

## SLEEP ENROLLMENT

### 1. Introduction

This section contains information about MrOS Sleep Enrollment Form. The Sleep Enrollment Form will allow us to track the number of participants contacted, the number that refused to complete the sleep visit and the number of people who were willing to participate but weren't eligible.

### 2. Guidelines

All MrOS participants that are contacted for the MrOS Sleep visit should have a Sleep Enrollment Form on file.

If the participant is not willing to participate in the MrOS Sleep Visit, indicate why not on the enrollment form.

All potential sleep participants should be asked the following screening questions:

1. In the past 3 months, have you slept with a pressure mask ("CPAP" or "BiPAP") for sleep apnea?
  - CPAP= Continuous Positive Airway Pressure
  - BiPAP = Bilevel Positive Airway Pressure
2. In the past 3 months, have you slept with a mouthpiece for snoring or sleep apnea?
3. Do you have an open tracheostomy?
  - A tracheostomy is a surgical procedure of creating a direct opening into the windpipe for breathing purposes.
4. In the past 3 months, have you usually used oxygen therapy (oxygen delivered by a mask or nasal cannula) during your sleep?

If the participant answers yes to one of the screening questions, they are not eligible for the MrOS sleep study. Do NOT schedule a sleep visit. Thank the participant for their time and let them know they will be contacted by the MrOS study in the near future.

**NOTE:** The one exception to these eligibility requirements is that if a participant uses CPAP intermittently (<2 times per week) and would like to participate in the study then they are eligible.

If the participant completes the MrOS Sleep Visit, indicate the date of the clinic visit, the type of visit (home or clinic) and if the participant is willing to complete PSG. Also indicate 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 in some cases it may be necessary to change the 'Will the participant complete PSG' answer after the form is submitted to the data system. If the participant initially says that they will complete the PSG section of the MrOS Sleep Visit (and 'yes' is marked on the Enrollment Form), but later does not actually complete PSG, a query will need to be posted via the MrOS web site to change the answer to 'no'. Please refer to the Data System Protocols for more information on posting queries.

### **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 sleep study.

If the participant completes the Sleep Visit, the Enrollment Form should be the first form that is submitted to the data system and should be submitted within 24 hours of the participant's visit. No other forms will be accepted by the data system until the Sleep Enrollment is in the data system. Please check the 'Data Inventory' link on the MrOS web site to confirm that the Enrollment Form is in the data system before submitting other Sleep Visit forms.