

Chapter 42: Core Sleep Study Monitoring Core MOP

Revision 12/29/2016

42.1 Purpose and Background:

The relationships of sleep disordered breathing and pulmonary hypertension have been described albeit data which have amassed thus far have been limited from the standpoints of small numbers of participants, limited study design and lack of inclusion and consideration of objective pulmonary hemodynamic parameters. The PVDomics study provides an ideal platform to more accurately and comprehensively characterize the relationships of sleep disordered breathing and pulmonary hypertension in a prospective manner. The collection of rich phenotypic data in the setting of pulmonary hypertension as proposed provides a unique opportunity to examine the sleep-pulmonary hypertension inter-relationships on a more granular level.

42.2 Logistics for Sleep Reading Core

The Sleep Reading Core under the supervision of Dr. Reena Mehra (email: mehrar@ccf.org), is part of the Data Coordinating Center at the Cleveland Clinic, Cleveland, Ohio. Additional contact information can be found in the PVDOMICS Address Directory. All sleep study files will be transmitted to the DCC Sleep Core for scoring of the data and assessment of quality grade.

42.3 Overview

This manual provides standard operating procedures for Readyng Core management of Overnight Sleep Study Monitoring. This manual will address the scoring, archiving, and transfer of data; as well as the certification of Clinical Centers.

42.3.1 Sleep Study for PVDOMICS Study

Overnight sleep monitoring will be performed routinely in all enrollees to acquire standardized baseline information on sleep disordered breathing and to quantify overnight oxygen saturation patterns. Participants already receiving oxygen supplementation and/or positive airway pressure therapy on a regular, nightly basis will be studied during use of these. A portable home monitoring system (Nox T3, Carefusion) will be used, with recordings of nasal airflow, chest wall and abdominal motion as well as pulse oximetry, heart rate, and position. Each center will purchase the equipment necessary to perform these studies, and study personnel will be trained in the proper application of the devices.

42.3.2 Historical Sleep Study

If the participant has had a sleep study within the last year of study enrollment, then it is at the discretion of the Center PI as to whether a research sleep study should be performed. The results of prior sleep studies as well as any additional testing or interventions obtained as a consequence of the portable monitoring will be recorded. The historical sleep study data must meet the PVDomics inclusion criteria. Sleep studies will be scored using standardized methods for home sleep apnea testing and will conform to American Academy of Sleep Medicine guidelines. The summary data will be electronically transmitted to the DCC for integration into the database and for statistical analysis. If this information is available on a clinical basis within 1 year prior to study entry and with no change in nighttime oxygen or sleep disorder therapy, and in the opinion of the investigator, no change in patient condition that would impact results, then the clinically available data may be considered adequate for inclusion in the case report form – if available, a copy of that study be acquired for Reading Core review, quality assessment and scoring.

42.4 Center and Equipment Study Certification

The Sleep Core requires at least one (1) Staff member at each Clinical Center to be certified to collect for the PVDOMICS study, two persons are preferred. This certified research staff will be responsible for protocol adherence by any study personnel performing data collection at that Center. Certification must be accomplished prior to the Center performing actual data collection. Sleep monitoring data collection certification is provided upon demonstration that the staff member has:

- Basic understanding of sleep-specific study objectives and protocol for PVDOMICS.
- Understanding of equipment and application of specific sensors to be used for the sleep monitoring data acquisition.
- Demonstrated compliance with the study protocol for sleep monitoring data collection and data transmittal **via secure file transfer** to Sleep Core including removal of identifier information and correct re-identification with participant ID.

In order to obtain sleep monitoring data collection certification, the following items must be met by the individual to be certified:

- Submission of two acceptable overnight pilot studies (non-participant) recordings. Pilot studies on volunteers are conducted to assure that all staff are familiar with the equipment and protocol.

These submissions must be correctly de-identified, re-identified with a standard convention, successfully converted to EDF format and upload to the secure server. This serves both as part of the research staff certification process and as practical experience in using the equipment in the study environment. Certification studies also allow for verification that all sensors and equipment are functioning properly before being used on a study participant, and that post-acquisition treatment and transfer of data is consistent with study protocol. The certifying research staff does need not to actually perform every required task, but will be responsible for the acceptable completion of each task.

To be considered acceptable, the recordings submitted for certification must:

- Have adequate quality signal on each channel (i.e. all electrodes must work) and signals must be relatively free from artifact.
- Reflect sleep monitoring protocol and procedure including placement of electrodes and sensors.
- Have correct study identification as a certification recording using the following format when naming (or re-naming) the recording: [CR] [staffID]_[date of study]. An example of this format would be CRstaffID_102916. The electronic recording file must be accompanied with paperwork that matches this naming convention and additionally includes the technician identification and equipment ID.
- Include the following:
 - Form 150- Clinical Center Participant Sleepy Study Initialization, Demonstration and Placement
 - Form 152- Clinical Center Sleep Study Download and File Transmission

Data Management at the Reading Core

42.5 Study Receipt

Upon receipt of studies at the Sleep Core, the study data will be checked for quality. The receipt information includes: Subject ID, Study Date, date received via FTP, unit ID, and Staff ID. If there is a discrepancy between the data contained on the Sleep study evaluation Form and Sleep Study recorded file or any missing data on the forms an e-mail will be sent to the Site Coordinator requesting clarification.

A copy of Form 150 and 152 is sent to the Reading Core regardless of the quality or length of the recording. If at time of download of the Sleep monitor unit there is no data, the Form 150 and 152 must be sent. A note should be made on the forms that there was no data at the time of download. Short studies or problem studies that do not meet the criteria to be "passed" for scoring at preliminary review, should still be sent to the Sleep Core with any notes as to what troubleshooting was done, and if the reason for the short study can be determined. The Sleep Core tracks all problems relating to lost sleep studies and must receive this paperwork on a regular basis. The problem studies are monitored and if any systemic pattern is observed study-wide, we will work to resolve the problem. These forms can be placed on the **secure server**.

42.6 Preliminary Review and Scoring

The Noxturnal ® Offline Analysis program will be run at the Sleep Core prior to review of studies by the Polysomnologist for accurate visualization of signals and graphic screens. After offline analysis of the record, the study will be reviewed to determine any signal quality issues, possible monitor/electrode malfunctions, pass/fail status and possible Urgent Alert status indicating need for priority scoring.

To be classified as “reliable sleep data”, the record must contain at least 3 hours of scorable/reliable oximetry accompanied by one scorable respiratory channel (either nasal cannula, thoracic, or abdomen inductance plethysmography) after reported bedtime. Studies containing less than the minimal requirements will not be processed for scoring and the site coordinator will be notified via e-mail to request a repeat study from the participant.

The following categories of discrete breathing events will be identified during scoring: obstructive apneas, central apneas, and hypopneas. If flow from the nasal mask has been collected then obstructive events will be scored.

42.7 Reliability

A registered polysomnologist will be assigned to score all PVDomics sleep studies. A sample of studies will be re-circulated after relabeling their identifying information to assess intrascorer reliability.

42.8 Archiving

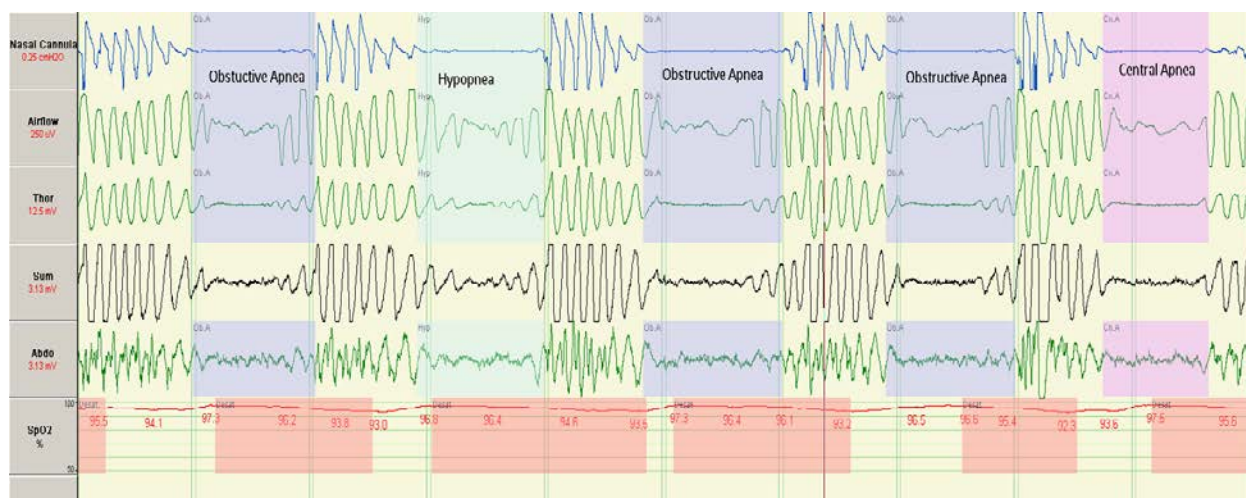
The clinical center must retain original versions of the sleep recording data files that have been created by the download of the overnight study. It is preferred that the site also retain copies of the EDF output files. However, if the EDF file is sent electronically, this is not

required. One CD-ROM disk containing a copy of the original sleep recording and a copy of the converted EDF files always must be retained at the local center in a secure location. These files are source documents and shall serve as “back up” files only.

42.9 Scoring Rules and Event Definitions

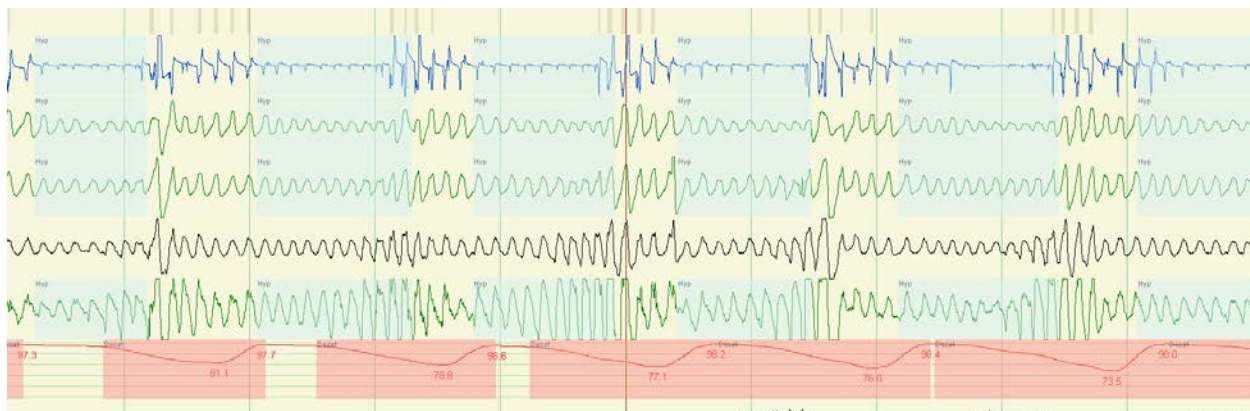
42.9.1 Apneic Events

An apnea occurs when there is a drop in the peak signal excursion by >90% of pre-event baseline using a nasal transducer and the duration of the drop is >10 seconds.



42.9.2 Hypopneic Events

A hypopneic event occurs when there is a peak signal excursion drop by >30% of pre-event baseline using nasal pressure or an acceptable alternative signal (e.g. RIP sum) lasting >10 seconds. The event must have a $\geq 3\%$ oxygen desaturation.

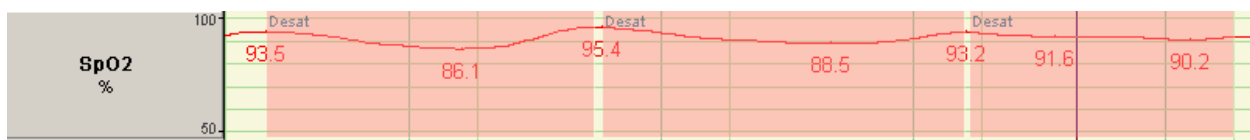


42.9.3 Duration of Apneic and Hypopneic Events

The beginning of an apneic or hypopneic event is defined as the first point at which cessation of airflow via nasal pressure transducer (for hypopneic events) is clearly evident on the tracing of nasal or mask. The end of an apneic or hypopneic event is defined as the last point at which cessation of airflow (for apneic events) or reduction of airflow (for hypopneic events) is clearly evident on the tracing of nasal or mask prior to an increase in airflow.

42.9.4 Oxygen Desaturation of $\geq 3\%$

A 3% oxygen desaturation refers to the change in saturation from a preceding stable level (immediately prior to the hypopnea) to the nadir level that follows the termination of the event (usually within 30seconds of the event). Saturation values that appear increased due to arousal and hyperventilation are not considered to represent the baseline value.



42.9.5 Nasal Flow Limitation

Nasal flow limitation is derived from the nasal cannula signal. A normal flow signal will present a regular sinus rhythm and curve. Flow limitation may occur with increase upper airway resistance, not sufficient enough to cause discrete apneas and hypopneas. A regular sinus curve will transform into a signal that resembles a lower case 'h'.



42.10 Medical Alerts

Studies identified as potential urgent alerts will be triaged for immediate scoring (within 48 hours of assignment to the scorer). Once fully scored and determined to meet criteria for Urgent Alerts, a physician investigator will be asked to review the study. Although not a medical alert, we will notify sites for those studies with an $AHI \geq 15$ suggestive of the diagnosis of moderate to severe obstructive sleep apnea so that this information can be shared with the participant.

- Urgent Alert criteria include: $AHI \geq 50$; $O_2sat < 85\%$ for $>10\%$ of TST.
- Unusual HR/ECG (Pertains to the following arrhythmias:

o Atrial Fibrillation/Atrial Flutter with rate < 50bpm or >150bpm



o Paroxysmal Atrial Fibrillation



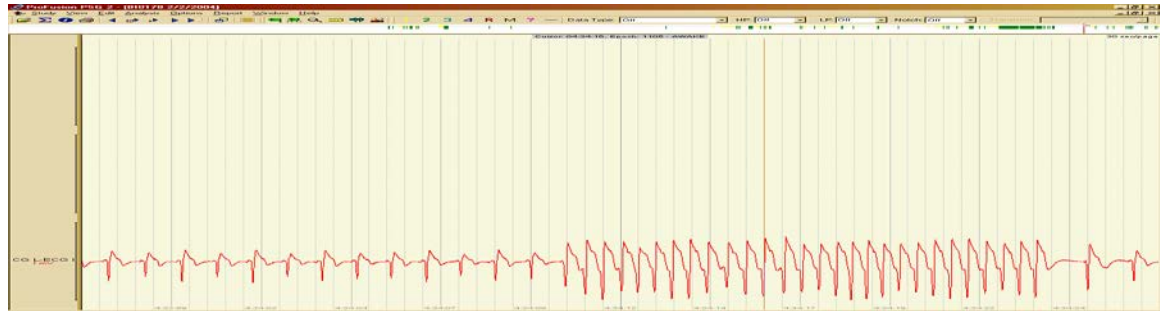
o Atrial Flutter



- o Supraventricular Tachycardia sustained for 30 seconds or greater with heart rate >150 bpm



- o Wide QRS Tachycardia (>4 beats with rate >100bpm)



- o Marked bradycardia (<30bpm for 6 seconds or greater)



- o Second degree AV block Mobitz Type II





o Third degree AV block



o Sinus Pauses >3 seconds



42.11 Abbreviations and Acronyms

AASM	American Academy of Sleep Medicine
AHI	Apnea Hypopnea index
ASV	Adaptive- Servo Ventilation
BIPAP	Bilevel Positive Airway Pressure
CPAP	Continuous Positive Airway Pressure
EDF	European Data Format
HR	Heart rate
PAP	Positive Airway Pressure
PI	Principal Investigator
PM	Portable Monitor
TST	Total Sleep Time

42.12 References:

[Berry RB¹](#), [Budhiraja R](#), [Gottlieb DJ](#), [Goza D](#), [Iber C](#), [Kapur VK](#), [Marcus CL](#), [Mehra R](#), [Parthasarathy S](#), [Quan SF](#), [Redline S](#), [Strohl KP](#), [Davidson Ward SL](#), [Tangredi MM](#); [American Academy of Sleep Medicine](#). Rules for scoring respiratory events in sleep: update of the 2007 AASM Manual for the Scoring of Sleep and Associated Events. Deliberations of the Sleep Apnea Definitions Task Force of the American Academy of Sleep Medicine. [J Clin Sleep Med](#). 2012 Oct 15;8(5):597-619.