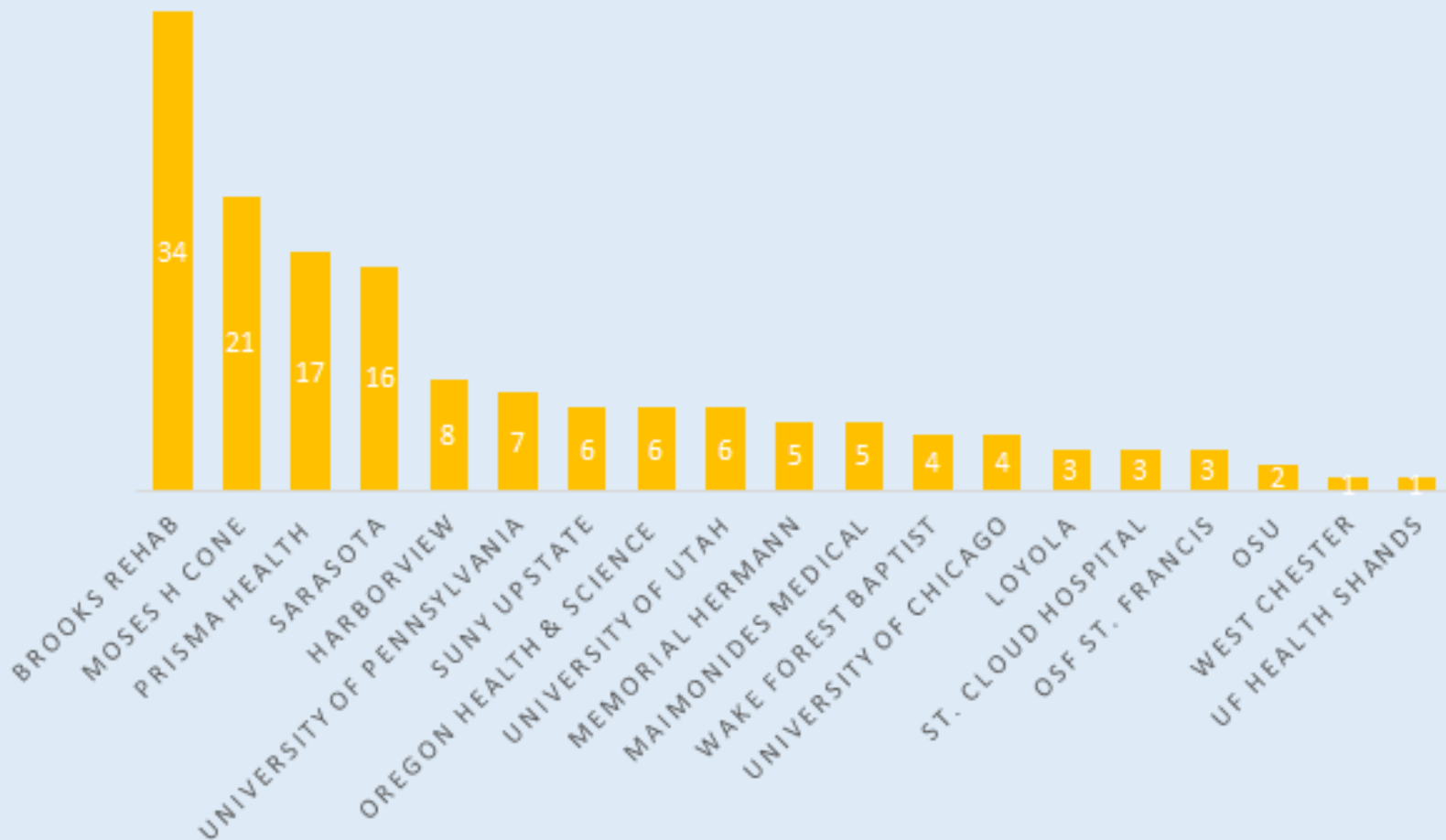


SLEEP SMART NEWSLETTER

Sleep for Stroke Management and Recovery Trial

All the sites who randomized in July & August with their total randomization numbers since study initiation! Thanks to all sites for your hard work!



Current trial numbers

Total consented: 864

Total randomized: 285

Sites currently released to enroll: 54

Reminders

- Please check to see if you received your disposable T3 wristbands, if you haven't please fill out a supply request in KOEO. You can order 20 or 40 wristbands. Be sure to provide the best address for shipment!
- Keep your DOA up-to-date! Study team members have been changing more frequently due to Covid and we have been having a difficult time contacting individuals.
- If you chose (H) Use KOEO system on your DOA as a responsibility, you will need to reach out to Helgi to create an account. KOEO accounts are not created automatically.
- Our next webinar will go over remote consent implementation. Have webinar ideas or topics you want to see covered? Let us know!

New Sleep SMART team member



Lauren Stricker is the newest NCC Regulatory Specialist. You likely have already received emails from her regarding your regulatory documents. She will be working with Emily Stinson and Jennifer Golan. Welcome Lauren!

Next Webinar

August 31, 2020
from 1-2pm ET

Please visit our Sleep SMART website to find helpful study-related materials: <https://www.nihstrokenet.org/sleep-smart-trial/home>

Protocol V5 & V6 documents: When did I get these and where do these go!?!?

- **Version 5** protocol- this was emailed to each site individually in June/July by Jennifer Golan, Emily Stinson, or Lauren Stricker
- **Version 6** protocol- this was sent as a mass email by Joelle on 8/6/2020

What do you need to do with these emails?

Follow the instructions that were sent in the email. You will need to upload the attachments in the email under Site documents in WebDCU. You can find this by clicking the tab in WebDCU labeled **Regulatory Documents -> Site Reg Doc Submission**

How do I get re-released?

If you are confused as to what the requirements are, contact Kayla or Joelle. We will let you know over email what is needed. Below you will find what needs to be completed prior to re-release to enroll.

1. If needed, please let your local IRB know that the study-wide hold on in-person activities has been lifted by the CIRB.
2. Once your amended consent is CIRB approved, please submit the latest Sleep SMART amendment (version 5) for acknowledgment by your local IRB, if needed.
3. Check “Alerts” in WebDCU to find unresolved queries. Respond to all DCRs and submit missing CRFs as best you can.
4. Update your COVID Impact Assessment survey in WebDCU.
5. When your site meets the criteria outlined in our memo dated 5/15/20, the PI will need to provide attestation and this can be done by having them log into WebDCU and indicating “confirmed” in the general comments field of the COVID Impact Assessment survey or emailing the project managers that the site meets all criteria.
6. Consents must be performed by a study team member who has completed the informed consent process training, so assure that at least 1 person listed on the DOA designated to perform consenting has completed this training and uploaded the attestation.
7. Assure that all people documents previously uploaded in WebDCU are still current and have not expired.

Continuing review

The annual continuing review (CR) forms were distributed to sites by email on August 13th. Please read the instructions in the email carefully before completing the forms. The CR forms should be returned to sicklejb@ucmail.uc.edu by **September 4th**. Thank you to the sites that have already returned their forms.

Sleep SMART Coordinator of the month

Congratulations to Phil Fleming!
Prisma Health-Midlands, Columbia SC



Phil was chosen as the coordinator of the month for going above and beyond in Sleep SMART. Not only is he a top enrolling coordinator, but he is always working with FusionHealth and the NDMC to ensure high subject compliance and quick data entry. His PI Souvik Sen said "he is one the best coordinators I have worked with, goes out of his way to screen, enroll and follow study subjects. He is currently mentoring junior coordinators on our team." Thank you for all that you do Phil!

If you are a site that has a coordinator that you think should be featured, let us know!

Monitoring Visits

In place of traditional in person monitoring visits, we will be doing virtual monitoring and virtual check ins. We take a risk based approach to monitoring, so visits will be scheduled based on central monitoring that is done at the NDMC. When your site is selected, Katie Trosclair will reach out to you.

Implementing a warm transition

Before hospital discharge, help initiate contact between intervention subjects and the Care Team: Program Care Team number in subject's cell phone if they agree, help them make a first call while they are still hospitalized, and remind them they can receive \$10 for another call completed after discharge but within the first week out of the hospital,



Are you sure your subject wants to be randomized?

What is the best way to find out? Ask! Remember even if your subject is eligible for randomization, they need to be asked if they are willing to continue. This is part of the eligibility criteria. No study team wants to find this out after randomization has occurred.

Antithrombotic confusion

On the Hospital discharge form (F123), please check your responses for Q5. If "No" please double check as most responses to this question should be "Yes." Please keep in mind that the question addresses quality of inpatient stroke care so it queries use of antithrombotics during the first 2 days AFTER hospital admission. Also, antithrombotics include both antiplatelets and anticoagulants.

Contacts

Eligibility questions: 9am to 8pm ET: sleepsmart@umich.edu

Fusionhealth (Nox T3, KOEO, aCPAP, Masks): 9am to 5pm ET: 1-888-505-0280 ext 4006

WebDCU emergency randomization hotline: 1-866-450-2016

Project Managers: Kayla Novitski kcgossel@med.umich.edu and Joelle Sickler sicklejb@ucmail.uc.edu

WebDCU help: Faria Khattak khattak@musc.edu and Jocelyn Anderson anderjoc@musc.edu

Regulatory help: Lauren Stricker strickla@ucmail.uc.edu, Jennifer Golan golanjl@ucmail.uc.edu, and Emily Stinson stinsoey@ucmail.uc.edu

Sites	FH/DUA	FH/Op-assignment	CTA	OPRB Approval	Sites	FH/DUA	FH/Op-assignment	CTA	OPRB Approval	Sites	FH/DUA	FH/Op-assignment	CTA	OPRB Approval
R01 Case Western Reserve University					R11 University of California Los Angeles					R19 University of Pennsylvania				
Mercy Health - St. Vincent Medical Center					Cedars Sinai Medical Center					Temple University Hospital				
Cleveland Clinic, Cleveland					Kaiser Permanente Los Angeles Medical Center					Hospital of the University of Pennsylvania				
UH Cleveland Medical Center					Ronald Reagan UCLA Medical Center					Robert Wood Johnson University				
MetroHealth Medical Center					UC Irvine					R20 University of Pittsburgh				
Ruby Memorial Hospital					UCLA Kaiser Fontana					UPMC Presbyterian Hospital				
R02 Columbia University					University of New Mexico					St. Luke's University Hospital - Bethlehem Campus				
NYP Columbia University Medical Center					Doctors Medical Center of Modesto					R21 The University of Texas Health Science Center at Houston				
Buffalo General Medical Center					Olive View- UCLA Medical Center					Memorial Hermann-Texas Med Center				
SUNY Upstate Medical University					Orange County Global Medical Center					University of Texas Southwestern				
Strong Memorial Hospital					R12 University of California San Diego					University Health Shreveport				
R03 Emory University					UCSD Health La Jolla					R22 University of Utah				
Grady Memorial Hospital					UCSD Medical Center - Hillcrest					Intermountain Medical				
R04 Massachusetts General Hospital					Dignity Health- St. Joseph Hospital					St. Mary's Grand Junction CO				
Beth Israel Deaconess Medical Center					Chandler Regional Medical Center					Banner University Medical-Phoenix				
Massachusetts General Hospital					Ochsner Medical Center					Banner University Medical-Tucson				
Tufts Medical Center					R13 University of California San Francisco					University of Utah Health				
Eastern Maine Medical Center					John Muir Concord Campus					R23 University of Washington				
Baystate Health					John Muir Walnut Creek Campus					Evergreen Health Medical Center				
Brigham and Women's Hospital					UCSF Helen Diller Medical Center					Virginia Mason Medical Center				
Boston Medical Center					Community Regional Medical Center of Fresno					Harborview Medical Center				
UVMC Main Campus (Vermont)					R14 University of Cincinnati					R24 University of Wisconsin				
R05 Medical University of South Carolina					University of Louisville Hospital					University of Wisconsin University hospital				
Greenville Hospital System					University of Cincinnati Medical Center					Gundersen Lutheran Medical				
Palmetto Health Richland					St. Elizabeth Edgewood					Marshfield Clinic Health System				
Gulford Neurologic Associates (Moses Cone)					Christ Hospital					R26 University of Alabama at Birmingham				
MUSC University Hospital					West Chester Hospital					UAB Hospital				
R06 MedStar Health Research Institute					R15 University of Iowa					University of Mississippi Medical Center				
University of Maryland					University of Iowa Hospitals & Clinics					R27 Wake Forest University				
George Washington University					University of Nebraska Medical Center					Wake Forest Baptist Medical Center				
UVA Medical Center					Sanford Medical Center					Novant Health Forsyth Medical Center				
R07 Icahn School of Medicine at Mount Sinai					R16 University of Miami					Mission Hospital				
NYU Langone- Tish Hospital Medical Center					Jackson Memorial Hospital					R28 The Washington University				
Maimonides Medical Center					UF Health Shands Hospital					Barnes-Jewish Hospital				
Montefiore Medical Center					Sarasota Memorial Hospital					OSF Saint Francis Medical Center				
R08 Northwestern University					Brooks Rehabilitation Hospital					St. Louis University Hospital				
Loyola University Medical Center					Tampa General Hospital					Cox Medical				
University of Illinois Hospital and Health sciences					Mayo Clinic Jacksonville					St. Luke's Hospital of Kansas City				
Medical College of Wisconsin					Baptist Hospital of Miami					University of Tennessee (Methodist Hospital)				
Rush University Medical Center					University of Miami Hospital					R29 Yale University				
University of Chicago Medical Center					R17 University of Michigan					Yale-New Haven Hospital				
R09 The Ohio State University					Detroit Receiving Hospital					Hartford Hospital				
OSU Wexner Medical Center					Henry Ford Hospital					Staten Island University Hospital				
R10 Stanford University					Mercy Health Saint Mary's					North Shore University Hospital				
Mercy San Juan Medical Center					Mary Free Bed Rehabilitation Hospital					No RCC				
Oregon Health and Science University Hospital					University of Kentucky Hospital					UC Davis				
					McLaren Flint					Bridgeport CT				
					R18 University of Minnesota					Geisinger Clinic PA				
					United Hospital					Advanced Neurology Specialists MT				
					Valley Baptist Medical Center - Harlingen					Baylor Scott & White Institute of Rehab TX				
					University of Minnesota Medical Center					Norton Healthcare				
					St. Cloud Hospital/Centracare					Carolina's Rehab Northeast				
					Southern Illinois University Memorial					Capital Health-NJ				
					Mayo Clinic Hospital Rochester - St Mary's Campus					Toledo Hospital				
										Penn State Milton S. Hershey Medical Center				
										Prairie Education and Research Cooperative				
										TMC HealthCare				