

SLEEP ENROLLMENT

1. Introduction

This section contains information about Enrollment for the second MrOS Sleep Visit (VS2). At this visit, we will utilize a Sleep Enrollment Form that will allow us to track the number of participants contacted, the number that refused to complete the second sleep visit and the number of people who were willing to participate but weren't eligible.

2. Guidelines

The goal of the Second MrOS Sleep Study is to see a total of 1000 participants with usable psg and actigraphy data. Ideally, all of these participants will have the spirometry measure as well.

To be eligible for the second sleep visit participants must:

- 1) Currently be active in the MrOS Sleep Study
- 2) Have usable psg and actigraphy data from the first MrOS Sleep Visit

All eligible minorities will be invited to return for the Second Sleep Visit. The Coordinating Center will provide each clinic with a listing of eligible minority participants. Site should try to see all minority participants within the first 18 months of recruitment. Recommendations for how many minorities to see per month will also be provided.

The Coordinating Center will also provide each clinical center with recruitment lists of eligible non-minority participants during the course of the visit. Each list will contain approximately 75 randomly selected white participants who are eligible for the Second Sleep Visit. Sites should contact all participants on the original recruitment list. Once a list has been exhausted, another list of 75 randomly selected white participants who are eligible for the Second Sleep Visit will be provided. Recruitment lists will be provided until sites reach their recruitment goals.

Sites should only contact participants on the recruitment lists provided by the Coordinating Center about participating in the Second Sleep Visit. Other MrOS participants should not be contacted. Sites may contact participants by location for ease of recruitment, but sites should try to work through the random order listings as much as possible.

Please note if a participant contacts the clinic about participating in the Second Sleep Visit and they are not a minority participant or are not on the current recruitment list, sites should contact the Coordinating Center to see if this participant can be seen 'out of order'. If the participant is eligible, most likely the participant can be scheduled. Sites will need to create specimen labels for participants not on recruitment lists. Please see the Specimen Collection Protocol for more information.

All MrOS participants who are contacted for the Second Sleep Visit should have a Sleep V2 Enrollment Form on file.

All participants who are scheduled for the Second Sleep Visit should be willing to complete the psg and actigraphy aspects of the visit at the time of recruitment. If the participant is not willing to participate in the second sleep visit (psg and actigraphy), indicate the reason on the enrollment form.

For all participants who are willing to complete the Second Sleep Visit, the following screening questions should be asked to determine if the participant is eligible for the Second Sleep Study:

- A. Do you have an open tracheostomy?
- A tracheostomy is a surgical procedure of creating a direct opening into the windpipe for breathing purposes.

If the participant answers yes, they are not eligible for the second sleep study. Do not schedule a Second Sleep Visit.

- B. In the past 3 months, have you used any of the following items:
- Pressure mask (CPAP or BiPAP for sleep apnea)
 - CPAP= Continuous Positive Airway Pressure
 - BiPAP = Bilevel Positive Airway Pressure
 - Mouthpiece (for snoring)
 - Oxygen therapy

Please note that this is a mark all that apply question. You can mark more than one item that is used. If no items are used, please mark 'None'.

If the participant indicates yes for any of the above, please ask 'When do you usually wear it?'

- During sleep and wake
- During sleep only
- During wake only

If the participant has used CPAP or BiPAP, a mouthpiece or oxygen therapy in the past 3 months, they are still eligible for psg at the second sleep study. (Please note that use of oxygen therapy is considered an exclusion for actigraphy. See below for more information.)

However, during the in-home psg, they will not be required to have all leads attached. They will be able to continue to wear their device as needed. See the psg protocol for more information.

- C. Sites should also ask participants about the exclusion criteria for actigraphy. If the participant uses oxygen or someone in the participant's home uses

oxygen or if the participant has a defibrillator, participants are not eligible for the actigraphy measure. See the Actigraphy Protocol for more details regarding exclusion criteria.

If a participant is not eligible for either psg or actigraphy, do not schedule a sleep visit.

At the time of recruitment, participants should also be asked if they have had any active respiratory symptoms (exacerbation, new cough or wheezing), obvious respiratory distress or recent onset of chest pains. This will help with scheduling as participants should not report any new respiratory systems within 2 weeks of the clinic visit (see the Spirometry protocol for more information).

If the participant completes the MrOS Sleep Visit, indicate the date of the clinic visit and who completed the SAQ. If the participant had help filling out the SAQ but answered most of the questions, indicate that the participant completed the SAQ. If someone other than the participant completed most of the SAQ and the participant did not answer most questions, indicate who completed most of the SAQ.

Please note that it is possible that a participant who is originally eligible for one of the sleep measures will refuse a measure or will be found to not be eligible for a measure at the time of the clinic visit. This is acceptable. All other measures should be collected. The reason why a measure wasn't completed should be noted on the appropriate TELEform.

If the participant is originally willing to complete the sleep visit and has provided information regarding the screening questions but never completes the visit (or later refuses), this should be counted as a refusal. Sites should change the information on the Enrollment form so that Question 1 indicates that the participant is not willing to complete the sleep visit and a reason why should be marked.

3. Submitting the Enrollment Form to the Data System

A Sleep Enrollment Form should be submitted to the data system for every MrOS participant that was contacted for the second sleep study. Please refer to the Data System Protocol for more information regarding submitting forms to the data system.