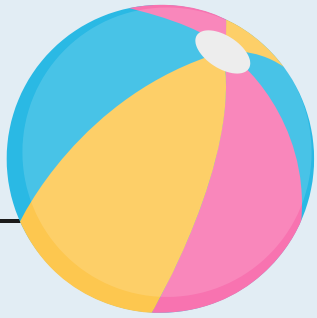
Sleep SMART

JULY 2023



# SLEEP SMART NEWSLETTER

Sleep for Stroke Management and Recovery Trial

**Thank you to the following sites for the month of July randomizations. We currently have 1233 randomized. That is 40.27% of our recruitment target. A special thank you to BSW Rehab team for randomizing subject #1,225! This number was needed to perform the interim analysis for Sleep SMART.**

Barnes Jewish Hospital, St. Louis MO- Angie Wolford & Eric Landsness MD
Carolinas Medical, Charlotte NC- Maria Helms & Rahul Karamchandani MD
OSU Wexner Medical Center, Columbus OH- Myah Mahayri & Sushil Lakhani MD
UH Cleveland, Cleveland OH- Valeria Wagner, Mary Andrews, & Sophia Sundararajan MD
WVU Healthcare Ruby Memorial, Morgantown WV- Jay Sherman & Mouhannad Azzouz MD
BSW Institute for Rehabilitation, Dallas TX- Sara Baltz & Chad Swank PhD
Jackson Memorial Hospital, Miami FL- Erick Lopez, Andrea Escobar & Jose Romano MD
Henry Ford Hospital, Detroit MI- Teresa Wiegand & Angelos Katramados MD
Hartford Hospital, Hartford CT- Radu Radulescu & Francoise Roux MD
Ronald Reagan UCLA, Los Angeles CA- Daisy Mercado & Alon Avidan MD
UPMC Presbyterian Hospital, Pittsburgh PA- Jason Weimer & Sarah Wondisford MD
UCSF Medical Center, San Francisco CA- Eliot Lee & Wade Smith MD
Rush University, Chicago IL- Henna Mccoy & Laurel Cherian MD
North Shore, Manhasset NY- Kirendra Pasram & Rohan Arora MD
SUNY Upstate, Syracuse NY- Sigiriya Smolen, Lena Deb, & Gene Latorre MD
St. Cloud Hospital, St. Cloud MN- Rachael Albrecht & Muhammad Suri MD
Chandler Regional, Chandler AZ- Allegra Sahelian & Dan Capampangan MD
Sarasota Memorial Hospital, Sarasota FL- Flora Arevalo & Mauricio Concha MD
University of Utah, Salt Lake City UT- Julia Darling & Jana Wold MD
University of Chicago, Chicago IL- Samantha Jankowski & Kenneth Lee MD

# Coordinator of the Month
# Eliot Lee from UCSF

Welcome to Sleep SMART Eliot! The entire Sleep SMART team has been nothing but impressed with UCSF's newest coordinator Eliot. RCC program manager Dominica Randazzo says "Eliot is UCSF's newest Sr. Clinical Research Coordinator in the Neuro Emergency Research Group and he hit the ground running! We feel so fortunate to have such a detail oriented, proactive, and thoughtful coordinator on our team. After enrollment challenges due to staffing, he has reinvigorated our clinical and research teams to enroll in SleepSMART consenting 6 participants and randomizing 2 in the last two months. In June, he set a record for most enrollments in a month at our site! He routinely goes above and beyond for our study participants including making home visits and staying late to ensure study compliance and in-servicing clinical staff. We thank Eliot for his outstanding work and contribution to SleepSMART."

## Next Webinar

No July Webinar. Our August webinar will be 8/8 at 12pm ET.

# Highlighted Tool

**Regulatory Document Parameters**
**Document #15 in WebDCU**

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|---|---|---|---|---|---|
| Curriculum Vitae | Principal Investigator, Sub-Investigator, and people who have overall responsibility for trial, obtain informed consent, determine eligibility, administer modified Rankin Scale, administer NIH Stroke Scale, and administer ABCD$^2$ (A, B, C, I, J, K) | People | Signature date | 5 years from signature date | No |
| Medical/ Professional License | Principal Investigator, Sub-Investigator, and people who have overall responsibility for trial, obtain informed consent, determine eligibility, administer modified Rankin Scale, administer NIH Stroke Scale, and administer ABCD$^2$ (A, B, C, I, J, K) | People | Issuance date on license, if present. Otherwise use date of upload. | Expiration date on license | Yes - if person licensed med profession |
| Human Subjects Protection Training Certification | Principal Investigator, Sub-Investigator, Primary Study Coordinator, Secondary Study Coordinator, and people who have overall responsibility for trial, obtain informed consent, determine eligibility, perform randomization, use KOEO system, administer modified Rankin Scale, administer NIH Stroke Scale, administer ABCD$^2$ , administer other study specific assessments, complete CRFs/respond to queries, and report adverse events (A, B, C, D, H, I, J, K, L, M, N) | People | Certification date | Expiration date on certificate. If no expiration date is listed, the expiration date is 5 years from certification date | No |
| | Principal Investigator, Sub-Investigator, Primary Study Coordinator, Secondary Study Coordinator, and | | | | |

This table will show which document is required for specific team members on your DOA. It will also give you the expected effective and expiration date if you aren't sure how long a document is good for. For example, CV's must be uploaded for any investigator and anyone that is obtaining consent, determining eligibility, administering the MRS, NIHSS, or ABCD2. It can never be waived and must always be signed and dated. A CV is good for 5 years from the date it is signed.

All previous webinars and newsletters can be found on https://www.nihstrokenet.org/trials/sleep-smart-trial/webinars. Password is Sleepy

# CPAP Run in Night, F506

Please remember that the protocol **requires** a daytime trial prior to completion of the aCPAP run-in night:

*Prior to the run-in night, the subject should practice placing and removing the mask/interface multiple times if possible during the day to gain experience with the equipment.* ***The subjects should also try to wear CPAP for 15-20 minutes prior to the run-in night to assist with acclimation and troubleshooting.***

Please note that if Q04 PAP device usage time does not appear consistent with a daytime trial and run-in night attempt, this will be queried.

# Discovery co-enrollment

We are now allowing co-enrollment between Discovery and Sleep SMART. Guidance and procedures can be found below:

1. The patient will participate in DISCOVERY as a Tier 1 participant.
2. In the judgement of the enrolling investigator, the participant is highly motivated to participate in both studies, understands the additional burden of dual participation, and very much intends to complete outcome assessments in full for both studies. (We anticipate this level of motivation to be uncommon.)
3. A site coordinator or PI must obtain approval from the national Sleep SMART team. Please email sleepsmart@umich.edu to justify the intention to dual enroll. If approval is given, please note the dual enrollment in the general comments section of F101 in WebDCU.
4. The mRS-9Q must be completed at the 3- and 6-month visits for Sleep SMART. The DISCOVERY mRS cannot be substituted for this assessment. The NIHSS for Sleep SMART must be completed by a certified assessor who is on the DOA.
5. The NIHSS and PROMIS-10 (outcomes for both studies) must be completed for Sleep SMART within the outcome windows for the 3- and 6-month outcomes.

## Responsibilities not listed on the DOA

If you receive a query because someone was not listed on the DOA with the correct responsibility to perform an outcome assessment, you must submit an Unanticipated Adverse event and also update the DOA.

## 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 Craven anderjoc@musc.edu, Faria Khattak khattak@musc.edu, Emily Kaestner kaestner@musc.edu
**Regulatory help**: Jordyn Schultz schuljd@ucmail.uc.edu