



JULY 2022

SLEEP SMART NEWSLETTER

Sleep for Stroke Management and Recovery Trial

Thank you to the following sites for a great month of June randomizations!

University of Cincinnati, Cincinnati OH- Sadie Caldwell & Natalie Kreitzer MD

OSU Wexner, Columbus OH- Myah Mahayri, Luke Herren, & Sushil Lakhani MD

Methodist University Hospital, Memphis TN- Quentin Thacker & Balaji Krishnaiah MD

Wake Forest, Winston-Salem NC- Madalyn Dillard & Cheryl Bushnell MD

Moses H. Cone, Greensboro NC- Pamela Sater & Pramod Sethi MD

Hartford Hospital, New Haven CT- Radu Radulescu & Francoise Roux MD

Brooks Rehab Hospital, Jacksonville FL- Taisiya Matev & Prag Shah MD

OSF St. Francis, Peoria IL- Jenny Bandy, Ashwath Ravisankar, & Sasikanth Gorantla MD

Buffalo General, Buffalo NY- Annemarie Crumlish & Amit Kandel MD

Prisma Health Richland, Columbia SC- Phil Fleming & Souvik Sen

Sarasota Memorial Hospital, Sarasota FL- Matt Moehr & Mauricio Concha MD

Valley Baptist, Harlingen TX- Olive Sanchez, Pualani Smith, & Ameer Hassan MD

NYP Columbia University, New York NY- Angela Velazquez & Joshua Wiley MD

Barnes Jewish, St. Louis MO- Jennifer Babka & Eric Landsness MD

SUNY Upstate, Syracuse NY- Lena Deb & Julius Latorre MD

Harborview Medical Center, Seattle WA- Allison Kunze & Sandeep Khot MD

St. Joseph Hospital, Phoenix AZ- Patricia Teran, Carmen Ramirez, & Supreet Kaur MD

Mayo Clinic, Phoenix AZ- Stephanie Ruiz Morales & Oana Dumitrascu MD

Hospital at the University of Pennsylvania, Philadelphia PA- Nichole Gallatti & Steven Messe MD

Providence St. Vincent Medical Center, Portland OR- Bo Banks & Biggya Sapkota MD

Chandler Regional, Chandler AZ- Allegra Sahelian & Dan Capampangan MD

Intermountain, Murray UT- Lindsey Bevan & Megan Donohue MD

St. Mary's Medical, Grand Junction CO- Lisa Bertrand & Logan McDanel MD

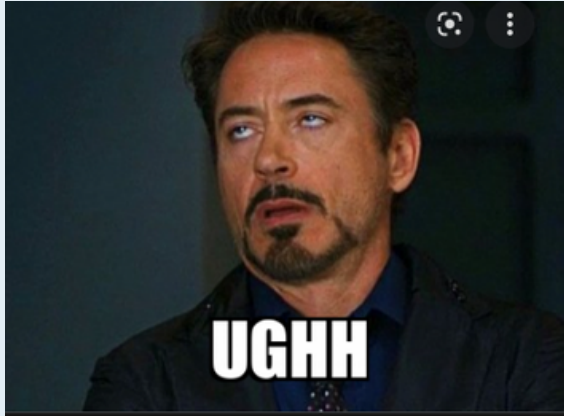
North Shore University, Manhasset NY- Courtney Kowalsky & Rohan Arora MD

**Coordinator of the Month
Congratulations to Radu Radulescu from Yale and Hartford Hospital
in New Haven, CT!**



Radu was chosen as coordinator of the month for all his work enrolling and randomizing after hours and on weekends. Dr. Roux from Hartford said "Radu is extremely dedicated and doesn't hesitate to drive long distance to enroll patients late in the evening and even on weekends. He is a very hard worker and a lovely person. All the patients love him and he is a great team player. We are so lucky to have him!". Dr. Yaggi at Yale said "He is excellent with patients and has a heart of gold. He is warm and has a wonderful sense of humor. He is willing to put in the extra time and go the extra mile for patients. He has been doing work in the domain of sleep apnea and stroke for over 10 years. We are very lucky to have him."

Continuing Review 2022



It's that time of the year, CR time!
Detailed instructions were sent on 6/9
by Joelle. **We need everyone's
documents turned in by July 8th.**
Questions? please email Kayla or
Joelle

Reminders

- At the same time that consent is obtained, Sleep SMART subjects should sign a medical record release form. Sites should use their own medical record release template, leave the hospital blank, and use dates from the consent date until 6 months hence. This form can then be used to obtain relevant medical records if an outcome event may have occurred and resulted in hospitalization at another facility.
- To ascertain race and ethnicity, please ask the participants themselves how they identify!
- Please remember to introduce Chatbot enrollment to all Randomized participants!

T-shirt contest

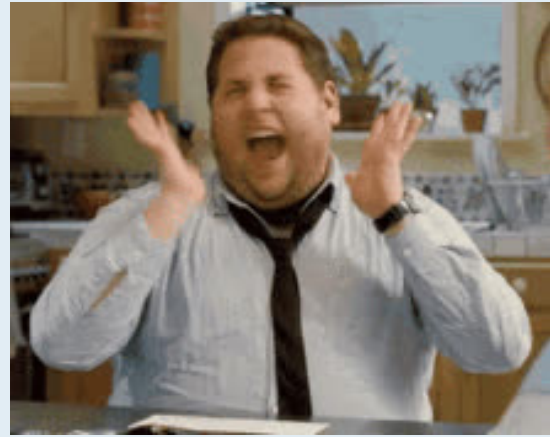
Thank you to everyone who submitted t-shirt designs! The winner will be announced on our July 25th webinar!

Next webinar date
Monday, July 25th at
1pm ET.

Nox T3 Scoring Hours
Scoring hours are 10am and 2pm
ET, 7 days per week.

Save the Date!

Our virtual Investigator Meeting will be October 3rd, 2022 from 1-4pm ET! Calendar invites will be sent soon. Snackmagic will be served again!



Consent table- Who can do what!

Consent Situation	Subject has trouble physically signing and dating the ICF	Subject is illiterate	Subject is blind	Subject does not speak English	Subject prefers to have friend/family member sign documents	Subject lacks cognitive ability to make decisions about study participation
Process	<ul style="list-style-type: none"> The subject should sign or make their mark if able If an impartial witness can't be found for this scenario or it is determined after the subject has signed that they had difficulty, the site should create a Note to File (NTF) to detail the process followed and the reason an impartial witness was unable to be used. 	Use Witnessed Consent Process	Use Witnessed Consent Process	Use short form and Use Witnessed Consent Process If site has an IRB approved full translated version of consent, that should be used instead of a short form.	Subject needs to consent for himself/herself	Use LAR and obtain verbal assent from subject if appropriate

Coordinator tips

Here are some tips that coordinators have found to be helpful:

- Use Epic/EMR to obtain daily list of all stroke patients admitted in last 24 hours
- Get a clinician to introduce Sleep SMART to subjects, even if it's very brief
- Give \$5 gift card to RTs who help Sleep SMART subjects at night
- Round with clinical team in morning

ADL exclusion and pre-stroke mRS

Determination for ADLs and the pre-stroke mRS should be made based on the best information – typically through an interaction with the patient/subject - NOT solely through the medical record.

Contact Information

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

Fusionhealth (Nox T3, KOEO, aCPAP, Masks): 8am to 7pm ET M-F: 1-404-480-5149 ext 4006 or sleepsmarttechsupport@noxhealth.com. Please use email after hours.

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

Regulatory help: Jordyn Schultz schuljd@ucmail.uc.edu

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