## Overview

Date of Polysomnography (m m/d d/y y y y):

Polysomnography:

Full

Limited, specify:

Start Time of Sleep Study (H H : M M):

AM

PM

End Time of Sleep Study (H H : M M):

Sleep Latency (H H : M M):

AM

PM

Total Sleep Time (minutes):

## Results

Apnea-Hypopnea Index (AHI) Results (record in events per hour of sleep)

Table 1 Apnea-Hypopnea Index (AHI)

| Apnea-Hypopnea Index (AHI) Results | Total Sleep | REM | Non-REM |
| --- | --- | --- | --- |
| Total AHI | Events/Hr | Events/Hr | Events/Hr |
| Central Apnea Index | Events/Hr | Events/Hr | Events/Hr |
| Obstructive Apnea Index | Events/Hr | Events/Hr | Events/Hr |
| Mixed Apnea Index | Events/Hr | Events/Hr | Events/Hr |
| Hypopnea Index | Events/Hr | Events/Hr | Events/Hr |

Table 2 Mean SpO2

| Mean SpO2 | Total Sleep | REM | Non-REM | Awake |
| --- | --- | --- | --- | --- |
| (%) | % | % | % | % |

Table 3 SpO2 Distribution Results (% of total sleep time)

| SpO2 | Total Sleep | REM | Non-REM | Awake |
| --- | --- | --- | --- | --- |
| <95%(if available) | % | % | % | % |
| <90% | % | % | % | % |
| <80% | % | % | % | % |
| <70% | % | % | % | % |

Table 4 Number of drops of SpO2 by 3% or more per hour of sleep from baseline

| Number of drops of SpO2 | Total Sleep | REM | Non-REM | Awake |
| --- | --- | --- | --- | --- |
| Per hour | Data to be filled out by site | Data to be filled out by site | Data to be filled out by site | Data to be filled out by site |

Was End-Tidal CO2 (ETCO2) measured?

Yes, complete the table below  No, skip table below

Table 5 CO2 Results

| CO2 Results | Total Sleep | REM | Non-REM | Awake |
| --- | --- | --- | --- | --- |
| Mean ETCO2 | % | % | % | % |
| Minimum ETCO2 | % | % | % | % |
| Maximum ETCO2 | % | % | % | % |

Was Trans-cutaneous CO2 (TcCO2) measured?

Yes, complete the table below  No, skip table below

Table 6 Trans-cutaneous CO2

| Trans-cutaneous CO2 | Total Sleep | REM | Non-REM | Awake |
| --- | --- | --- | --- | --- |
| Mean TcCO2 | % | % | % | % |
| Minimum TcCO2 | % | % | % | % |
| Maximum TcCO2 | % | % | % | % |

Was there an increase in ETCO2 or TcCO2 of > 10mmHg at any time during sleep?

Yes  No

Table 7 Heart Rate Results

| Heart Rate Results | Total Sleep | REM | Non-REM | Awake |
| --- | --- | --- | --- | --- |
| Mean HR | BPM | BPM | BPM | BPM |
| Minimum HR | BPM | BPM | BPM | BPM |
| Maximum HR | BPM | BPM | BPM | BPM |

## General Instructions

This CRF contains data that would be collected when a pulmonary study is performed studying sleep and sleep disorders.

Important note: None of the data elements included on this CRF Module are classified as Core (i.e., strongly recommended for pediatric neuromuscular disease clinical studies to collect if pulmonary studies are performed). All data elements are classified as supplemental (i.e., non Core) and should only be collected if the research team considers them appropriate for their study. Please see the Data Dictionary for element classifications.

## Specific Instructions

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module*.*

The CRF includes all instructions available for the data elements at this time. More detailed instructions will be added in Version 4.0 of this CRF Module.

* Start Time of Sleep Study – The preferred format for recording time is HH:MM (24-hour clock). 99:99 can be used to indicate an unknown time.
* End Time of Sleep Study – The preferred format for recording time is HH:MM (24-hour clock). 99:99 can be used to indicate an unknown time.