sam Thavarajah,** and the **Stroke Research Team** at **Prisma Health / Greenville Hospital System, Greenville, SC** for enrolling their first subject!

## STUDY NEWS:

Protocol v1.3 was approved by the cIRB on 2/10/2021. The primary change is:

- Removal of exclusion for life expectancy <1 year.
    - Please review your screening logs from the last 1-2 months because patients previously excluded for this criteria are likely now eligible!

Other changes include:

- Addition of procedures to minimize losses-to follow up and ensure ascertainment of vital status for all subjects.
- Several measures have been moved from baseline to screening (after informed consent obtained). These changes have been made to reduce the amount of time required to complete the baseline/randomization visit.
- Procedures for obtaining subject/LAR signatures on medical record release form have been added. (Template record release form was approved/posted in Toolbox.)

When screening ICH patients for the study, please remember:

- ICH patients with atrial fibrillation are often elderly and frail. But this is precisely the population of interest for ASPIRE!
- If you find a patient who qualifies for the study, we recommend you consent the patient or LAR prior to hospital discharge and work out the logistics for randomization in the 14-120 day post-ICH window.

## STUDY NETWORK

**95 sites** have been released to enroll and **36 sites** are pending activation.

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

**Our next Webinar** is February 24, 2021 3:00p-4:00p ET.

SATURN has 94 sites open for enrollment and has randomized 56 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. An amended Provider Follow Up Letter has been cIRB approved, distributed to sites and added to the project toolbox; this updated letter includes a place to note the randomization assignment.

SATURN held the monthly PI/Coordinator webinar 1/28/2021

Please find the recording here: https://www.nihstrokenet.org/saturn-trial/webinars

The next monthly SATURN PI/Coordinator webinar will be held 2/25/2021 at 12:30pm EST

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

**SAVE THE DATE: SATURN INVESTIGATOR MEETING (VIRTUAL) will be held April 8th 12:30p-3:30p EST**
Invitations went out to site PIs and Primary Study Coordinators; we welcome anyone from your site study team who would like to join, you may forward the Zoom invitation.

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**. **Every site MUST complete a form.**
The site-specific eICF templates are beginning to be distributed.

SATURN has received approval on a recruitment video.

The video may be viewed here: https://www.nihstrokenet.org/saturn-trial/home

Sites were sent 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
- Sarah Marchina Prime Project Manager (BIDMC) smarchin@bidmc.harvard.edu

**IMPORTANT STAURN CONTACTS:**

- **Questions regarding eligibility or protocol implementation**
  - Email: 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.

Sleep SMART

Thank you for your continued dedication to Sleep SMART. We truly appreciate all your hard work.
As of February 10, 2021, 1243 subjects have been enrolled and 424 subjects have been randomized.


Congratulations to the following two sites for randomizing their very first subjects in February 2021:

- MetroHealth Medical Center, Cleveland, OH; Dennis Auckley, MD and Hailey Chesnick
- UH Cleveland Medical Center, Cleveland OH; Sophia Sundararajan, MD and Mary Andrews

**IMPORTANT INFORMATION TO REMEMBER:**

The 3-month mRS is a primary outcome for Sleep SMART. Please complete all 3-month assessments within window [90 days from randomization (-14 days, +30 days)]. These can be done by phone, if needed and should be completed by a blinded assessor if possible.

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.

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 aCPAP 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.

**SAVE THE DATES:**

PI/Coordinator webinar March 8, 2021 1-2 EST

Virtual Investigator/Coordinator Meeting June 7, 2021 1-4 EST. Please save the date!

Our next PI and Coordinator call will be on **Monday, 2/22/2021 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).

13 sites have reopened to enrollment! Congratulations to MUSC, Burke, Baystate, Medstar, UAB, USC, Kentucky, Houston, Cincinnati, Moss, Emory, UPMC, and Duke for being re-open to enrollment amidst the COVID-19 restrictions. Cleveland VA has received IRB approval and are finalizing study start-up activities. We are hopeful that our last pending site will open in the next month. There are 26 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.

-TRANSPORT2 Team

FASTEST is 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, February 17th 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. We hope you enjoy and find useful the FASTEST EFIC video, now available! Please reach out to the FASTEST team for the video. The FASTEST EFIC video in Spanish is coming soon!

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(s) and need access.

Congratulations to our **23** sites that have submitted EFIC plans to Advarra and are taking next steps to implement them!

Upcoming Advarra EFIC Panel meeting dates -- February 22nd, March 8th and 22nd

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

MOST
Multi-Arm Optimization of Stroke Thrombolysis

**MOST Enrollment Update:**
Total randomizations: **127**
Randomizations between 27Jan2021 and 10Feb2021: **1**
Sites released to enroll with at least one subject consented: **36**
There are now **71** sites that have been released to enroll, **52** of which are actively recruiting!

Congratulations to the following sites for randomizing a subject this period!

- M Health Fairview Hospital - Dr. Oladi Bentho and Megan Tessmer **(1 new subject, 12 total subjects!)**

Thank you to those 52 sites who have completed the study drug administration retraining and upload the **Study Drug Administration Retraining Attestation** form in WebDCU™ in order to reactivate enrollment at their site.

Out of the 71 sites initially released to enroll, **35 of those sites are pending their first enrollment in the MOST trial**. Please work towards achieving your first subject enrollment. Thank you for all your work on the MOST study!

**Regulatory Document Reminders:**

- Study Drug Administration Retraining Attestation à signed by PI and uploaded to "Attestation of Study Drug Administration Retraining" placeholder under Site Documents
- MOST Protocol v5.1 PI Training Attestation à signed by PI and uploaded to PI's "Protocol Training" placeholder under People Documents
- Local Tenecteplase Protocol à You may waive this document and the reason waived should state that the site will not be treating subjects with tenecteplase. If you intend to use tenecteplase, documentation uploaded to the "Local Tenecteplase Protocol" placeholder under Site Documents should include the following information:
    - The date that the site switched to tenecteplase
    - The tenecteplase dosage used, including max dose
    - If alteplase will still be used for acute stroke treatment and the indication for when
    - The institution's acute stroke treatment decision algorithm or protocol.

Please refer to the MOST Regulatory Document Parameter Guidelines in the Toolbox.

Please mark your calendar for the February **MOST Trial Investigator Call** scheduled for Monday, 22Feb2021 at 2:00 PM ET. As a reminder, the MOST Trial Investigator Call invitations are sent to the principal investigator and all study coordinators at each site. If you would like your pharmacist(s) and/or other study team members to join the call, please be sure to forward the call invitation to them.

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

## Site Startup and Enrollment Updates:

sites: 56; enrollments: 178/350

CREST-2 has just over 700 patients left to recruit. We need 172 of them for CREST-H. Thanks to **Ochsner Health** and **Louis Stokes Cleveland VA** for enrollments last week! 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, Ron Lazar rlazar@uabmc.edu, Jaya Vijayan vijayan.jaya@mayo.edu, or Kevin Slane KJS4@columbia.edu with any questions.

## From the CREST-2 Clinical Coordinating Center:

| 1779 Overall | 937 CEA | 842 CAS |
|---|---|---|

**Great job, StrokeNet sites!** Out of the 5 randomizations we've had so far in the month of February, 4 of them were from StrokeNet sites! Congratulations to the CREST-2 teams at the following StrokeNet sites: **University of Kentucky, San Francisco VA, UPMC Hamot, and Seton Heart Medical Center**. The 5th site to randomize this month was from our first greenlighted site in Israel …. **Soroka University Medical Center!** Located in Beersheba, Soroka University Medical Center randomized their first CREST-2 patient exactly one month to the date of being approved to enroll!

Dr. Anat Horev

Congratulations to Dr. Anat Horev and team for randomizing your first CREST-2 patient!

## Congratulations to the Chicago Site for randomizing their first participant!

We now have **44** study participants enrolled. Everyone's hard work is greatly appreciated!

- Ann Arbor, MI – **5** participants randomized
- Boston, MA – **15** participants randomized
- Chicago, IL - **1** participant 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 – **2** participants randomized
- Roanoke, VA – **4** participants randomized

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

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

The Global Alliance of Independent Networks focused on Stroke trials (GAINS) was created to facilitate, strengthen and nurture stroke trial networks and stroke trials worldwide. It is a "networks of networks" comprised of network leaders from around the globe to facilitate communication, best practices, funding opportunities, and educational efforts. The ultimate purpose of GAINS is to accelerate the pace and success of stroke clinical trials by enhancing communication between leaders and participants of funded as well as developing national stroke trial networks. If you are interested in seeing GAINS in action, feel free to join the next **Virtual GAINS Clinical Trials Forum II**, on **Monday, 17-May 2021 from 8-10 am ET.** More information can be found on our website https://www.globalstroketrials.org/.

# NIH News

**Friendlier Format for Key Dates in Funding Opportunities**

The NIH has begun posting research opportunities with a new, friendlier table format for the Key Dates section. The table format allows readers to easily identify the available due dates in each review and award cycle. New applications received for the February 16, 2021 due date, Resubmission applications for the March 16, 2021 due date, and AIDS applications for the May 7, 2021 due date will all go to Scientific Merit Review in July 2021 and Advisory Council Review in August 2021. The Earliest Start Date for those applications is in December 2021.

A few important points to keep in mind when reading the table:

- Applications are still due by 5:00 PM local time of applicant organization as indicated beneath the table.
- Note the "as allowed" in the Renewal / Resubmission / Revision column header. Section II of each funding opportunity announcement (FOA) specifies the Application Types Allowed for that specific opportunity.
- In our example, Section II. Award Information of PA-21-110 indicates only New and Resubmission applications are allowed. So, even though the column header includes "Renewal" and "Revision", the dates provided in the "Renewal / Resubmission / Revision (as allowed)" column in the PA-21-110 key dates table only apply to Resubmission applications.
- Due dates that correspond to Standard Due Dates are marked with an asterisk.
- Some NIH policies (e.g., Continuous Submission) only apply to applications submitted on "Standard Due Dates". Going forward, either Due Dates that state "Standard dates apply" or Due Dates in the table marked with an asterisk will both meet that criteria.
- If a Request for Application (RFA) does NOT allow late applications, the statement "No late applications will be accepted for this Funding Opportunity Announcement" will appear beneath the table (found in due date field for FOAs that do not use the table format.)

Currently, the new table format can be found in new, single-project research opportunities. The NIH hopes to roll out the table format for key dates in other opportunities (e.g., training, fellowship, career development, multi-project) soon. With many FOAs remaining on the streets for several years, we can expect a mix of key dates formats in our FOAs for the foreseeable future.

The table is available below, which you can also review along with the relevant guidance, via https://nexus.od.nih.gov/all/2021/02/02/friendlier-format-for-key-dates-in-funding-opportunities/.

**NIH standard due dates are marked with an *.**

| Application Due Dates | | | Review and Award Cycles | | |
|---|---|---|---|---|---|
| **New** | **Renewal / Resubmission / Revision (as allowed)** | **AIDS** | **Scientific Merit Review** | **Advisory Council Review** | **Earliest Start Date** |
| February 16, 2021 * | March 16, 2021 * | May 07, 2021 * | July 2021 | October 2021 | December 2021 |
| June 16, 2021 * | July 16, 2021 * | September 07, 2021 * | November 2021 | January 2022 | April 2022 |
| October 16, 2021 * | November 16, 2021 * | January 07, 2022 * | March 2022 | May 2022 | July 2022 |
| February 16, 2022 * | March 16, 2022 * | May 07, 2022 * | July 2022 | October 2022 | December 2022 |
| June 16, 2022 * | July 16, 2022 * | September 07, 2022 * | November 2022 | January 2023 | April 2023 |
| October 16, 2022 * | November 16, 2022 * | January 07, 2023 * | March 2023 | May 2023 | July 2023 |
| February 16, 2023 * | March 16, 2023 * | May 07, 2023 * | July 2023 | October 2023 | December 2023 |
| June 16, 2023 * | July 16, 2023 * | September 07, 2023 * | November 2023 | January 2024 | April 2024 |
| October 16, 2023 * | November 16, 2023 * | January 07, 2024 * | March 2024 | May 2024 | July 2024 |

**FY 2021 Fiscal Policies for Grant Awards: Funding Levels, Salary Limits, and Stipend Levels**

NIH issued guidance for NIH Fiscal Operations for FY 2021 including the following policies:

- **FY 2021 Funding Levels:** Non-competing continuation awards made in FY 2021 will generally be issued at the commitment level indicated on the Notice of Award.
- **Ruth L. Kirschstein National Research Service Awards (NRSA):** NIH will increase NRSA stipends by approximately two percent for predocs and two percent for postdocs.
- **Next Generation Researchers Initiative Policy:** NIH will prioritize meritorious R01-equivalent applications from Early Stage Investor (ESI) PD/PIs.
- **Salary Limits:** Salary limit is set at $199,300.

For additional information, please visit https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-058.html.

# NIH StrokeNet Coordinator Webinar

*Coordinator Webinars are a requirement for the NIH StrokeNet RCC Coordinators/Managers however, all are welcome to attend*
**Wednesday, February 24, 2021**
**1:30 pm ET**

| | |
|---|---|
| Topic: | Site Clinical Profile Annual Survey in Relation to Feasibility Surveys |
| Presenters: | Logan Sirline, MPH, MUSC, StrokeNet NDMC<br>Joe Broderick, MD, University of Cincinnati, StrokeNet NCC |
| Moderator: | David Haney, RT, Case Western Reserve University |

# 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-March, 2021, at 11:00 am ET.** Join us for "StrokeNet Goes to the Movies"!

***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, February 25, 2021**
**4:00 pm ET**

Topic: Robotics & Physiology of Recovery of Function after Stroke

Presenter: George Wittenberg, MD, PhD, University of Pittsburgh

Moderator: Farhaan Vahidy, 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

**Cooper Neurological Institute**
Cooper Health System, Camden, NJ

**Research Manager**

Manage the operations of all research in Cooper Neurological Institute, including conduct of student, resident and faculty research projects, both externally sponsored and investigator-initiated studies. Responsible for budget oversight, monthly research meetings, research team development and supervision, and regulatory compliance and quality. Meet with key stakeholders in various Cooper Health System departments. Maintain compliance with Good Clinical Practices and Cooper IRB SOPs. Conform to Cooper's management practices and policies.

Coordinate and manage assigned clinical research trials, including IRB submission, oversight of budget and contract negotiations, interface with sponsors and CRO's, conform to regulatory requirements, protocol implementation, staff education and supervision, and data/sample collection and query response. Participate in clinical trial monitoring/auditing internally and externally as required and oversee research trial representatives (CRAs) when monitoring ongoing clinical trial data, internal company audits and external reviews. Utilize clinical knowledge, technical expertise, interpersonal and organizational skills to manage multiple priorities. Exercise initiative, creativity and motivation. Delegate and use resources effectively. Handle complex challenges and other duties that are assigned.

Minimum requirements:

Education: Bachelor's degree with significant research/clinical training required, Masters in scientific or clinical field preferred.

Experience: 8 years relevant research experience required. Additional clinical and management experience preferred.

**Clinical Research Coordinator**

Assists the Principal Investigator and other members of the research team with research study start-up and amendment preparations, to include IRB submissions, regulatory document collection, study training, and communication with sponsors and CRA's.

Conducts clinical research trials, including: assist with the identification and enrollment of study participants, both during normal office hours and when on-call (overnight and weekends); conduct follow-up visits, both in-person and via phone; collect, process, and ship laboratory samples; collect and enter study data and respond to queries; completes and maintains all study documents as required; coordinate with pharmacy staff for drug studies; interface with and train clinical staff; assist with monitoring visits; abide by GCP; perform other duties as assigned.

Work as a team player with all involved in the studies; reports to Research Manager.

Minimum requirements:

Education: Training in a clinical field with research training required, Bachelor's degree in scientific or clinical field (e.g. RN) preferred.

Experience: 1 year relevant research experience required; 2 to 3 years preferred. Additional clinical experience preferred.

Qualified candidates should contact:

**Bethann Mercanti, Director of Clinical Operations, Cooper Neurological Institute**

Mercanti-Bethann@cooperhealth.edu

**Data Management Director – Department of Public Health Sciences**

**Medical University of South Carolina - NIH StrokeNet National Data Management Center (NDMC)**

The NDMC is searching for a Data Management Director. This person will serve as the Data Management Director for assigned StrokeNet studies, assist the NDMC StrokeNet Program Manager with network responsibilities, and assist with Site Monitoring Manager responsibilities for assigned StrokeNet studies.

**Job Duties:**

- Serve as the Data Management Director for assigned DCU studies. Direct, implement, oversee, and manage all project specific data management activities for assigned projects. Provide comprehensive guidance and direction to collaborators pertaining to data management issues.

- Assess data management procedures with a focus on risk in accordance with the FDA policies and guidance on centralized monitoring and electronic health systems, and implement changes to ensure high quality data.
- Direct and oversee the activities of external site monitors. Coordinate all necessary contractual and financial paperwork for monitoring activities, ensuring that all required monitoring can be completed within the allowed budget. Work with study team and coordinate with external monitors to ensure study-specific monitoring plan is followed appropriately.
- Conduct post-installation studies and evaluations. Ensure system meets the requirements of the end users. Review software data. Design and write SQL code for data cleaning procedures.
- Perform and document on-going end-user database system validation. This includes validating the data entry screens and other system modules (such as regulatory document, drug tracking, randomization, and monitoring) to ensure accuracy and appropriateness of data fields, data types, codelists, and validation rules. Troubleshoot web pages, check grammar and spelling, and verify links during database validation.
- Coordinate the planning and development of database systems. Maintain good relations with the sponsor officials, vendors and users. Consult with sponsors on software packages and hardware. This includes providing information regarding the capabilities of the software and customizing the software to meet the needs of the sponsor. Provide comprehensive guidance and direction to users regarding clinical database systems and data management processes including user hardware and software training.
- Evaluate system for accuracy, efficiency, and intuitiveness. Survey users, including principal investigators, enrolling sites, central pharmacists, adjudicators, and safety monitors, regarding software satisfaction. Relay information to IS team for consideration and implementation.
- Coordinate and lead internal study meetings. Prioritizes the work being conducted in a constantly changing environment. Provide information regarding resource allocation and needs within the unit.

**Link for more information and to apply**: https://careers.pageuppeople.com/756/cw/en-us/job/526486/univ-data-management-director-dcu-public-health-sciences-phs

**Please contact Jessica Griffin (simonsjl@musc.edu, 843-792-1677) at the NDMC with any questions.**

**University of Illinois at Chicago (UIC) College of Medicine**
**Vascular Neurology Faculty Positions**

The University of Illinois at Chicago (Department of Neurology) and the UI Hospital and Health Sciences System are undergoing a major Neurology expansion. Positions are currently available for Vascular Neurologists. Successful candidates will join a multidisciplinary team that treats a high volume of complex stroke patients as part of UI Health's Comprehensive Stroke Certified program. The ideal candidates should have completed an ACGME-approved fellowship and be board certified (or board eligible) in vascular neurology. In addition, the candidates should have a strong academic interest. A track record of leadership and research is preferred but not required. The new faculty will have access to cutting edge treatment modalities and will have a significant impact on building the program further. Salary/rank/tenure is commensurate with experience. A competitive start-up package including protected time for academic development is available to qualified applicants. **Interested parties should send curriculum vitae and statement of interest to FD Testai, MD, PhD c/o David Katz at davkatz@uic.edu . Please call 312-355-1748 for additional information.**

***The University of Illinois at Chicago is an Equal Opportunity, Affirmative Action employer. Minorities, women, veterans and individuals with disabilities are encouraged to apply.***

**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 sub-specialty 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.

*For more information about StrokeNet employment opportunities, please visit*
*http://nihstrokenet.org/education/employment-opportunities*

**Please share your satellites and study teams!**
*Contact: Jamey Frasure, PhD, RN, Administrative Director · frasurjs@ucmail.uc.edu https://www.nihstrokenet.org*