



JANUARY 2024

SLEEP SMART NEWSLETTER

Sleep for Stroke Management and Recovery Trial

Thank you to the following sites for the month of January randomizations. We currently have randomized 1401 subjects. That is 46% of our recruitment target.

North Shore University Hospital, Manhasset, NY- Vishal Mehta, Sabah Iqbal, Kirendra Pasram & Rohan Arora, MD

Moses H. Cone Memorial Hospital, Greensboro, NC- Lakisha Hinnant, Pamela Sater & Pramod Sethi, MD
Memorial Hermann Texas Medical Center, Houston, TX- Ariana Aquino Hernandez & Anjail Sharrief MD, MPH

Orange County Global Medical Center, Santa Ana, CA- Natalia Dorantes & John Chen MD
Sarasota Memorial Hospital, Sarasota, FL- Flora Arevalo & Mauricio Concha, MD

UH Cleveland Medical Center, Cleveland, OH- Varinder Kaur, Mary Andrews & Sophia Sundararajan, MD
Cox Medical Center South, Springfield, MO- Jessica Ratcliff & Benjamin Lisle, MD
Intermountain Medical Center, Murray, UT- Dominique Colipi & Paul Johnson, MD

UVA Medical Center, Charlottesville, VA- Allison Ramsey & Nina Solenski, MD

Chandler Regional Medical Center, Chandler, AZ- Allegra Sahelian & Dan Capampangan, MD
University of Cincinnati Medical Center, Cincinnati, OH- Jennifer Powers, Ranjaka Gunawardena & Natalie Kreitzer, MD

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

SUNY Upstate Medical University, Syracuse, NY- Sigiriya Smolen & Julius-Gene Latorre, MD

University of Wisconsin University Hospital, Madison, WI- Sima Sayyahmelli, MD, Robert Dempsey, MD & Jamie Elliott, MD

UC Davis Medical Center, Sacramento, CA- Duyen Dao-Tran & Kwan Ng, MD

Brooks Rehabilitation Hospital, Jacksonville, FL- Taisiya Matev & Parag Shah, MD

Henry Ford Hospital, Detroit, MI- Teresa Wiegand & Angelos Katramados, MD

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

Prisma Health Greenville Memorial Hospital, Greenville, SC- Reilly Leonard & Paulo Zortea, MD

University of Maryland Medical Center, Baltimore, MD- Delaram Doorandish & Seemant Chaturvedi, MD

Christ Hospital, Cincinnati, OH- Ranjaka Gunawardena & Karthik Kanagarajan, MD

Carolinas Rehabilitation - NorthEast, Concord, NC- Christine Patino & Nicole Rup, MD

Ronald Reagan UCLA Medical Center, Los Angeles, CA- Sucheta Waghmare & Alon Avidan, MD

University of Alabama Hospital, Birmingham, AL- Mitzi Roberts & Kristin Sandefer, MD

Coordinator of the Month

Sigiriya Smolen

SUNY Upstate Medical University, Syracuse, NY

The prime team would like to recognize Sigiriya for her recent recruitment efforts and hard work and dedication to Sleep SMART!

PI Dr. Gene Latorre said: “Sigiriya is one of the most hardworking coordinators I have ever worked with. She is tireless with her effort in optimizing enrollment in all of the trials she is involved with. I have the great honor of working with her in a number of clinical trials in both stroke and COVID.

Because of her, we surpassed our site enrollment significantly. Despite her busy schedule, she is always smiling. Thank you Sigiriya for everything you do!”



PSC Lena Deb said: “I am fortunate to have been able to follow Sigiriya’s journey in clinical research and have witnessed many amazing milestones she has met very early on in her career. On top of a growing list of studies she coordinates, she regularly recruits for Sleep SMART, often times more than one enrollment a day. She is always willing to help and go the extra mile, enrolling after hours, weekends etc. In Sleep SMART particularly she has taken a very hands on role. On top of assisting the PI/sub-I’s with screening/enrollment she is also setting up the Nox device for enrolled subjects. She has established a great work flow for this study which has contributed to our site’s success in Sleep SMART. She routinely works with our residents, attendings, respiratory therapists and nurses to improve the conduct of the study and to troubleshoot any issues that may arise. We are very fortunate to have Sigiriya part of our Neurology Research team at Upstate! Thank you for all of your hard work and dedication!”

Congratulations Sigiriya!

Outstanding Sleep SMART Site Principal Investigator Award January, 2024

We are very pleased to announce the first winner of the Outstanding Sleep SMART Site Principal Investigator award: Dr. Rohan Arora, Assistant Professor of Neurology, Vascular Neurology Fellowship Director, Stroke Program Director (LIJ), Donald and Barbara Zucker School of Medicine at Hofstra/Northwell.



Congratulations, Dr. Arora, on this significant achievement! We are grateful for your highly engaged leadership!

2023 Awards

Sleep SMART: Top randomizing sites in 2023

Site	Number randomized
Memorial Hermann Texas Medical Center, Houston, TX	22
Buffalo General Medical Center, Buffalo, NY	14
North Shore University Hospital, Manhasset, NY	14
Moses H. Cone Memorial Hospital, Greensboro, NC	12
Methodist University Hospital, Memphis, TN	10
Sarasota Memorial Hospital, Sarasota, FL	10

Highlighted Tool

3 and 6 Month Assessment Guide #63 in WebDCU

This document:

- Reviews which assessments can be done via proxy
- Reviews which assessments can be done via phone
- Provides instructions on how to document an assessment which cannot be done



3 and 6 Month Assessments Guide

Assessments that can be done via proxy

- F151 Short SSQOL
- F241 Epworth Sleepiness Scale
- F292 Modified Rankin Scale - 9Q
- F502 Sleep Duration Questionnaire
- F507 Retrospective Modified Rankin Scale - 9Q
- 3 and 6 Month New Stroke and ACS Assessment

Assessments that can be done via telephone

- F139 HADS-D
- F151 Short SSQOL
- F167 Short MoCA
- F241 Epworth Sleepiness Scale
- F255 PROMIS Global Health
- F292 Modified Rankin Scale - 9Q
- F502 Sleep Duration Questionnaire
- F507 Retrospective Modified Rankin Scale - 9Q
- 3 and 6 Month New Stroke and ACS Assessment

If an assessment is not done or cannot be done due to the type of visit, or who is answering the questions, then you will need to still complete the form in WebDCU and indicate in the general comments a short explanation as to why this was not able to be done.

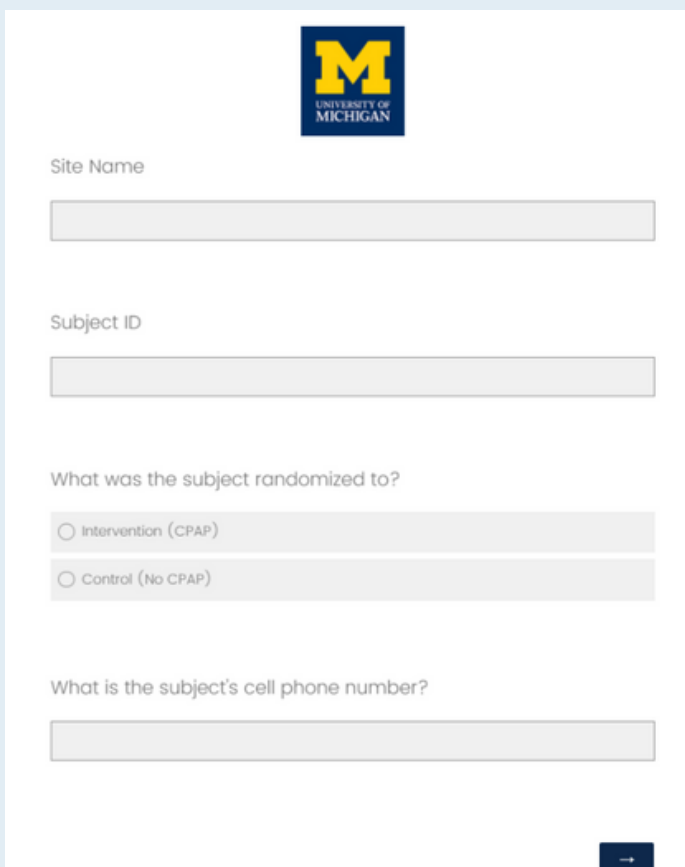
Message from Fusion Health - New Supply Catalogue

In order to make the ordering process as transparent and easy as possible, we at Fusion Health have developed a supply catalogue that includes all of the items we can ship to your site. This is designed to be a quick reference guide, to allow you to ensure you are ordering the correct part, and understand the purpose of each item. Additionally, there are links to the ordering form and even a QR code! If you have any questions, please let us know!

Data Entry and Data Clarification Request (DCR) Responses

- All CRF data must be submitted within 5 days of collection
- All responses to DCR's must be submitted within 5 days of query generation

Tess who?



The screenshot shows a web form for data entry. At the top left is the University of Michigan logo, a blue square with a yellow 'M' and the text 'UNIVERSITY OF MICHIGAN'. Below the logo are four input fields: 'Site Name' (a text box), 'Subject ID' (a text box), 'What was the subject randomized to?' (a radio button selection with two options: 'Intervention (CPAP)' and 'Control (No CPAP)'), and 'What is the subject's cell phone number?' (a text box). A blue submit button is at the bottom right.

Just a reminder that we are still using Tess for all randomized subjects. In order to make Tess more user friendly, we created a Qualtrics link, https://umich.qualtrics.com/jfe/form/SV_b73MvftChJgdfAa.

Now instead of having a participant text Tess for the first time, the subject's information can be entered using this link. All that is needed is subject ID, randomization assignment, and cell number!

Nox T3, KOEO, aCPAP, & Mask Questions



A friendly reminder to direct all questions related to Nox T3, KOEO, aCPAP, and Face Masks to FusionHealth at sleepsmarttechsupport@noxhealth.com (preferred) or 1-404-480-5149 ext. 4006 8am to 7pm ET M-F.

Response times are fastest when the group email address is used - please avoid emailing individuals directly.

Outcome visits

If a CPAP subject no longer wants to use CPAP, they can still participate in the 3 & 6 month visits if willing. If a control subject starts using CPAP, they can also participate in their follow up visits. This is not considered an automatic withdrawal of consent.

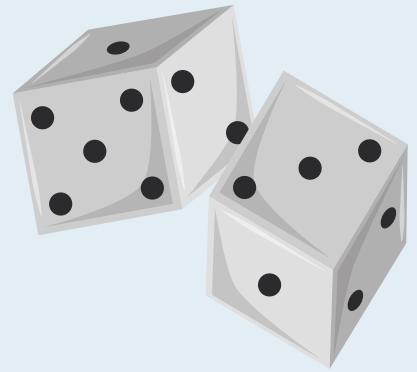
Outcome assessment completion time windows

	Primary outcome window	Last Day to complete outcome within visit window	Visit window where outcome can still be completed but considered as late	No more attempts should be made after
3 mos outcome	days 60-120	day 120	days 121-165	day 165
6 mos outcome	days 166-240	day 240	days 241-270	day 270

3-month outcomes should be pursued until the 6-mos window opens. However, only those obtained within window (day 60-120) will contribute to the primary outcome analysis. Similarly, 6-mos outcomes should be pursued until day 270, although only those collected between day 166-240 will contribute to the primary outcome. Please always do your best to obtain 3 and 6-month outcomes well within the "green" windows in the table just above.

My subject meets randomization criteria, but should they be randomized?

You must ask them! The patient has to be willing to accept a 50% chance of CPAP for 6 months and a 50% chance of no CPAP for 6 months. Participants/families with strong preferences should not be randomized.



Contact Information

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

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

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

Project Managers: Kayla Novitski kcgossel@med.umich.edu | Amanda Rasnake arasnake@med.umich.edu | Joelle Sickler sicklejb@ucmail.uc.edu

WebDCU help: Faria Khattak khattak@musc.edu | Emily Kaestner kaestner@musc.edu

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

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

Password is Sleepy