
SLEEP SMART NEWSLETTER

Sleep for Stroke Management and Recovery Trial

CORONAVIRUS (COVID-19)

ENROLLMENT ON HOLD

- **Continue to follow subjects: schedule and complete 3 and 6 month visits by phone with a blinded assessor** (see page 2)
- Fusion Health continues to remotely support intervention arm subjects

Sleep SMART Amendment

Remember to submit the amended protocol and consent to your local IRB for acknowledgement

Protocol v5.0 Highlights:

- Expanded number of enrollment sites
- Added option for home CPAP run-in night
- Expanded criteria for repeat Nox T3 study and CPAP run-in night
- Added information in the consent to encourage initial contact with FusionHealth

3- and 6-month Assessment Reminders

- The visit window for the 3-month assessment is: 90 days (-14 days, +30 days)
- If the window for the 3-month visit ends and you have not been able to reach a subject, continue to reach out until the 6-month window begins.
- The visit window for the 6-month assessment is: 180 days (-14 days, +60 days)
- Continue to try to reach the subject for the 6-month assessments for 3 months after the visit is due before considering the subject lost to follow-up.
- Please prioritize achieving outcome assessments within the window

Contacting Subjects:

If you can't get in touch with the subject by phone to schedule the outcome assessment:

- Check the back of the consent form to see if you have permission to contact them by text or email.
- Alternative contacts may also be found in the back of the consent.
- The Sleep SMART website has an "unable to reach" template letter for subjects as well as a "lost to follow-up" for those on the verge of being lost to follow-up.

(<https://www.nihstrokenet.org/sleep-smart-trial/research-team>).

What can I do remotely?

If your site is NOT released to enroll:

- Complete all contracts: CTA, Fusion Health DUA and Consignment
- CIRB submission
- Sleep SMART trainings for all team members
- Complete DOA in WebDCU
- Complete dummy T3 test

If your site IS released to enroll:

- Ensure all trainings are up to date in WebDCU for all team members
- Schedule and complete 3 and 6 month visits by phone with a blinded assessor
- Respond to WebDCU queries
- Review the website to refamiliarize yourself with the available Sleep SMART tools

Investigator Webinars

April Webinar Recap

- The April webinar covered an issue that is critical to the success of SleepSMART: intervention-arm subject adherence to CPAP.
- If you were not able to view in real time, the webinar is available at: <https://nihstrokenet.org/sleep-smart-trial/webinars>
- Initial education of subjects and strategies to maximize CPAP adherence by the research team plays a particularly important role.
- This is especially true while intervention-arm subjects are still hospitalized.

Next Webinar

May 20, 2020

1-2pm ET

Protocol v.5.0
changes

FusionHealth T3 reading times

10am and 2pm EST, 7 days per week

New Documentation Needed

- All individuals who are consenting patients will be required to attest that they have reviewed the Informed Consent Training slides.
- Attestation form will be uploaded in WebDCU

Reminders

- Video visits are not allowed, per protocol. Visits can be done over the phone for the duration of the suspension of in-person activities
- Subjects who want to discontinue CPAP intervention should still have the 3 and 6 month follow-up assessments completed
- Remember to upload all CIRB Modification Letters to WebDCU in the CIRB Approved Administrative Amendments space holder
- Be sure to update the COVID-19 Impact Assessment in WebDCU

No.	Item Description	Data Value
a	Project	Sleep SMART
b	Site	University of Cincinnati Medical Center, Cincinnati, OH (Clinical Site)
Impact on Patient Screening		
Q01	Patient screening impacted	No <input type="radio"/> Yes <input type="radio"/>
Q02	Restrictions on patient screening	
Q03	Date restrictions on screening started	
Q04	Date restrictions on screening will be ended	
Impact on Subject Enrollment		
Q05	Subject enrollment impacted	No <input type="radio"/> Yes <input type="radio"/>
Q06	Restrictions on subject enrollment	
Q07	Date restrictions on enrollment started	
Q08	Date restrictions on enrollment will be ended	
Impact on Subject Follow-up		
Q09	Subject follow-up impacted	No <input type="radio"/> Yes <input type="radio"/>
Q10	Restrictions on subject follow-up	
Q11	Date restrictions on subject follow-up started	
Q12	Date restrictions on follow-up will be ended	
c	General Comments	

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

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

FusionHealth (Nox T3, KOEO, aCPAP, Masks): 9am to 5pm ET: 1-888-505-0280 ext 4006

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

Project Managers: Kayla Novitski kcgossel@med.umich.edu (on leave until 7/2020)
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