**Summary of Sleep SMART Enrollment, Randomization, and Study Procedures (**Version 5/22/2020)

**During acute or rehab hospitalization**

□ Screen records for consent eligibility

□ If a patient declines consent, please enter him/her into the screen failure report

□ Show recruitment video, have consent conversation

□ Obtain consent (use IC Process Checklist), obtain local medical record release for next 6 months

□ Register subject in WebDCU (<https://webdcu.musc.edu/>)

□ Obtain all baseline information from chart, interview, and interview of a close proxy (IQCODE)

□ Enter Medicare Beneficiary ID in non-WebDCU form (Qualtrics)(e.g., 1EG4TE5MK73)

**Night 1 (ideally the night or next major sleep period just following consent):**

□ Replace batteries in Nox T3 unit and oximeter

□ Set up Nox T3 in KOEO system (app.koeo.com in chrome): First Name: “Sleep SMART”; Last

Name: [Subject ID]; DOB: “1/1/1900”; Identification: [Subject ID]

□ May hang Nox T3 / CPAP information sheet in subject room

□ Apply overnight sleep apnea test (Nox T3)

□ Next morning: download Nox T3 study data into KOEO (app.koeo.com in chrome)

□ That day: Will receive email after T3 has been processed (processing times: 10am/2pm)

□ Check in KOEO for eligibility to continue based on Nox T3 results

□ ONLY IF NOT eligible for Run-In Night, provide Nox T3 test report to subject and clinical team, let

them know participation in Sleep SMART is complete, and enter information in WebDCU.

**If eligible for aCPAP Run-In Night:**

□ Preferably during the day, check prospective fit for all eligible & preferred mask types, using

templates for full face & nasal masks, & actual nasal pillows to assess nasal pillows fit; indicate

mask sizes and fit in KOEO

□ Select the first mask to try, put “good” fit masks at bedside

□ Have subject practice applying/removing mask (repeatedly)

□ Assure that new tubing, and humidifier basin are used, and that the air outlet is cleaned

□ Apply aCPAP treatment overnight

□ RT to assess subject overnight to assist with any challenges that might arise

□ In AM, inquire about experience with aCPAP and whether subject would be willing to continue

if eligible

□ Check device readout for randomization eligibility. If usage hours ≥ 4.0 hours and CAI from

aCPAP < 10 / hour, and subject is willing to proceed, then he/she is eligible for randomization.

□ Enter aCPAP data in WebDCU

□ Log into KOEO to indicate randomization eligibility

□ aCPAP filters do not need to be replaced every Run-In Night, but should be replaced monthly

**If NOT eligible for randomization:**

□ Within KOEO, let FusionHealth know what equipment needs to be replaced. We suggest sites have   
 ≥4 of everything. If any of your supplies are depleted to 3, then send FusionHealth a supplies

request. Note, you will not need to order replacements after every unsuccessful Run-In Night.

□ In WebDCU, complete F506 and then move the subject to End of Study and complete F126. Answers entered for Q04-Q08 should represent actual numbers and not placeholders for values not obtained. If you are unable to answer a question, then leave it blank and respond to the rule explaining why that value is not available.

**If eligible for randomization:**

□ Randomize subject in WebDCU

□ Update status in KOEO: provide treatment assignment

□ Let subject know result of randomization and what to expect

□ Provide stroke symptom recognition handout to subject

□ At or after discharge, site PI or clinical team provides secondary prevention recommendations

to PCP

**Intervention arm (aCPAP):**

□ If assigned to intervention arm, log into KOEO and enter data to enroll in FusionHealth care

management program: update patient info (enter PHI), document equipment provided to subject

□ Provide new aCPAP box and include the items from the run-in night: tubing, humidifier basin, masks

□ Provide education to subject and caregiver about aCPAP

□ Instruct subject to apply aCPAP nightly during hospitalization, and any time that the subject intends

to sleep or nap, with assistance if needed from nurse or RT

□ Establish personal motivation for using aCPAP and communicate this with support team (nursing

staff, family, home support staff and FusionHealth care management team)

□ Let nursing know that subject needs to use CPAP; hang CPAP reminder sign in room

□ Have RT assist with nightly use (utilize personal motivational coaching techniques and small step

positive reinforcement – e.g. incremental increases in use time, AHI control, leak management

using aCPAP display functions)

□ Assist subjects if willing to put Sleep SMART Care Team number(470-655-6688) in their cell phone

□ Help subject make initial call to Care team (470-655-6688) prior to discharge

□ Discharge subject with all of his/her aCPAP equipment; show subject the contents of the CPAP bag

including the handouts and magnet that are included

□ Provide aCPAP and mask instructions (included in their boxes, carrying case, etc.) to subject

□ Remind subject to use aCPAP every time subject sleeps; to take aCPAP on trips and any future

hospitalizations; to plan for follow-up visits at 3 months and 6 months

**□ Remind the subject that care management will be in contact with them**

**□ Remind subject that if he/she completes a call with the Care Team within 7 days of discharge**

**and provides the team with an email address, will receive $10 Amazon gift card**

□ **Provide CPAP order if intervention subject discharged to site other than home**

□ **At time of hospital discharge, document hospital discharge with date in KOEO**

□ **When subject is discharged from hospital, please call (FusionHealth) Sleep SMART Care**

**Team at** **470-655-6688 to let them know**

**Outcome assessments (timed from randomization)**

□ 3-month (-14 days/+30 days) assessment by blinded study team member (includes walk test)

□ 6-month (-14 days/+56 days) assessment by blinded study team member (includes CPAP questionnaire – save for end of visit)

* Options: return for in-person assessment; study team go to home; telephone if in-person not possible (video assessments not included in protocol)
* If difficulty reaching: check consent for alternative means to reach subject or alternative contact. Unable to reach letter template, final lost-to-follow letter on website (<https://www.nihstrokenet.org/sleep-smart-trial/research-team>)
* Provide sleep apnea test (Nox T3) results to subject and clinical team (AFTER subject completes all 6-month assessments, or immediately after any necessary early termination of participation in Sleep SMART)
* If desired by subject, help arrange local Sleep Medicine follow-up to start after termination of participation in Sleep SMART
* If assigned to aCPAP arm, subject keeps device and supplies
* Please refer to the Sleep SMART Data Collection Guidelines (DCG) located in [Project Documents] for more information on how to complete the case report forms.