
SLEEP SMART NEWSLETTER

Sleep for Stroke Management and Recovery Trial

Current trial numbers

Total consented: 1726

Total randomized: 565

Sites currently released to enroll: 98




Please make sure you are doing these 3 things

- **Scripts-** We have scripts to provide language for coordinators to use with subjects at each step of enrollment. If you have these acknowledged by your local IRB (or do not need to), please use them. If you have not yet submitted, please do so.
- **myAir-** this app is freely available to intervention subjects to use to track their own CPAP use. The scripts will help you introduce the app to intervention subjects. Please offer to help the subject or LAR enroll in myAir (myair.resmed.com). myAir is a resMed app subject to Resmed privacy policy.

- **CPAP Dispensing Information-** If you randomize someone to CPAP, please login to KOEO and enter CPAP dispensing information as soon as possible. More information can be found on page 15 of the FusionHealth aCPAP Use and Maintenance MOP.

Dispensing aCPAP Equipment

After the demographic information has been entered in the **Edit Patient Info** task, the **Dispensing Questions** task will appear. Click on the *Dispensing Questions* task:

		Task Name	Patient MR	Patient Name	Substatus	Best Time To Call	Created On	Tenant
		Dispensing Questions	MR043326	Doe, John		16:00 - 17:00 (EST)	2019-02-19	SleepSMART

Subjects randomized to the Intervention Group in Sleep SMART will be issued new aCPAP equipment that has been provided by FusionHealth and kept in stock on site. PLEASE DO NOT SEND A SUBJECT HOME WITH THE RUN-IN NIGHT DEVICE. The site coordinators must enter both the **11-digit serial number** and the **3-digit device number** of the aCPAP into KOEO for the successful transmission of treatment usage and efficacy data throughout Sleep SMART.

May & June randomizations

- Brooks Rehab, FL
- Methodist University, TN
- University of Kentucky, KY
- Cleveland Clinic, OH
- UCSD Health La Jolla, CA
- UCSD Health Hillcrest, CA
- Greenville Hospital, SC
- Moses H. Cone, NC
- Penn State Hershey, PA
- St. Mary's Grand Junction, CO
- OSU Wexner, OH
- Beth Israel Medical Center, MA
- McLaren Flint, MI
- University of Chicago, IL
- Barnes Jewish, MO
- North Shore, NY
- George Washington, DC
- Memorial Hermann, TX
- Jackson Memorial, FL
- Palmetto Health, SC
- UVA Medical, VA
- SUNY Medical, NY
- St. Luke's Bethlehem, PA
- Sarasota Memorial, FL
- John Muir Walnut Creek, CA
- University of Cincinnati, OH
- WVU Healthcare, WV
- Providence St. Vincent, OR
- Orange County Global, CA
- University of Maryland, MD
- Chandler Regional, AZ
- Wake Forest, NC
- Henry Ford, MI
- Massachusetts General, MA
- Oregon Health, OR
- Mayo Clinic Jacksonville, FL

For technical support regarding KOEO, T3 devices, or any other technical process related to SleepSMART, please send an email to sleepsmartechnsupport@noxhealth.com. If you need to create a KOEO account please also use this email

For phone calls regarding technical support within normal business hours, please continue to use the 404-480-5149 ext. 4006.

Investigator Meeting



















































Thank you everyone for attending our virtual Investigator Meeting on June 7th! If you were not able to make it, you can find the slides and recording on our website.

Link: <https://www.nihstrokenet.org/sleep-smart-trial/webinars>

What are those placeholders that just appeared in WebDCU?!

Yes it's confusing, but nothing you need to worry about yet. Currently we have an amendment with the CIRB, but it is not approved yet. Once approved, we will be sending the following items for you to upload to those placeholders (screenshot below):

- CIRB Approval (Protocol v8 - 15Jun2021)
- CIRB Approved Full Translated Informed Consent Forms (v6)
- CIRB Approved Informed Consent Form (v6)
- Protocol Signature Page (Protocol v8 - 15Jun2021)

Site Status	Preparing - High Priority
CIRB Approval (Protocol v7 - 06Oct2020)	  
CIRB Approval (Protocol v8 - 15Jun2021)	 
CIRB Approved Administrative Amendments	  
CIRB Approved Full Translated Informed Consent Forms (v5)	  
CIRB Approved Full Translated Informed Consent Forms (v6)	 
CIRB Approved Full Translated Site Specific Stand-Alone Bill of Rights	 
CIRB Approved Full Translated Site Specific Stand-Alone HIPAA Authorization Form	 
CIRB Approved HIPAA Waiver of Authorization for Screening	  
CIRB Approved Informed Consent Form (v5)	  
CIRB Approved Informed Consent Form (v6)	 
CIRB Approved Recruitment Material	  
CIRB Approved Translated Short Forms	  
Local IRB acknowledgement	  
Protocol Signature Page (Protocol v5 - 26Mar2020)	 
Protocol Signature Page (Protocol v6 - 06Jul2020)	  
Protocol Signature Page (Protocol v7 - 06Oct2020)	  
Protocol Signature Page (Protocol v8 - 15Jun2021)	 
Site Specific Stand-alone Bill of Rights	  
Site Specific Stand-alone HIPAA Authorization Form	  

Reminders

- Use the document "Data Collection Guidelines" to reference when filling out any CRFs. This will show you how each assessment should be completed.
- Please use the consent checklist when consenting all subjects. If your site has a local checklist, please fill out both.
- If you consent a subject, please obtain baseline information on them as soon as possible.

Next Webinar

July 12th at 1pm ET. There will be a focus on WebDCU- great for new coordinators or those who need a refresher

Continuing Review

It's that time of the year again. An email has been sent from Joelle to all sites with CIRB approval.

- All sites will need to **complete and return the NIH StrokeNet CR Form to Joelle by 7/9/2021**
- A StrokeNet FCOI is required for all team members. These need to be kept on site for monitoring purposes. The form can be hand signed and dated or electronically signed using DocuSign or Adobe that stamps the date when electronically signed.
- Upload the forms for the PI, and for any other team member who has something to disclose, all as one document to the WebDCU StrokeNet CIRB Financial Interest Disclosure Form placeholder.

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

Fusionhealth (Nox T3, KOEO, aCPAP, Masks): 9am to 5pm ET: 1-404-480-5149 ext 4006 or sleepsmarttechsupport@noxhealth.com

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: Emily Stinson stinsoey@ucmail.uc.edu