

Nox T3 Sleep Apnea Test

What tools are available to me to help troubleshoot technical issues related to the T3?

Slides: <https://webdcu.musc.edu/campus/>

Video: <https://www.youtube.com/watch?v=PwFq3uWZIHQ&feature=youtu.be>

KOEO/KIT/T3 Troubleshooting Guide:

<https://drive.google.com/file/d/1DuT8TxmKnQaENq0ICTuiTlx6kO6xjBYR/view?usp=sharing>

Fusion Health technical support: 404-480-5149 extension 4006 (M-F 8am-7pm) or sleepsmarttechsupport@noxhealth.com (anytime)

Which team members will need KOEO access?

Only those team members who are responsible for setting up the Nox T3 (prior to application to the subject), uploading the T3 data, and randomization will need KOEO access. This should include investigators and coordinators.

How do I select the size of the abdominal and chest bands?

The medium size comes in the kits and will fit most subjects. Large bands (respiratory inductance plethysmography, or RIP belts) are also available when needed. Select the large if the subject's BMI is >40.

Do you have any tips for getting the belts on a large and immobile subject?

Because the belts are soft, stretchy, lightweight, and can record signals effectively even if the belts are twisted, getting them around a large or immobile individual should not prove to be difficult. It is possible to lay the belts flat across the bed and then have the individual lie down on top of them. The belts easily snap to the appropriate connector.

What if the belt is twisted? Will it still work?

It will not diminish the signal quality even if the belt is twisted. Respiratory inductive plethysmography (RIP) technology ensures data integrity as long as the copper wire sewn into the belts is intact, regardless of whether the bands are twisted.

What if I can't get one of the belts on the subject due to patient refusal, an obstruction, or wound? May I run the study without one of the two belts? Without the two belts?

It may not be possible to render a valid outcome of the test unless signals from both belts are recorded. When only 1 belt can be used, it should be up to the scoring tech at FusionHealth to certify the adequacy of the signals for scoring on a case by case basis.

How tight should the abdominal and chest belts be?

The belts should not be overly tight. They should fit snug around the chest and abdomen.

What do I do if the subject has a tube in the nose such as an NG or dobhoff tube?

Try to fit the nasal cannula of the T3 with the other tube in the nostrils simultaneously. If this is not possible, omit the T3 nasal cannula and run the study without it.

What if the patient is using nasal cannula or face mask oxygen?

Try to fit the nasal cannula of the T3 in the nose with the oxygen cannula simultaneously. If this is not possible, omit the T3 nasal cannula and run the study without it. If the study during administration of supplemental O₂ is negative for obstructive sleep apnea, the study may be repeated when the subject is off supplemental O₂, if the patient still meets eligibility requirements. Note: O₂ supplementation >4 liters is an exclusion criterion for Sleep SMART.

Are there any reasons why a T3 sleep apnea test should be repeated?

1. If insufficient data are obtained, the test may be repeated on a subsequent night. The test may also be repeated if the subject denied sleeping for at least 4 hours during the night of testing.
2. If an initial sleep apnea test fails due to technical reasons, subject non-compliance, interruption for clinical testing, or any reason other than the test simply proving negative for sleep apnea, the test may be repeated on up to two subsequent night(s) if the subject is amenable.
3. The study may be repeated if the subject used supplemental O₂ during the test and it failed to show obstructive sleep apnea (OSA, considered absent if $AHI_{T3} < 10$). If the subject still meets eligibility criteria, the test may be repeated.

Must the T3 test be applied during the night or are other times of day ever acceptable?

If good reasons exist to think the patient will sleep for at least 4 hours during daytime testing -- for example the subject was awake the previous night or usually sleeps during the day -- the T3 study may be conducted during the day. The T3 should be left on for at least 3 hours, but ideally for 8 hours or more if a major sleep period of that length can be obtained.

What if the subject is wearing a heart monitor that hangs on the chest? How do I apply the T3 device?

The T3 unit should be clipped to the subject's hospital gown so it is closest to the body - beneath the other device. There should be nothing except a hospital gown or a t-shirt between the T3 device and the subject's body.

The subject complains about the O₂ sensor being too tight. Is there anything I can do?

The index finger of either hand generally should be used. If the subject complains about the sensor being too tight, it is fine to switch the probe between fingers. Ring finger is an appropriate alternative. Pinky finger can also work if large enough.

The subject complains about the nasal cannula. Is there anything I can do?

If the nasal cannula causes initial discomfort encourage the subject to put it on themselves in order to help with desensitization. It may just take a few attempts and time to get used to the cannula, especially the nasal prongs inserted into the nares. If the nasal prongs are problematic, minimize prong movement by securing the cannula with tape at two or more locations along the cannula length. The nasal cannula signal is required for recording airflow and snoring.

The subject doesn't want the nasal cannula taped onto his/her face. What should I do?

Forgo the tape and try to secure the nasal cannula in place by adjusting under the subject's chin, as usual.

Do I really need to change the batteries between each use?

Yes, please change the batteries in between each study, even if the T3 suggests a remaining charge. Use the device that comes with the kit to open the battery door. The T3 uses a single AA battery that must be replaced after each use. The Nonin wrist-worn oximeter uses 2 AAA batteries. To ensure integrity of the power supply in the study, replace all batteries after each use.

What equipment should I use to repeat a T3 study on the same subject?

The same nasal cannula and abdominal and chest bands should be used on the same participant to repeat a study. A new nasal cannula and new bands must be used for each participant during the first study. Nasal cannula and chest/abdominal bands should not be shared across subjects.

How do I clean the T3 between subjects?

Wipe down with alcohol prep pads the reusable items, such as the snap-on leads, oximeter, oximeter probe, the Nox T3 device itself, and Nox Abdomen Cable. Also, wipe down the Nox T3 device and oximetry probe with alcohol prep pads. Follow any additional cleaning instructions recommended locally. Do not submerge.

Why can't I see how severe the OSA is after each T3 study?

Participants and the study team are masked to the severity of the OSA. They should not access the detailed T3 report until the subject has completed participation in Sleep SMART. This helps avoid bias in the study.

Should I provide the results of the T3 to subjects?

Reports of T3 sleep apnea test results are found in KOEO. The study team should only access this report after the subject completes participation in the study. This can occur after the T3 sleep apnea test or aCPAP run-in results disqualify the subject for continued participation, at the time of the 6-month assessment, or when the subject withdraws. The clinical team and the subject should then be given a copy of the T3 results. (If an intervention subject is being referred for local sleep medicine assistance, the report may be accessed and shared with the sleep medicine team.)

Our site has its own home sleep apnea testing devices. May I use one of them instead of the T3?

No, the T3 provided by the study must be used.

A subject has already been diagnosed in the past with sleep apnea, and has an outside report to prove it. Does he or she still need to have testing with the Nox T3?

Yes.

Where should the T3 and aCPAP devices be stored?

Sites are responsible for the equipment provided by the study. Lost, stolen, or damaged items are the responsibility of the site. Please store them in a secure location.

Do the study devices need to be inspected by our hospital's clinical/biomedical engineering unit?

The Nox T3 and aCPAP devices may need to be inspected, approved, and stickered by your institution's biomedical engineering unit. Sites are required to follow their local policies related to this. Sleep SMART itself does not require local inspection by the individual hospitals' biomedical engineering staff.

Automatically-Adjusting Continuous Positive Airway Pressure (aCPAP)

What tools are available to me to help troubleshoot technical issues related to aCPAP?

Slides: <https://webdcu.musc.edu/campus/>

aCPAP video: <https://www.youtube.com/watch?v=oqvYJ5WXIn0&feature=youtu.be>

Mask fit video: <https://www.youtube.com/watch?v=oqvYJ5WXIn0&feature=youtu.be>

Fusion Health technical support: 404-480-5149 extension 4006 (M-F 8am-7pm) or sleepsmarttechsupport@noxhealth.com (anytime)

How do I decide what type of mask (nasal mask, nasal pillows, or full face mask) to select first?

Written materials: See MOP section on mask fitting

Present all three masks in their packaging to the subject and ask which the subject thinks he/she is likely to prefer. The nasal mask is the default mask to try first if the subject has no preference and no compelling reason exists to select an alternative. If the subject has skin irritation on the bridge of his nose, facial hair, dentures, or sensitive skin, a nasal pillows interface may be better. If the subject is an obligate mouth breather (someone who insists he or she essentially can never breathe comfortably through the nose) and has no contraindications, he or she may start with a full face mask. Note that the full face mask and nasal masks used in Sleep SMART have magnets. Per ResMed, these masks should not be used in a subject with a metallic hemostatic clip implanted in the head to repair an aneurysm, or a subject with metallic splinters in one or both eyes following a penetrating eye injury. If the first mask tried is successful, use this mask without trying the others. Try another mask only if the first or second mask is not successful.

Who can perform the mask fit?

We advise that the person who performs the mask fit be either a Respiratory Therapist or Sleep Technologist. As an alternative, for times when this is not possible, a trained study staff member can perform the mask fit.

How do I decide what size to use?

Written materials: See MOP section on mask fitting

For the nasal and full face masks, use the templates provided. For the nasal pillows, compare the nostril size to the size of the pillows. The outer diameter of the nasal pillow should not exceed the inner diameter of the nares. As each nasal pillows mask comes with three sizes of nasal pillow attachments, you can try different sizes on a subject without being wasteful. Once a mask is selected for the subject, connect and turn on the aCPAP device and confirm that the fit is adequate by using the "Run Mask Fit" setting in the "My Options" menu.

When would I avoid use of a full face mask?

Use a nasal mask or nasal pillows interface rather than a full face mask for a subject with decreased mental status, tube feeds, or inability to remove the mask without assistance. Do not use a full face mask in these situations. (Also avoid use of the full face mask (and nasal mask)

in a subject with a metallic hemostatic clip implanted in the head to repair an aneurysm, or a subject with metallic splinters in one or both eyes following a penetrating eye injury.)

If I can't tell when the subject is awake and asleep due to decreased level of consciousness, when should I apply the aCPAP?

The participant should remain on aCPAP, and avoid a full face mask. When aCPAP is needed for more than 12 hours at a time, the participant should alternate between two mask models, the nasal mask and nasal pillows interface, even if it requires modest reduction in the upper limit of applied pressure with the help of an RT or FusionHealth (remotely). Nasal pillows can be prone to substantial leaks if the machine is cycling up to high pressure settings.

When may an aCPAP run-in night be repeated?

If the aCPAP run-in night proves to have been interrupted and limited by clinical care (or was thought to have been poorly tolerated because of a specific situation that will not likely re-occur (e.g. failure to use the humidifier)), and for this reason does not meet the ≥ 4 -hour criterion, testing should be repeated up to two additional times, if possible. If the CAI was < 10 but usage hours were < 4.0 for any reason, and the subject would like to repeat the run-in night for any reason, it may be repeated once.

The subject could not complete the run-in night due to aCPAP intolerance but is interested in repeating it. Should we repeat it?

If the CAI was < 10 but usage hours were < 4.0 for any reason, and the subject would like to repeat the run-in night for any reason, it may be repeated once.

The participant is worried about inability to manipulate the mask. Is there anything I can do?

The MOP calls for attempts to fit the mask during the day and recommends that the participant practice putting it on and taking it off before the beginning of the aCPAP run-in treatment.

Taking the mask on and off can be accomplished one-handed for some of the interfaces more easily than others. All three of the mask types that will be available for new subjects to use initially, at sites, can be put on with one hand – after practice – with relative ease. We have found that if a one-handed approach is needed, the following options work easiest:

One useful strategy is to assemble the mask and headgear, and then “hook” the headgear onto the back of the head, in the approximate position where it should rest once the mask is in its final position. Then, with one hand, pull the mask down over the forehead and eyes, until it rests where it should on the nose or nose and mouth, all while trying to keep the headgear in place at the back of the head.

Furthermore, we found that there is a steep learning curve for manipulating the mask and headgear successfully. With some practice, it becomes much easier. For subjects who are not likely to learn, or whose motor deficits make handling the mask unfeasible, efforts should focus on teaching the main caregiver how to put on and take off the mask gently, safely, and efficiently, for the subject.

The subject complains about the sensation of breathing against the pressure provided by the mask. Is there anything I can do?

If the subject does not have a contraindication, try a full face mask as this may reduce the perception of confinement, pressure “build up” or claustrophobia. A nasal mask or nasal pillows, although smaller in profile, can have a “restriction of breathing” effect for some people. Increasing the humidifier settings on the machine counters the drying effects of the air flow, and can make the pressure less noticeable. In addition, once the subject leaves the hospital, and FusionHealth assumes management for aCPAP issues, they may modify the pressure settings delivered by the machine to improve comfort.

At the beginning of the run-in night, the participant complained about a specific issue. Where can I go to find ways to troubleshoot the issue?

The mask fitting guide and the aCPAP use guide each contain the same useful table where troubleshooting techniques are offered for specific issues. Please consult this table. Please call FusionHealth for assistance if this advice is unsuccessful or confusing.

Should I place an order with a DME company to have the subject acquire aCPAP for home use?

No, only the devices provided by the study should be provided to participants in the aCPAP arm. Sleep SMART devices are equipped with remote monitoring capabilities so that FusionHealth can provide care management.

In rare cases where FusionHealth cannot achieve an adequate response with a FusionHealth-supplied aCPAP or automatically-adjusting bilevel PAP device, FusionHealth may encourage, and ask you to facilitate, local sleep medicine assistance and intervention. In such a case, a study subject may end up using a local DME-supplied, non-FusionHealth, non-KOEO-enabled PAP variant that cannot transmit data wirelessly to FusionHealth. In such cases, efforts may be made to transmit the data in other ways (for example from downloads of the data card within each machine).

Am I responsible for helping to troubleshoot aCPAP equipment or compliance issues after the participant has been discharged?

Once the participant leaves the hospital, FusionHealth assumes responsibility for aCPAP troubleshooting. As above, in unusual circumstances, FusionHealth may suggest that a sleep medicine consult be placed after FusionHealth has been unsuccessful, if the participant is amenable.

Can subjects use aCPAP if they require oxygen?

Yes, oxygen can be “bled” into the aCPAP circuit (usually at the attachment of the hose to the mask) if the requirement does not exceed 4 liters/min.

Does aCPAP deliver oxygen?

aCPAP generally delivers filtered room air only. Supplemental oxygen, when needed in a minority of cases, can be added as above

When should a chin strap be used?

A chin strap should be considered for subjects who mouth breathe, in general before consideration of a full face mask. A chin strap may also be considered in those not eligible for a full face mask because of a contraindication (decreased mental status, tube feeds, or inability to remove the mask without assistance).

What should I do if a subject is randomized to use aCPAP, starts to use his or her kit including the machine, and then refuses to use aCPAP again, wanting to return the equipment? Can anything be used, cleaned, or recycled, for other subjects?

The machine can be cleaned and reused following local hospital guidelines, if such exist, or by contacting FusionHealth to see whether it should be sent back to them. The mask, tubing, and other supplies cannot be reused.

How will FusionHealth know that a subject has left the hospital in order to contact him/her directly?

When a subject is discharged, please call FusionHealth at 404-480-5149 extension 4006 (M-F 8am-7pm) and let them know. Home contact info should already be loaded in KOEO from the dispersement of equipment task, however, FusionHealth will not know the contact info for a SNF, rehab or other facility that a subject may be discharged to other than home. In these cases, the unblinded site coordinator should notify the Sleep SMART Care Team as soon as he/she knows where the subject is going. If the subject will reside in rehab or similar for a number of days/weeks, it makes sense for FusionHealth to have contact info for the medical staff so that they are able to communicate as needed while the subject is in the facility.

Eligibility

A patient is eager to use aCPAP to treat sleep apnea, and would like to participate in Sleep SMART if randomized to the aCPAP arm. However, if randomized to the no-CPAP arm, the patient is likely to withdraw. Can this patient be randomized, and decide whether to withdraw at that point?

A subject, once randomized, is always free to withdraw from a clinical trial. However, reasonable suspicion in advance of randomization that a subject is likely to withdraw if randomized to one particular arm, should generally preclude participation. Please refer to Section 9 of the MOP for screening and eligibility.

What should happen if a subject who has already been randomized develops an exclusion criterion?

Because the study will be analyzed as intent-to-treat, these subjects remain in the trial and should have assessments performed as usual. For the time period that the exclusion criterion exists, aCPAP should be held. aCPAP can be resumed after the exclusion criterion resolves.

If a patient initially has an exclusion to enrollment, but the exclusion resolves, is the patient then eligible?

Yes. (Some exclusions cannot resolve however, such as a history of pneumothorax.)

A patient considering participation in Sleep SMART would like to try a mask and aCPAP before deciding whether to enroll. Is this permitted?

No.

Is a prior history of OSA exclusionary? What about prior use of CPAP?

Neither is exclusionary. Patients who currently use CPAP are not eligible. Those who used CPAP within the prior one month are not eligible. Failed prior use of CPAP may make the patient less likely to be interested in enrollment, despite still being eligible. Such patients may, with newer equipment designs or the assistance of FusionHealth, be able to use aCPAP successfully even if they could not in the past.

Are patients with TIA based on the current definition (lack of associated infarction) eligible?

Yes, if the ABCD² score is ≥ 4 .

Are patients with venous sinus thrombosis eligible as long as they have associated tissue injury?

No. Ischemic stroke due to an arterial cause is needed.

Are any ischemic stroke subtypes excluded?

No, all ischemic stroke subtypes are included, and in fact desirable. Sleep SMART will be most effective if results can, as planned, be generalized to the full, wide spectrum of ischemic stroke subtypes, severities, and brain regions affected.

Is hemorrhage into infarction an exclusion criterion?

No.

Is a decreased level of consciousness or elevated aspiration risk exclusionary?

No. For the run-in night, and thereafter if the participant is randomized to the intervention arm, use nasal masks or nasal pillows rather than full face masks for subjects with decreased mental status, tube feeds, or inability to remove the mask without assistance. Do not use a full face mask.

I have a time-sensitive question about eligibility of a specific patient, and I cannot find the answer in these FAQ pages, the protocol, the MOP, or other sources. How can I obtain a timely answer?

For a response likely to be generated within the same business day, please send your question to the following Sleep SMART study email address: sleepsmart@umich.edu

This email account will be monitored by the Sleep SMART PIs with assistance from others who are familiar with the protocol. Please do not include PHI in any email to the study email address.

Assessments

Do I perform the 10-meter walk test at both 3 and 6 months?

No, the 10-meter walk test is only performed at 3 months.

Which assessments can only be performed in person?

The NIHSS, 10-meter walk test, and blood pressure assessments can only be performed in person. The remainder of the assessments can be performed over the phone.

What do I do if the participant fails to show up for a scheduled assessment at 3 or 6 months?

Try to reschedule the follow-up during the targeted time window. If unable to reach the participant or designated family member/caregiver by phone, try texting if permission has been granted. Try the alternative contacts to reach the subject, designated family member/caregiver, or legally-authorized representative (LAR). If the participant is unable to present for an in-person follow-up, the study team may go to the participant's home to perform the full assessment. If this is not possible, a telephone follow-up should be performed. (Because the telephone follow-ups have fewer components and take less time, sites are compensated less (by \$200 directs).)

If a subject is aphasic or otherwise is unable to participate in the question-based assessments, what should I do?

The MoCA, Global PROMIS-10, HADS, and medication adherence questions should only be administered directly to subjects. The NIHSS can always be performed with the subject only. The 10-meter walk test may be possible with a subject who cannot complete questionnaires. The mRS-9Q, Epworth Sleepiness Scale, and short SSQOL should be completed by a proxy who knows the participant well, if the participant cannot complete them directly.

In what order should I complete the assessments?

1. mRS 9Q
2. NIHSS
3. 5-minute MoCA
4. PROMIS
5. SS-QOL
6. HADS
7. ESS

Other Protocol Questions

What should I do with control participants who are interested in OSA treatment at the conclusion of participation?

Refer them to a clinician with expertise in sleep medicine.

When an intervention subject's participation is about to end, what should we do about management of aCPAP? Will FusionHealth continue to follow them?

FusionHealth will not continue to follow intervention subjects who have completed Sleep SMART participation. Subjects in the intervention arm may keep the aCPAP and supplies. If an intervention arm participant plans to continue use of aCPAP after his/her trial completion, referral should be made to a clinician with expertise in sleep medicine.

What happens with a participant who becomes pregnant during the study?

The study team should offer to facilitate referral for clinical care for OSA (on a clinical and insurer or self-pay basis). If the participant is in the intervention arm, the aCPAP and supplies should be left with the subject. Follow-up assessments (3- and 6-months) should be performed.

A control subject is interested in CPAP. What should I do?

Any control subject may seek referral at any time from his/her clinical team or PCP to a sleep medicine physician, for further evaluation and treatment of OSA. The study team should not facilitate this and should record it as a protocol violation. A control subject who pursues OSA treatment remains in the control arm and should have the follow-up assessments performed. An opportunity will be provided – and this is important – to enter into WebDCU at the conclusion of the subject's participation in Sleep SMART the fact that the subject received OSA treatment outside of Sleep SMART.

FusionHealth tells us that the subject's OSA is not best treated by CPAP or bilevel PAP. They request assistance from a local sleep medicine physician. What should I do?

Try to facilitate referral to a sleep medicine physician if the subject is agreeable. The subject will remain in the study and continue to have assessments performed.

I am the study coordinator and I know the treatment assignment for a subject. I may not recall it correctly however. May I perform the 3- or 6-month assessment?

The outcome assessments should be performed by a study team member who is masked to treatment assignment. In this scenario the study coordinator is not masked to study treatment and another study team member (listed on the delegation of authority [DOA] list to perform outcome assessments), if available, should perform the evaluation. If an unmasked study team member performs the evaluation, it is a protocol violation. If the only choice is between an evaluation by an unmasked study team member, and no evaluation, the best choice is to obtain the evaluation by the unmasked team member.

Can patients participate in Sleep SMART if they do not have internet access?

Yes. The CPAP data are transmitted by way of cellular signals.

Will subjects receive any payments?

Yes, subjects will be given \$25 after completion of the study enrollment interview and sleep apnea test. If they qualify for the aCPAP run-in night and attempt it, they will be given another \$25. When more than a one-night attempt is made to obtain a successful sleep apnea test or aCPAP run-in, subjects are not paid for the additional nights. Subjects receive \$75 for completion of the 3-month visit and another \$75 upon completion of the 6-month visit. The total amount a participant can receive for participation in Sleep SMART is \$200. These payments are managed by the local site team. (If an intervention subject participates in a FusionHealth call during the one week after discharge, he/she is eligible for a \$10 Amazon gift card, managed by the University of Michigan team.)

Are sites required to have source documents on paper as well as electronically?

StrokeNet only requires sites to have source documents electronically through WebDCU, but each institution may vary with respect to source document requirements. Please check with your institution to know what you are required to do.

Will CRF's be made available?

Yes, all CRF's are available electronically on WebDCU.

Regulatory

When do I obtain consent from a legally authorized representative (LAR)?

Use of an LAR for consent is only appropriate when a subject lacks capacity to provide consent. LAR consent is not appropriate in circumstances where a subject is capable of giving consent but is unable to read or physically sign an informed consent document. If a subject is unable to read or sign and date the consent, the following procedures should be followed:

- If the patient is unable to read, please read the consent to him/her
- Subjects who are able should “make their mark” on the signature lines of the consent.
- An impartial witness, who is neither a member of the study team nor a friend/family member of the subject, should observe the consent process and should sign the consent as a witness. Please note that this is not an option during remote consent.

Can I obtain electronic consent remotely, from a legally authorized representative who is not physically at the bedside?

eConsent is allowable in Sleep SMART through REDCap. If you would like to have this option locally, please contact Joelle Sickler (sicklejb@UCMAIL.UC.EDU) or Kayla Novitski (kcgossel@med.umich.edu). Each site has to complete a remote informed consent implementation form, and should follow the Sleep SMART remote consent procedure (found in WebDCU – F2332).

Do we have to use the central IRB?

All StrokeNet trials require review and approval by the NIH StrokeNet Central Institutional Review Board (SN CIRB) located at the University of Cincinnati IRB. The SN CIRB is the IRB of record for all StrokeNet studies. No other IRB may make changes to documents previously approved by the SN IRB. A CIRB reliance agreement is required from each clinical enrollment site.

Does my institutional IRB, in addition to the CIRB, have to approve the study?

You should check with your Institutional Review Board (or equivalent) as to what process is needed for an NIH-funded grant that uses the StrokeNet Central IRB. It may be an abbreviated process, as the protocol and template informed consent, along with other documents, already have CIRB approval and the CIRB is the IRB of record for Sleep SMART. Official acknowledgement by your local IRB may also be needed. Your site will also need to complete the Local Context Form provided by StrokeNet in your IRB Packet. This will need to be completed and signed by your local IRB.

Is there a paper version of the Delegation of Authority (DOA) Log?

No, this is kept electronically in WebDCU™. This ensures that the DOA is always up to date, and it allows the CIRB to have access to it.

What is the anticipated number of subjects to be enrolled at our site?

On average, we would expect about 3 subjects screened (with sleep apnea test +/- aCPAP run-in night) plus one screened and successfully randomized (and thus being followed for outcomes) each month. Of course more would be welcome, and anticipated from sites with high volumes of admissions for stroke.

Will we have to invoice to get paid?

Study sites will not have to invoice the NCC for payments for study activities. Complete data entered into WebDCU, and test completion and upload to Fusion Health, will trigger payments.

When will we receive our startup funds?

Sites receive start-up funds upon full execution of the Fixed Price Clinical Trial Subaward Agreement.