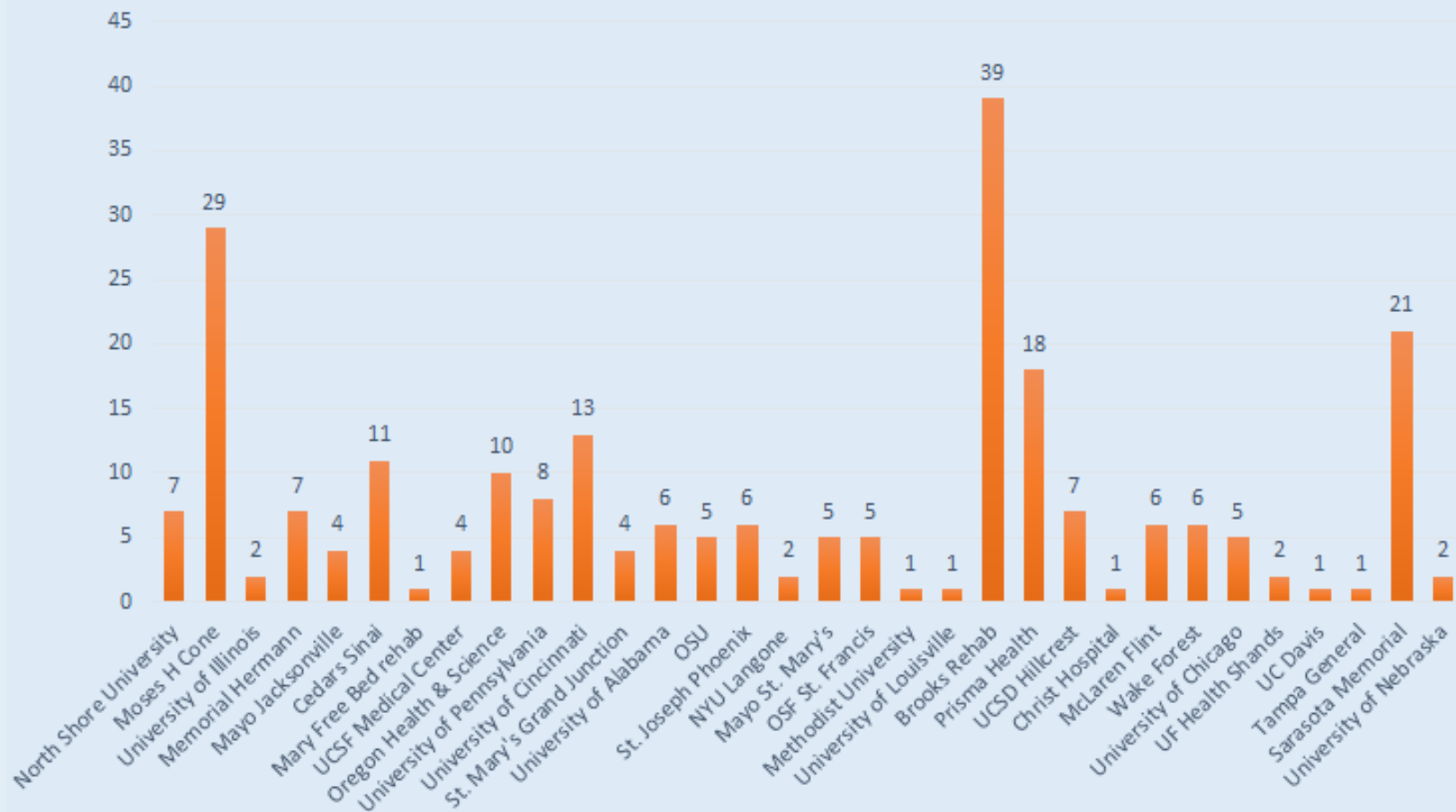


## SLEEP SMART NEWSLETTER

Sleep for Stroke Management and Recovery Trial

**All the sites who randomized in Sep & Oct with their total randomization numbers since study initiation! Thanks to all sites for your hard work!**

**Total Randomization numbers**



### Current trial numbers

Total consented: 1045

Total randomized: 357

Sites currently released to enroll: 77

# Reminders

- The recorded FusionHealth workshop can be found here:  
<https://www.nihstrokenet.org/sleep-smart-trial/webinars>
- Keep your DOA up-to-date! Study team members have been changing more frequently due to Covid and we have been having a difficult time contacting individuals.
- If you chose (H) Use KOEO system on your DOA as a responsibility, you will need to reach out to Helgi to create an account. KOEO accounts are not created automatically.

## Site Implementation Forms

The site implementation form is a document asking whether or not your site will be implementing remote consent procedures (including eConsent through REDCap).

- All Sites need to fill it out whether you will be using remote consent procedures (including eConsent through REDCap) or not
- Originally emailed by Joelle on 8/6. If you cannot find it, there is a blank copy in the WebDCU Toolbox
- Please return it to Joelle or Kayla

## Next Webinar

November 30,  
2020 from 1-2pm  
ET

Our next webinar will go over study startup. This is for newer sites or sites that need a refresher

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

# Protocol V7 documents: When did I get this and where do they go?!?

**Version 7** protocol- this was sent as a mass email by Joelle on 10/20/2020. *You should add the approval letter and protocol signature page in WebDCU*

## Protocol changes:

- Correct 1 error-removed an "X" from Baseline MoCA in Table 3. We have not been collecting a baseline short MoCA and did not intend to collect it.
- Intervention subjects should also be shown the video introducing the CPAP Care Team was added to page 17, section 6.1.1

## New Tools:

- Thank you note text: to use for intervention subjects if we think it may help motivation if CPAP adherence remains an issue. These will be sent by the Michigan team only
- Letter template for sites to use if intervention subjects are having particular difficulty with CPAP
- New video to introduce CPAP care team

## Listing RT on your DOA

- Only 1 RT or sleep tech needs to be listed on the Sleep SMART DOA. This person would be responsible for training other RTs/Sleep techs working on the trial.
- We recommend the person in this role only have 3 responsibilities on the DOA: (E) Administer Nox T3, (F) Administer aCPAP, and (G) perform mask fittings.
- If limited to these 3 responsibilities, the RT will not need to do CITI or protocol training since we consider these responsibilities within their normal scope of work.
- EXCEPTION: If RTs are doing roles outside of responsibilities E, F, and G then each of them need to be listed. GCP and HSC training would then be required.

## 3 month mRS-9Q

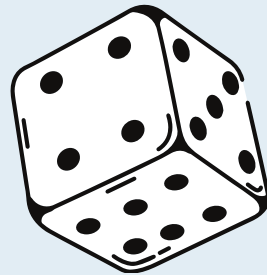
- Please get this assessment completed in window
- Each individual question must be asked (subject or proxy)- cannot be abstracted from the medical record
- Ideally done by a blinded assessor, but prioritize in window
- Can be done by phone
- Site coordinators and PIs will be receiving an email from Kayla if a 3 month window is pending and the visit has not been completed

# Implementing a warm transition

Before hospital discharge, help initiate contact between *intervention (CPAP) subjects only* and the Care Team: Program Care Team number in subject's cell phone if they agree, help them make a first call while they are still hospitalized (leaving message with Fusion if call is not answered), and remind them they can receive \$10 for another call completed within the 7 days after discharge from their enrollment hospitalization.

## Are you sure your subject has equipoise and wants to be randomized?

What is the best way to find out? Ask! Remember even if your subject is eligible for randomization, they need to be asked if they are willing to continue. This is part of the eligibility criteria. No study team wants to find this out after randomization has occurred.



In particular, at two time points – enrollment, and just after a successful CPAP run-in night – please make sure each subject has the equipoise needed to proceed. This means making sure that the subject is not counting on a) receiving CPAP, or b) not receiving CPAP. They must be comfortable with whatever the “flip of the coin” (randomization) determines. If they really want CPAP, or want not to have CPAP, they can pursue that through clinical routes and probably should not proceed further with Sleep SMART.

## Contacts

**Eligibility questions:** 9am to 8pm ET: [sleepsmart@umich.edu](mailto: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](mailto:kcgossel@med.umich.edu) and Joelle Sickler [sicklejb@ucmail.uc.edu](mailto:sicklejb@ucmail.uc.edu)

**WebDCU help:** Jocelyn Anderson [anderjoc@musc.edu](mailto:anderjoc@musc.edu) and Katie Trosclair [trosclak@musc.edu](mailto:trosclak@musc.edu)

**Regulatory help:** Lauren Stricker [strickla@ucmail.uc.edu](mailto:strickla@ucmail.uc.edu) and Emily Stinson [stinsoey@ucmail.uc.edu](mailto:stinsoey@ucmail.uc.edu)



Sites	FH DUA	FH Consignment	CTA	CIRB Approval	Sites	FH DUA	FH Consignment	CTA	CIRB Approval	Sites	FH DUA	FH Consignment	CTA	CIRB Approval
R01 Case Western Reserve University					R11 University of California Los Angeles					R19 University of Pennsylvania				
Mercy Health - St. Vincent Medical Center					Cedars Sinai Medical Center					Temple University Hospital				
Cleveland Clinic, Cleveland					Kaiser Permanente Los Angeles Medical Center					Hospital of the University of Pennsylvania				
UH Cleveland Medical Center					Ronald Reagan UCLA Medical Center					R20 University of Pittsburgh				
MetroHealth Medical Center					UC Irvine					UPMC Presbyterian Hospital				
Ruby Memorial Hospital					UCLA Kaiser Fontana					St. Luke's University Hospital - Bethlehem Campus				
R02 Columbia University					University of New Mexico					R21 The University of Texas Health Science Center at Houston				
NYP Columbia University Medical Center					Doctors Medical Center of Modesto					Memorial Hermann-Texas Med Center				
Buffalo General Medical Center					Olive View- UCLA Medical Center					University of Texas Southwestern				
SUNY Upstate Medical University					Orange County Global Medical Center					University Health Shreveport				
Strong Memorial Hospital					R12 University of California San Diego					R22 University of Utah				
R03 Emory University					UCSD Health La Jolla					Intermountain Medical				
Grady Memorial Hospital					UCSD Medical Center - Hillcrest					St. Mary's Grand Junction CO				
R04 Massachusetts General Hospital					Dignity Health- St. Joseph Hospital					Banner University Medical-Phoenix				
Beth Israel Deaconess Medical Center					Chandler Regional Medical Center					Banner University Medical-Tucson				
Massachusetts General Hospital					Ochsner Medical Center					University of Utah Health				
Tufts Medical Center					R13 University of California San Francisco					R23 University of Washington				
Eastern Maine Medical Center					John Muir Concord Campus					Evergreen Health Medical Center				
Baystate Health					John Muir Walnut Creek Campus					Virginia Mason Medical Center				
Brigham and Women's Hospital					UCSF Helen Diller Medical Center					Harborview Medical Center				
Boston Medical Center					R14 University of Cincinnati					R24 University of Wisconsin				
UVMC Main Campus (Vermont)					University of Louisville Hospital					University of Wisconsin University hospital				
R05 Medical University of South Carolina					University of Cincinnati Medical Center					Gundersen Lutheran Medical				
Greenville Hospital System					St. Elizabeth Edgewood					Marshfield Clinic Health System				
Palmetto Health Richland					Christ Hospital					R26 University of Alabama at Birmingham				
Guilford Neurologic Associates (Moses Cone)					West Chester Hospital					UAB Hospital				
MUSC University Hospital					R15 University of Iowa					University of Mississippi Medical Center				
R06 MedStar Health Research Institute					University of Iowa Hospitals & Clinics					R27 Wake Forest University				
University of Maryland					University of Nebraska Medical Center					Wake Forest Baptist Medical Center				
George Washington University					Sanford Medical Center					Novant Health Forsyth Medical Center				
UVA Medical Center					R16 University of Miami					Mission Hospital				
R07 Icahn School of Medicine at Mount Sinai					Jackson Memorial Hospital					R28 The Washington University				
NYU Langone- Tish Hospital Medical Center					UF Health Shands Hospital					Barnes-Jewish Hospital				
Maimonides Medical Center					Sarasota Memorial Hospital					OSF Saint Francis Medical Center				
Montefiore Medical Center					Brooks Rehabilitation Hospital					St. Louis University Hospital				
R08 Northwestern University					Tampa General Hospital					Cox Medical				
Loyola University Medical Center					Mayo Clinic Jacksonville					St. Luke's Hospital of Kansas City				
University of Illinois Hospital and Health sciences					Baptist Hospital of Miami					University of Tennessee (Methodist Hospital)				
Medical College of Wisconsin					University of Miami Hospital					R29 Yale University				
Rush University Medical Center					R17 University of Michigan					Yale-New Haven Hospital				
University of Chicago Medical Center					Detroit Receiving Hospital					Hartford Hospital				
R09 The Ohio State University					Henry Ford Hospital					Staten Island University Hospital				
OSU Wexner Medical Center					Mercy Health Saint Mary's					North Shore University Hospital				
R10 Stanford University					Mary Free Bed Rehabilitation Hospital					No RCC				
Mercy San Juan Medical Center					University of Kentucky Hospital					UC Davis				
Oregon Health and Science University Hospital					McLaren Flint					Bridgeport CT				
Providence St. Vincent Portland					R18 University of Minnesota					Geisinger Clinic PA				
					United Hospital					Advanced Neurology Specialists MT				
					Valley Baptist Medical Center - Harlingen					Baylor Scott & White Institute of Rehab TX				
					University of Minnesota Medical Center					Norton Healthcare				
					St. Cloud Hospital/Centracare					Carolinas Rehab Northeast				
					Southern Illinois University Memorial					Capital Health-NJ				
					Mayo Clinic Hospital Rochester – St Mary's Campus					Toledo Hospital				
										Mayo Clinic Arizona				
										Penn State Milton S. Hershey Medical Center				