

MAY/JUNE 2021

# 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 dispending
  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:



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

For technical support regarding KOEO, T3 devices, or any other technical process related to SleepSMART, please send an email to **sleepsmarttechsupport@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**

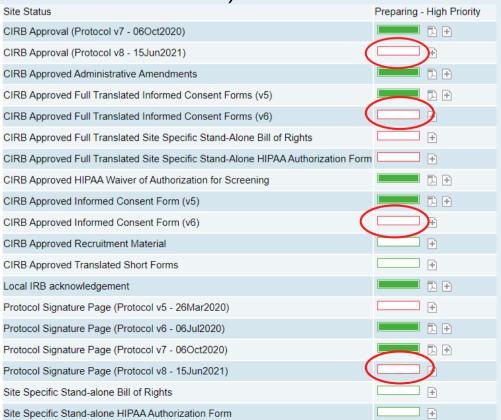
Thank you everyone for attending our virtual Investigator Meeting on June 7th! If you were not able to make it, you can find the slides and recording on our website.

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

### <u>What are those placeholders that just appeared in WebDCU?!</u>

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)



#### 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 WebDCUgreat 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 StokeNet 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