THE COLLEGE OF PHYSICIANS AND SURGEONS OF ONTARIO

Independent Health Facilities

Sleep Medicine – Facility & Patient Record Review – Assessors' Checklist

INSTRUCTIONS: **Please complete (✓) the attached checklist during the assessment. Ensure that all the questions have been answered. Please do not leave any questions blank. A space has been provided at the bottom of each section for your comments.**

INDEPENDENT HEALTH FACILITIES
ASSESSORS PROTOCOL CHECKLIST – SLEEP STUDIES

Facility Name/No:_____ Date:_____

Services Provided in a Sleep Disorder Facility		Meets	Meets with Recommendations	Does not Meet	N/A
S1.1.1	Does the IHF provide consultation with a sleep medicine physician in all major areas of sleep medicine with the exception of Pediatric Sleep Medicine?				
S1.1.2	Does the IHF provide investigative services for facility assessment of sleep, sleep pathology, drowsiness and alertness including but not limited to polysomnography (PSG), MSLT, and MWT?				
S1.1.3	Do consultation and follow-up visits with sleep medicine physicians conform to MOHLTC standards including documented notes that include clearly stated opinions and recommendations, clear follow-up plans and clear, reasonable designation of who is responsible for ongoing care?				
S1.1.4	For the investigating and treatment of children less than 13 years of age, does the facility comply with the standards and guidelines detailed in the Pediatric section of the CPPS and FS?				
S1.1.5	When PSG is indicated, is an overnight study performed except when the patient's normal sleep schedule does not correspond to a normal day/night schedule?				
S1.1.6	When the study is performed at significant variance to the patient's habitual sleep schedule is this variance clearly justified in the clinical record and noted in the PSG report?				
S1.2.1	Does the facility perform in-lab Level diagnostic PSG based on the indications outlined in S1.2.1?				
S1.2.2	In a patient with a previous in-lab Level 1 diagnostic PSG, when a repeat diagnostic PSG is indicated does a sleep medicine consultant clearly document in the patient's chart that there have been significant changes in clinical history or findings or important diagnostic information for current management that cannot be obtained from a prior PSG?				
S1.2.3	Does the facility perform Level 1 in-lab therapeutic PSG based on the indications outlined in S.1.2.3?				
S1.2.4	When performing split-night PSG, does the facility ensure all the following condition as outlined in S.1.2.4 met?				
S1.2.5	Does the facility follow the indications for **NOT** performing PSG's?				
S1.2.6	Is a physician immediately available to make decisions and provide advice to facility staff re problems or issues with any aspect of the study?				
S1.3.2	Has a clinical assessment been performed by the sleep medicine physician prior to any sleep study to titrate or adjust therapy or being issued any prescription for therapy of a sleep disorder?				
S1.3.3	Has the facility met all the conditions when the initial PAP prescription precedes the patient's assessment by a sleep medicine physician?				

INDEPENDENT HEALTH FACILITIES
ASSESSORS PROTOCOL CHECKLIST – SLEEP STUDIES

Services Provided in a Sleep Disorder Facility		Meets	Meets with Recommendations	Does not meet	N/A
S1.4.1	Are MSLT's ordered for the evaluation of patient suspected of having narcolepsy, idiopathic hypersomnia, or with significant secondary hypersomnia that hasn't responded to therapy of a diagnosed sleep disorder?				
S1.4.2	Does the facility have a written protocol that meet the indications of when a repeat MSLT is warranted as outlined in the CPPS and FS?				
S1.4.3	Does the facility have a policy indicating when MSLT will not be performed?				
S1.4.4.	Does the MSLT protocol indicate a minimum of four 20 minute opportunities to fall asleep during the day beginning at 1.5-3 hours after awakening and recurring every two hours and is this protocol followed by staff?				
S1.4.5	If required, is an additional 5th nap performed if REM intrusion has occurred only once during the first four sleep opportunities?				
S1.4.6	Does the MSLT protocol follow all the elements as outlined in the CPPS and FS?				
S1.4.7	Does the scoring of the MSLT follow standard AASM sleep stage rules with the exception that any interval of clear REM physiology is to be scored as a REM intrusion, even if it doesn't meet criteria to score the entire epoch stage R?				
S1.5.1	Does the facility follow the indications for MWT in individuals whom inability to remain awake constitutes a safety issue?				
S1.5.2	Does the facility have a written protocol to appropriately select patients for MWT as outlined in in S1.5.2 in the CPPS and FS?				
S1.5.3	Does the MWT protocol indicate four 40 minute test intervals beginning 1.5-3 hours after the usual wake-up time and recurring every two hours?				
S1.5.4	Does the MWT protocol follow all the elements as outlined in S1.5.4 in the CPPS and FS?				
S1.5.6	Does the scoring of the MWT follow standard AASM sleep stage rules?				
S1.5.7	Are all deviations of this protocol or additions are documented in the report with justifications?				
S1.5.8	Is the normal value for the MWT average (+/- 2SD) sleep latency to the first epoch of sleep 30.4 +/- 11.2 minutes?				

INDEPENDENT HEALTH FACILITIES
ASSESSORS PROTOCOL CHECKLIST – SLEEP STUDIES

Facility Name/No:_____ Date:_____

Staff in the Facility		Meets	Meets with Recommendations	Does not Meet	N A
S2.2	Do the physicians providing services meet the expectations as outlined in the CPPS and FS?				
S2.6	Do physician who practice pediatric sleep medicine meet the qualifications as outlined in the CPPS and FS including the requirement of Change of Scope of Practice?				
S2.7	Do physicians who perform Mechanical Ventilation meet the training requirements with the ATS/ASDA accreditation document?				
S2.8	Is there a designated Quality Advisor?				
	• Is there a written agreement in place that acknowledges their role in connection with Quality Assurance and the duties and responsibilities as outlined in S2.8.1?				
S8.2.8.1	Does the QA personally attend the facility at least twice each year or more frequently where in the opinion of the QA it is necessary based on the volume and types of services provided in the facility?				
	• Does the QA document all visits to the facility made in connection with the QA's role?				
	• Does the QA ensure that a qualified physician is available for consultation during the facility's hours of operation?				
	• Does the QA seek advice from other health professionals where in the opinion of the QA it is necessary to ensure that all aspects of services provided in the facility are provided in accordance with generally accepted professional standards and provide such advice to the licensee?				
	• Does the QA chair the Quality Advisory Committee meetings?				
	• Does the QA ensure that regular agenda items such as review of cases, policies and procedures, quality control matters on equipment, incidents, medical and technical staffing issues are discussed?				
	• Are all QAC meetings documented?				
	• Does the QA obtain copies of assessment reports from the licensee; ensure that they are reviewed, and discussed with the QAC?				
	• Is there documented evidence that such a review has taken place?				
	• Does the Quality Advisor advise the licensee on the implementation of an ongoing QM program which should include but not limited to: • Ensuring ongoing and preventive equipment maintenance				
	• Follow-up of interesting cases				
	• Follow-up of patient and/or medical and technical staff incidents				

INDEPENDENT HEALTH FACILITIES
ASSESSORS PROTOCOL CHECKLIST – SLEEP STUDIES

STAFF IN THE FACILITY		Meets	Meets with Recommendations	Does not meet	N/A
	• Continuing education for medical and technical staff				
	• Ensuring certificates of registration, BCLS etc. are current				
	• Regular medical and technical staff performance appraisals				
	• Patient and referring physician satisfaction surveys				
	• Has the Quality Advisor fulfilled his duties and responsibilities as outlined with respect to advising the licensee on the facilities' quality management program?				
2.9	Has the facility appointed a Medical Director for the facility that meets the qualifications as outlined in the CPPS and FS?				
2.10	Does the Medical Director/Quality Advisor ensure all physicians in the facility maintain CPD relevant to the practice of sleep medicine which complies with their College?				
	• Are these activities documented at a minimum of 25 hours per year?				
	• Does these activities include attendance at case presentations, quality assurance work, journal reading, on-line education as well as attendance at local, national and international meetings?				
2.11.1	Does the facility hire Sleep Medicine Associates who provide consultation and follow-up visits within their medical specialty and scope of practice for patients diagnosed with sleep disorders?				
2.11.2	Does the facility have at a minimum one dedicated Registered Polysomnographic Technologist (PRSGT/RST)?				
	Does all staff providing direct patient care have current certification in cardiopulmonary resuscitation (BCLS/CPR)?				
2.11.2.1	Is the Technical Director registered by the Board or Registered Technologists (BRPT) or Registered Sleep Technologist (RST) and hold current certification in BCLS?				
2.11.2.1	Has a Technical Director been appointed by the facility and is this individual a member of the Quality Advisory Committee?				
	Does the Technical Director responsibility include but is not limited to: • Ensuring the Quality Assurance program is carried out?				
	• Ensuring appropriate patient appointments and staff work schedules for a safe patient: technologist ratio each night.				
	• Distributing to the referring physicians and agencies the test requisitions and the completed test reports.				
	• Maintaining proper policies and procedures				
	• Maintaining records of equipment calibration, maintenance, and repair procedures				

INDEPENDENT HEALTH FACILITIES
ASSESSORS PROTOCOL CHECKLIST – SLEEP STUDIES

STAFF IN THE FACILITY		Meets	Meets with Recommendations	Does not meet	N/A
	• Maintaining copies of test observations and reports				
	• Maintaining administrative records				
	• Ensuring that safety policies and the equipment and facilities necessary for their implementation are in place and in working order				
	• Ensuring the safe and reliable performance of tests				
	• Observing infection control measures				
	• Maintaining all necessary facility supplies				
2.11.2.3	Does the Technical staff employed by the facility meet the qualifications as outlined on pg 17 of the parameters and standards?				
2.11.2.4	Do the Technical Staff fulfill their duties including but not limited to: • Gathering and analyzing patient Information				
	• Explaining pre-testing, testing and post-testing procedures to patient?				
	• Prepare and calibrate equipment required for testing to determine proper functioning and making adjustments if necessary				
	• Apply electrodes and sensors according to accepted published standards				
	• Perform appropriate physiologic calibrations to ensure proper signals and make adjustments if necessary				
	• Perform positive airway pressure (PAP) titrations				
	• Follow procedural protocols to ensure collection of appropriate data				
	• Follow “lights out” procedures to establish and document baseline values (such as body position, oxyhemoglobin saturation, respiratory and hearts rates, etc.)				
	• Perform polysomnographic data acquisition while monitoring study tracing quality to ensure signals are artifact free and make adjustments if necessary				
	• Document routine observations together with associated sleep stages and clinical events, change in position, snoring and significant events in order to facilitate scoring and interpretation of polysomnographic results. Make use of notes in data collection to report on study and observations				
	• Create a summary of the night’s observations to include all physiological and polysomnographic events				
	• Implement appropriate interventions (including actions necessary for patient safety and therapeutic intervention such as continuous and bi-level positive airway pressure, oxygen administration, etc.) as indicated by the physician or facility specific policies and procedures				

INDEPENDENT HEALTH FACILITIES
ASSESSORS PROTOCOL CHECKLIST – SLEEP STUDIES

STAFF IN THE FACILITY		Meets	Meets with Recommendations	Does not meet	N/A
	• Follow "lights on" procedures to verify integrity of collected data and complete the data collection process (repeats the physiological and instrument calibrations and instructs the patient on completing questionnaires, etc.)				
	• Document and report any adverse events				
	Do Scoring Technologists: • Demonstrate knowledge and skills necessary to recognize and provide age specific care in the treatment, assessment and education of neonatal, pediatric, adolescent, adult and geriatric patients, appropriate to their patient population.				
	• Score sleep/wake stages by applying professionally accepted standards				
	• Score clinical events according to facility specific protocols – the scoring technologist must provide a documented summary of their findings for the interpreting physician				
	• Generate accurate reports by tabulating sleep/wake disorder and clinical event data				
	• Comply with applicable laws, regulations, guidelines and standards regarding safety and infection control issues				
	• Perform routine and complex equipment care and maintenance				
	• Evaluate sleep study related equipment and inventory				
	• Maintain current CPR or BCLS certification				
	• Demonstrate effective written and spoken communication skills				
	• Respond to study participant's procedural –related inquiries by providing appropriate information				
	• Demonstrate the ability to analyze complex situations and apply policy				
	• Comply with the Board of Registered Polysomnographic Technologist standards of conduct				
	• Does both full and part-time technical staff undertake continuing education activities directly relevant to the practice of sleep medicine which includes both accredited and non-accredited activities which must be documented at a minimum of 25 hours per year?				

INDEPENDENT HEALTH FACILITIES
ASSESSORS PROTOCOL CHECKLIST – SLEEP STUDIES

POLICIES AND PROCEDURES		Meets	Meets with Recommendations	Does not meet	N/A
3.1	Is there a policy and procedure manual for sleep studies available within the facility?				
3.2.1	***FACILITY*** Written policies and procedures are available for the following: • Overview of the lab				
	• Scope and limitation of services				
	• Map location of the lab				
	• Floor plan and emergency evacuation routes				
	• Organizational structure				
	• General office policies and procedures				
	• Patient Booking System and clinic patient flow				
	• New patient process including accepted referral sources; procedure to triage/process referrals and book appointments; standard procedure for consultations, office visits, diagnostic and treatment services, management of patient declining assessment or therapy				
	• Policies and standard procedures for follow-up of established patients				
	• Management and mandatory reporting of patients to the Ministry of Transportation				
	FACILITY STAFF • Appointment and role of the Quality Advisor				
	• Job descriptions of clinical and technical staff including BCLS &CME/CPD activities				
	• Delegated acts				
	• Training of new staff hires				
	FACILITY CONTACTS • Staff				
	• Technical support				
	• Building hydro and security				
	• Emergencies – Fire, Police, Hospitals				
	• Vendors				
	RECORDS AND COMMUNICATION/REPORTING &PRIVACY PRINCIPLES • Policies and procedure for record structure				
	• Policies for maintenance, storage &destruction as per the *IHF Act – Ontario Regulation 57/92 – Amended to O.Reg. 14/95*				
	• Policies for Protection of Personal Health Information and Privacy of Information				

INDEPENDENT HEALTH FACILITIES
ASSESSORS PROTOCOL CHECKLIST – SLEEP STUDIES

POLICIES AND PROCEDURES		Meets	Meets with Recommendations	Does not Meet	N/A
	• Patient Consent and Procedures				
	• Reporting Policies and Procedures of consultations and tests				
	• Standard forms including (but not limited to): requisitions, flow sheets, handouts and prescriptions, logs, incident/accident/complaint forms				
3.2.5	***DIAGNOSTIC AND THERAPEUTIC SERVICES (ADULT)*** • Scope and limitations of services				
	• Patient preparation				
	• Methods for performing each test				
	• International 10-20 system				
	• Equipment and physiological calibration				
	• Methods of performing each test including, but not limited to: CPAP, Bilevel PAP, ASV, $ETCO_2/TCO_2$, Split, supplemental O_2, MSLT, MWT				
	• Artifact recognition and remedies				
	• Data analysis and interpretation including AASM and lab specific scoring rules				
	• Normal values for tests in the lab including but not limited to Sleep Architecture, Respiratory Events, Periodic Leg Movements, Arousals, MWT and MSLT				
	• Scoring Manual				
3.2.7	***EQUIPMENT MAINTENANCE (ADULT)*** • Equipment list				
	• Routine maintenance, validation and calibration of equipment (logs to be maintained separately for these procedures)				
3.2.8	• Basic supplies for infection prevention and control is on site and used appropriately as per current provincial guidelines/policies.				
	• Equipment and disinfecting procedures				
	• Universal precautions and waste disposal procedures				
	• Policies for containing highly contagious infections e.g. SARS, Ebola, influenza etc.				
3.2.9	***EMERGENCY PROCEDURES AND SAFETY POLICIES*** • Fire safety and evacuation plan				
	• General safety and prevention of adverse effects of testing procedures				
	• Policy for Oxygen administration and storage				

POLICIES AND PROCEDURES		Meets	Meets with Recommendations	Does not meet	N/A
	• Specific first aid measures and emergency procedures for: syncope, cardiac arrest/respiratory arrest, chest pain, shortness of breath, Automated External Defibrillator, suspected seizures, suspected Stroke or TIA, suspected hyper or hypoglycemia, other medical or psychiatric emergencies, how to arrange for transfer of patient to a hospital				
	• Safety equipment list and medication storage and control				
	• Policies for staff and patient security: general security policies and procedures; inappropriate patient behavior; sexual harassment or abuse of patients or staff; workplace violence and harassment.				
	• Current Workplace Hazardous Materials Information System (WHMIS) and Material Safety Data Sheets (MSDS)				
	• Current BCLS/CPR certification (according to current Heart & Stroke Association Guidelines)				
	• Annual Fire Drill for staff				
3.2.10	General policies on dealing with and documenting incidents and complaints in the facility including follow-up.				

Comments:

INDEPENDENT HEALTH FACILITIES
ASSESSORS PROTOCOL CHECKLIST – SLEEP STUDIES

FACILITIES, EQUIPMENT, TEST COMPONENTS & SUPPLIES STANDARDS		Meets	Meets with Recommendations	Does not meet	N/A
BUILDING, FACILITY AND EQUIPMENT STANDARDS					
S4.2.2.	***Building Codes:*** Does the Sleep facility conform to the appropriate municipal and provincial regulations governing fire safety standards, accessibility standards, building standards, and medical gas systems?				
S4.2.3	***Electrical*** Is all medical equipment properly grounded?				
	• Is all medical equipment with the exception for the recording wires physically away from the patient?				
	• Does all electro-medical equipment adhere to the Canadian Electric Codes for Electromechanical Equipment or its equivalent according to the appropriate Risk Class?				
S4.2.4	***Access*** Does the facility fully comply with the requirements under the Accessibility for Ontarians with Disabilities Act 2005 (AODA)?				
S4.2.5	***Layout*** Is each bedroom quiet, with appropriate ambient temperature control?				
	Are the washrooms easily accessible to patients ensuring that washroom doors are wheelchair accessible?				
	Do the equipment permit the technical staff to monitor each patient unobtrusively and permits the patient to communicate with the technical staff in the event that he/she requires assistance?				
	Does the facility have the capability to administer supplemental oxygen to patients while following the facility's protocol to administer supplemental oxygen?				
S4.2.6	***Fire Safety*** Are flow plan and evacuation route diagrams posted in each room for easy orientation and evacuation?				
	Does the facility ensure that emergency exits are not blocked and fire barrier doors are not proposed open?				
	Is there a fire safety manual available and reviewed annually and signed off by staff?				
	Does the fire safety manual include: • Responsibilities for fire prevention				
	• Classes of fires and extinguishers				
	• Steps for safe storage of oxygen cylinders				
	• Plans for reporting a fire				

FACILITIES, EQUIPMENT, TEST COMPONENTS & SUPPLIES STANDARDS		Meets	Meets with Recommendations	Does not meet	N/A
	• Emergency evacuation				
	• Plans and maps				
	Is there a facility specific fire evacuation plan and fire drill prepared and practiced annually and is this documented?				
	Is the building and facility in compliance with the applicable building code and equipped with safety equipment such as: fire alarms, smoke detectors, carbon monoxide detectors, fire extinguishers and/or sprinklers?				
	Is the location and functioning of the fire extinguisher, smoke detector and carbon monoxide detectors checked regularly and logged by a fire safety company?				
	Are emergency phone numbers are posted near all phones?				
S4.2.7	Is the following emergency equipment available at the facility: • Ambubag with mask interface				
	• Resuscitation (CPR) board				
	• Airway - adult and paediatric (if conducting paediatric studies)				
	• First Aid Kit				
	• Oxygen concentrator/cylinders with nasal cannula or a T-connector for patients undergoing CPAP titration				
	• Automated External Defibrillator				
4.3	***TEST COMPONENTS AND SUPPLIES***				
4.3.1	Level 1 Sleep Study – Are the required equipment and test components utilized as outlined on in the subsequent pages?				
	• Are impedances less than 10,000 ohms but less than 5,000 ohms which is preferred?				
	Do Level 2 Sleep Studies utilize the appropriate equipment and test components?				
4.4	Studies Assessing Drowsiness, Sleep Structure During Naps, and Ability to Stay Awake/Alert - Are the required equipment and test components utilized on the subsequent pages?				
4.5	***Other Procedures***				
4.5.6	Are the requirement and test components utilized as outlined on the subsequent page for seizure montage?				
	Is the current AASM Manual for the Scoring of Sleep and Associated Events – Rules, Terminology and Technical Specifications which is the standard for sleep disorder facilities used by the facility?				

INDEPENDENT HEALTH FACILITIES
ASSESSORS PROTOCOL CHECKLIST – SLEEP STUDIES

Level 1 Sleep Study – Required Equipment and Test Components

Impedances need to be less than 10,000 ohms but less than 5,000 ohms is preferred.

- **Electroencephalogram (EEG) –** The recommended derivations are F_4-M_1, C_4-M_1, O_2 –M_1 . The back up derivations are: F_3-M_2, C_3-M_2, O_1-M_2.

- **Electrooculogram (EOG) –** E1-M2 (E1 is placed 1 cm below the left outer canthus); E2-M2 (E2 is placed 1 cm above the right outer canthus**)**

- **Electromyogram –(EMG) –** Two or three electrodes are placed to record EMG: one midline 1 cm above the inferior edge of the mandible and one 2 cm below the inferior edge of the mandible and 2 cm to the right of the midline and/or 2 cm below the centre of the inferior edge of the mandible and 2 cm to the left of the midline. The standard chin EMG derivation consists of either of the electrodes below the mandible referred to the electrode above the mandible. The other inferior electrode is a backup electrode to allow for continued display of EMG activity if one of the primary electrodes malfunctions. For diagnosis of REM Behaviour Disorder (RBD), along with Chin EMG electrodes, time synchronized, audio equipped video PSG is essential to document complex motor behaviours and vocalizations during REM sleep. A diagnosis of RBD is based on such episodes or a characteristic clinical history of dream enactment in addition to PSG evidence of a lack of chin EMG atonia in REM sleep. ***Note: For accurate electrode placement, the patient should be asked to activate the specified muscles so the muscle can be more readily felt. Anterior tibalis – Patient should raise their foot or tape their foot up and down.***

- **Limb Movement EMG:** For monitoring leg movements (LM), surface electrodes are placed longitudinally and symmetrically in the middle of the anterior tibialis muscle so that they are 2 to 3 cm apart or 1/3 of the length of the anterior tibialis muscle, whichever is shorter. Both legs are monitored for the presence of the leg movements. Separate channels for each leg are strongly preferred. Combining electrodes from the 2 legs to give 1 recorded channel may suffice for some clinical settings, but this strategy may reduce the number of LM's detected. Sensitivity limits of -100 and 100 µV (upper/lower) are preferred. Use of 60 Hz (notch) filters should be avoided. Impedances need to be less than 10,000 Ohms. Less than 5,000 Ohms is preferred but may be difficult to obtain. Movements of the upper limbs may be sampled using a similar method as for legs if clinically indicated, or necessary.

- **Respiratory Diagnostics:** The sensor for detection of blood oxygen is pulse oximetry with a maximum acceptable signal averaging time of 3 seconds. The sensor to detect absence of airflow for identification of apneas is an oronasal thermal sensor. The sensor for detection of airflow for identification of a hypopnea is a nasal air pressure transducer, with or without square root transformation of the signal. The sensor for detection of respiratory effort is either Piezoelectric belts, esophageal manometry, or calibrated or uncalibrated inductance plethysmography.

- **Respiratory Therapeutic:** The sensor for detection of blood oxygen is pulse oximetry with a maximum acceptable signal averaging time of 3 seconds. To detect airflow include the digital flow signal integrated from the PAP unit. Include the digital mask leak reading (with or without intentional leak accounted for) from the PAP unit. For BPAP studies in particular, include the digital pressure reading and the tidal volume where available. The sensor for detection of respiratory effort can be Piezoelectric belts, esophageal manometry, or calibrated or uncalibrated inductance plethysmography**.** ***(Note: Alternative sensors or signals must be used when the signal from the recommended sensor is not reliable. Alternative signals or sensors include: nasal pressure transducer to detect absence of airflow for identification of an apnea when the oronasal thermal sensor (thermistor) signal is unreliable. Uncalibrated or calibrated inductance plethysmography or an oronasal thermal sensor to score hypopneas when the nasal pressure device is not functioning.***

- **Electrocardiogram (ECG) –a single modified electrocardiograph Lead II using torso electrode placement.** *Note: Additional leads may be placed if clinically indicated by physician)*
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- **Ancillary Equipment: Arterial Oxygen Saturation – oximeter, external oximeter for validation; body position sensor; infared/low light audio/visual capability with ability to record.** *Note: Each bed must have an audio visual system of sufficient quality to identify and assess snoring while continuously monitoring patients.*
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- **Optional Equipment:** Transcutaneous or end tidal carbon dioxide, body position sensors, snoring sensors/microphones (independent of the room microphone for patient communication).

Studies Assessing Drowsiness, Sleep Structure During Naps, and Ability to Stay Awake/Alert (MSLT/MWT)

The required nap test components for all types of sleep studies include:

- **Electroenceophalogram (EEG):** The recommended derivations are: F_4-M_1, C_4-M_1, O_2-M_1.
- **Electrooculogram (EOG):** E1-M2 (E1 is placed 1 cm below the left outer canthus). E2-M2 (E2 is placed 1 cm above the right outer canthus)
- **Electromyogram (EMG):** Two or three electrodes are placed to record EMG – one midline 1 cm above the inferior edge of the mandible **and** One 2 cm below the center of the inferior edge of the mandible and 2cm to the right of the midline, and/or 2 cm below the center of the inferior edge of the mandible and 2 cm to the left of the midline. The standard chin EMG derivation consists of either of the electrodes below the mandible referred to the electrode above the mandible. The other inferior electrode is a backup electrode to allow for continued display of EMG activity if 1 of the primary electrodes malfunctions.
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- **Electrocardiogram (ECG)**: A single modified electrocardiograph Lead II using torso electrode placement. ***Note: Additional leads may be placed if clinically indicated by physician.***
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- **Audio Visual:** Monitoring of all patients for recording events of interest or special studies (ancillary equipment). Each bed must have an audio visual system of sufficient quality to identify and assess snoring while continuously monitoring patients.

Other Procedures

A larger number of bilateral EEG leads is required (seizure montage) including biopolar derivations assuring coverage of frontal and temporal regions: Fp1-F7-T3-T5-01; Fp1-F3-C3-P3-01; Fp1-Fz-Cz-Pz-O2; Fp2-F4-C4-P4-O2; Fp2-F8-T4-T6-O2.

INDEPENDENT HEALTH FACILITIES
ASSESSORS PROTOCOL CHECKLIST – SLEEP STUDIES

REQUESTING AND REPORTING MECHANISMS		Meets	Meets with Recommendations	Does not Meet	N/A
5.2	***REFERRALS*** Are all referrals received by the facility triaged to: • confirm it is appropriate for the facility to provide the assessment requested				
	• determine if more information is required before further action				
	• determine if there is information that would improve the assessment				
	• assign appropriate priority for assessment				
	• assign the initial components of assessment and the sequence of those components. In particular triage must reliably identify patients who require, and patients whose care would be optimized, by clinical assessment preceding any sleep lab testing				
	Is triage performed by a sleep physician?				
	If not, is the triage done by an appropriately trained designate with a knowledge of sleep medicine?				
	• Is there a comprehensive written protocol detailed in the facility's policies and procedures manual which is designed to reach the requirements noted above, should the sleep physician chose to delegate this task?				
	• Is final approval of the triage for each case made by a sleep medicine physician?				
	Are there mechanisms in place to: • Identify patients who should be seen urgently, and tracked so they are seen in a timely manner?				
	• Discuss cases where appropriate triage is unclear, with a designated sleep medicine physician if a non-physician is doing triage, or with the Medical Director if the triage is being done by a sleep medicine physician				
	• Check that triage targets are being adequately met?				
	Does the Quality Advisor measure and evaluate the effectiveness of any such triage process as part of their Quality Management Program.				
	Do the referrals contain the following: • signature of the physician, surgeon or nurse practitioner				
	• demographic data including any medical conditions and medications				
	• clinical information relevant to the referral				
	• options for "Study Only", "Consultation", or "Both"				
	• each diagnostic or therapeutic study, or split night study, or Home Sleep Apnea (HSAT) requires a separate specific requisition?				

5.3	***ELECTRONIC RECORDS***	**Meets**	**Meets with Recommendations**	**Does not meet**	**N/A**
5.3.1	Do the computer based records conform to the *Components of Medical Records Required by Law*. Ontario Regulation 114/94 Section 20 made under the Medicine Act, 1991?				
5.3.2	Are log books maintained by the facility for the following: • Patient Log – patient's name, date of referral, referring physician, date of study, recording technologist, scoring technologist and reporting date?				
	• Incident Log – all adverse health effects occurring during testing, action taken and outcome?				
	• Maintenance Log – all maintenance, repair, and calibration procedures performed, results obtained and where appropriate, corrective action taken?				
5.4.2	Is the visual scoring of the polygraph-generated reports based on the materials presented in *The AASM Manual for the Scoring of Sleep Associated Events – Rules, Terminology and Technical Specifications?*				
	Is the facility compliant with: • The new AASM rules for EEG, EOG, EMG and respiratory signals, including using both thermal and nasal pressure sensors to record respiratory events?				
	• Having modified the reporting software to reflect the parameters to be reported and the new sleep stage terminology?				
	• Scoring stages and events according to the new rules?				
5.6	For patients who have been tested and CPAP or other positive pressure therapy is being supplied on a trial or final basis, does the sleep facility ensure the patient is aware of the ADP program and there is evidence that the patient has signed a document demonstrating their awareness that they can choose a vendor of their choice?				

Comments:

INDEPENDENT HEALTH FACILITIES
ASSESSORS PROTOCOL CHECKLIST – SLEEP STUDIES

QUALITY MANAGEMENT PROGRAM		Meets	Meets with Recommendations	Does not Meet	N/A
S6.1.1	Does the facility have a Quality Management Program supervised by a Quality Advisory Committee (QAC) as set out in the IHFA Regulations?				
S6.1.2	Does the Quality Advisor fulfill his duties and responsibilities as outlined in Chapter 2- Staffing a Facility?				
S6.1.3	Does the QAC consist of the Quality Advisor, Technical Director and at least one other health care professional who provides health services in, or in connection with, the IHF; including at least one technologist who conducts overnight PSG at the IHF, who may be the Technical Director?				
S6.1.4	Does the QAC supervise the creation and maintenance of a quality management program to reach specific goals detailed in the policies and procedures manual?				
S6.1.5	Does the QAC meet at least twice a year with proceedings documented in official minutes maintained by the Quality Advisor or their designate?				
	• Do the minutes include all recommendations or conclusions reached by the QAC?				
	• For members who cannot attend the QAC meeting, review the minutes of that meeting and sign that they concur with each decision, or comment in detail?				
	• Are all such comments reviewed by the Quality Advisor and action documented or another meeting organized, as appropriate?				
S6.1.8	If all items on the agenda are not discussed at the QAC meeting, does the Quality Advisor ensure the minutes include a brief statement about the item(s) and when they will be discussed?				
S6.1.9	Do regular QAC agenda items include: • All issues raised by any accreditation visit and that such issues remain on the agenda until they are clearly finalized?				
	• Any incidents or complaints recorded or received since the last meeting?				
	• Any staff or staffing issues submitted to the QAC				
	• Review of current statistics on the time between referral and subsequent events				
	• Review of recent difficult or inconclusive cases				
	• All equipment or lab configuration issues new or unresolved since the last meeting that have quality assurance implications				
	• Review of referrer and client satisfaction surveys				
	• Status of the systematic review of the facility's policies and procedures				
	• Any items from previous agendas that have not been finalized				

INDEPENDENT HEALTH FACILITIES
ASSESSORS PROTOCOL CHECKLIST – SLEEP STUDIES

QUALITY MANAGEMENT PROGRAM		Meets	Meets with Recommendations	Does not meet	N/A
6.2	***QUALITY MANAGEMENT PROGRAM GOALS***				
S6.2.1	Are program goals detailed in the facility's manual and include but are not limited to the following? • Services provided in the facility are safe?				
	• Services provided are appropriate to the problem(s) being investigated				
	• Services provided are done in accordance with recommendations and standards available at the facility and published by: CPSO, Canadian Sleep Society; or Ontario Medical Association or the Canadian Medical Association?				
	• If no applicable recommendation or standard has been published by any of the organizations noted above, is the service provided in accordance with recommendations and standards available at the facility published by the American Academy of Sleep Medicine or the European Sleep Society or a peer reviewed journal in the field?				
	• Ensuring indications for each sleep study are adequately documented?				
	• A system to deal with incomplete or inappropriate requests for services, such as a request for a sleep study without consultation on a patient with insomnia, or a request for assessment of a pediatric patient in a facility that is not staffed or equipped for such work?				
	• Studies are conducted so that results are accurate, with minimal artifact, and minimal variation or error in procedure?				
	• Testing is scored accurately and consistently in accordance with currently published standards and methods as noted above?				
	• Studies are interpreted correctly and as completely as possible from the data, with interpretation that addresses the clinical issues and questions raised that is not limited to assessment of sleep disordered breathing when there are other significant issues or findings?				
	• Study Reports contain clear plans for management including reference to the problems or questions raised by the patient, the referring physician, and the physician requisitioning the study?				
	• Study reports detail clear plans for follow-up with clear assignment of responsibility for follow-up?				
	• Are the reports completed and transmitted to the referring and other relevant health care providers promptly?				
	• Do staff maintain up-to-date knowledge of sleep medicine appropriate to their role at the facility in accordance with current guidelines for continuing education from the relevant professional societies, colleges, academies and/or association?				

INDEPENDENT HEALTH FACILITIES
ASSESSORS PROTOCOL CHECKLIST – SLEEP STUDIES

QUALITY MANAGEMENT PROGRAM		Meets	Meets with Recommendations	Does not meet	N/A
S6.3.1	Does the Quality Advisor ensure all the following standards are completed and appropriately documented by the Quality Advisor and the Quality Advisory Committee, or an appropriate designate?				
S6.3.2	Is a review of the quality goals and objectives reviewed by staff annually?				
S6.3.3	Is the facility policy and procedures manual reviewed and revised systematically such that the entire manual is reviewed and revised within a 5 year cycle?				
S6.3.4	Are MSDS sheets maintained in the facility with any new MSDS/WHMIS reviewed at the next QAC meeting with any appropriate policies and procedures added to the facility manual?				
S6.3.5	Review of safety data on any equipment new to the facility since the last meeting to ensure that all equipment in the facility meets safety standards?				
S6.3.6	Is all staff or patient complaints, and all incident or any accident reports since the last meeting discussed at the next QAC meeting with documentation of any actions taken to prevent similar issues?				
S6.3.7	Does the facility have a program to periodically calibrate and validate facility equipment with results of any corrective actions if required and the outcome of those actions reviewed and documented by the Quality Advisory Committee?				
S6.3.8	Does the QAC review the tests and procedures conducted at the facility each year for anomalous or unusual patterns, particularly if any patterns were noted in an assessment of the facility?				
S6.3.9	Does the QAC supervise and document a review, at least annually, of a random selection of at least 10 polysomnograms records, including a selection of diagnostic and therapy/split studies to ensure that: • Any tests conducted were appropriate to the problems presented by the patient, and to any issues or clinical questions raised by the referring/ordering health care provider?				
	• Technical problems or issues encountered during the study were clearly documented and appropriately addressed during the study?				
	• Any treatment introduction/titration conducted was clearly indicated, appropriate to the problems presented by the patient properly conducted?				
S6.3.10	Does the QAC supervise and document a review, at least annually, of a random selection of at least 1% of records, or 10 records, whichever is greater, to ensure that Home Sleep Apnea Testing (HSAT) was utilized appropriately?				
S6.3.11	Does the QAC supervise and document both internal and external programs checking inter-scorer reliability of all scoring technicians/technologists as outlined on the following page?				
	Does the QAC supervise and document internal and external programs checking the interpretation of polysomnograms for all sleep medicine physicians as outlined on the following page?				

INDEPENDENT HEALTH FACILITIES
ASSESSORS PROTOCOL CHECKLIST – SLEEP STUDIES

TECHNOLOGIST SCORING

INTERNAL FACILITY PROGRAM: A sample of at least 2 hours of scoring for all parameters from a minimum of 10 PSG records (and an additional 10 HSAT records if applicable) is to be checked by another board registered technologist at least annually. The committee is to document action taken and results achieved to correct any significant anomaly in scoring patterns that are identified with a further review of any technician/technologist with significant scoring anomalies to take place within 3 months.

EXTERNAL PROGRAM: All scoring technologists are to participate in a regular external assessment/review, such as the American Academy of Sleep Medicine Inter-Scorer Reliability Program, or similar – using that program's standards. The committee is to document action taken and results achieved to correct any significant anomalies identified, with a further review is to take place within 3 months. If significant scoring anomalies by any technician/technologist persist at the 2nd review in either of the programs listed above, then all records from that scorer are to be reviewed in detail, corrected, and countersigned by the facility's Technical Director until the QA committee demonstrates and documents that the anomalous pattern has been resolved.

SLEEP MEDICINE PHYSICIAN RECORD REVIEW AND REPORTING

INTERNAL PROGRAM: A sample of at least 5 randomly selected diagnostic polysomnograms and at least 5 randomly selected therapy or split night polysomnograms is to be reviewed at least annually by a sleep medicine physician who meets the qualifications outlined in this manual, and who did not interpret the study. At least one study must be included from each physician interpreting studies at the facility. If there is only one physician interpreting studies at a facility then an internal program is not required.

EXTERNAL PROGRAM: Every facility must have a minimum of 10 randomly selected representative records (and an additional 10 HSAT records if applicable) reviewed annually by a sleep medicine physician from another facility, who meets the qualifications outlined in this manual. Both review processes are to assess whether or not:

1. The studies done were appropriate to the problems presented;
2. The studies were done following appropriate protocols
3. The results were reported and interpreted correctly
4. Clear and appropriate recommendations and suggestions were made to the referring physician.

The Quality Advisor shall document that they have:

1. Reviewed both the internal and external review reports at least annually
2. Discussed all comments and recommendations with the relevant physician(s) and/or technologist(s) and
3. Undertaken any appropriate action or follow-up

INDEPENDENT HEALTH FACILITIES
ASSESSORS PROTOCOL CHECKLIST – SLEEP STUDIES

QUALITY MANAGEMENT PROGRAM		Meets	Meets with Recommendations	Does not meet	N/A
S6.3.12	Does the QAC supervise and document a program of annual performance reviews for all staff who have patient contact, including documentation of action taken to correct any significant deficiencies in performance?				
	• Ensure that all registration certificates, BCLS certificates are valid and current for all staff?				
	• Ensure the review of CPD activities of the technical and medical staff meets the relevant College or Society requirements?				
S6.3.13	Does the QAC arrange regular discussion of interesting/challenging cases seen at the facility at least annually, and ensure any teaching points are disseminated to the staff?				
S6.3.14	Does the QAC review any training or education program at the facility and prepare a brief report on the program at least annually for discussion at a QAC meeting?				
S6.3.15	Does the QAC document corrective action for anomalies identified in any of the reliability checks detailed above, and document further checks that show effectiveness of the corrective action?				
S6.3.16	Does the QAC review results from regular surveys of patient, physician and staff satisfaction conducted at least annually and documents actions to address any suggestions, problems or issues raised?				
	MONITORING THE PROGRAM				
S6.4.1.	Is the Quality Advisor carrying out their responsibilities for all aspects of the program including any aspect delegated to any other staff member?				
S6.4.2	Are the minutes of each QAC meeting circulated to all members of the QAC for comment and revision, finalized by the Quality Advisor and circulated to all staff?				
	• Are the recommendations from the QAC reviewed at a General Staff meeting at least annually which includes all staff who provide health services in or in connection with the facility?				
	• If the staff is unable to attend do they review meeting minutes and sign that they concur or comment?				
S6.4.3	Are records maintained at the facility and include: • Minutes of the Quality Advisory Committee?				
	• Minutes of General Staff Meeting?				
	• All the reviews and surveys noted above, and any subsequent commentary/suggestions/ recommendations/follow-up?				

INDEPENDENT HEALTH FACILITIES
ASSESSORS PROTOCOL CHECKLIST – SLEEP STUDIES

QUALITY MANAGEMENT PROGRAM		Meets	Meets with Recommendations	Does not meet	N/A
6.5	***QUALITY MANAGEMENT OF OUTSOURCED STUDY SCORING***				
S6.5.1	Does the facility that utilizes an external service for scoring PSGs follow all of the components of a Quality Management Program detailed above?				
S6.5.2	Does every scoring technologist have timely and complete access to all technical notes taken during the study and to all other appropriate data collected pre-and post- study including the requisition and all questionnaires?				
S6.4.3	Is there at least one staff member who attends the facility who is trained and experienced in scoring PSGs and who participates in an external assessment/review program as detailed above with acceptable results that re documented in the facility?				
S6.4.4	Does the external service maintain regularly updated documentation that any service utilized completes their own internal and external facility programs as noted above?				
	• If the external services does not have regularly updated evidence of such programs, does the facility access the raw data and must be able to generate reports and snapshots from the record without unreasonable delay?				
S6.4.5	As the facility that utilizes any form of external scoring of sleep studies owns the records, does the facility ensure that these records are maintained and stored in accordance with applicable laws?				
	• Does the facility have the ability to access the raw data and are able to generate reports and snapshots from the record without unreasonable delay?				

INDEPENDENT HEALTH FACILITIES
ASSESSORS PROTOCOL CHECKLIST – SLEEP STUDIES

Note: Please complete only for facilities who provide Pediatric Sleep Studies

PERFORMANCE, DIAGNOSIS AND MANAGEMENT OF PEDIATRIC SLEEP RELATED DISORDERS		Meets	Meets with Recommendations	Does not meet	N/A
7.2	***DEFINITIONS***				
	Does the facility adhere to the relevant definition of pediatric patients as described in the standards				
	Does the facility have • Personnel with the necessary knowledge regarding pediatric sleep disorders, sleep disordered breathing, as well as normal childhood development and diseases?				
	• Staff knowledgeable of and use the appropriate scoring criteria for each age range?				
	• Appropriate equipment for the ages studies (appropriate sized cribs, facilities for the parent to sleep, for breast feeding etc.)?				
7.3	***STAFFING***				
	Physician – Do the physician who practice in the area of pediatric sleep medicine meet the qualifications as outlined in Chapter 2 of the standards including meeting the requirement of Change of Scope of Practice?				
	Facility Physician – Is the sleep facility physician aware of: • The age-appropriate rules for scoring sleep studies to ensure quality assurance while overseeing the technologist?				
	• The physiologic changes occurring during normal childhood, as well as the presentation and pattern of sleep associated disorders occurring at different ages in order to accurately interpret the study?				
	Sleep Technologist Is the technologist aware of the appropriate sensors to be used in children, as well as the age-appropriate techniques required for setting up a sleep study in uncooperative subjects?				
	Do the sleep technologists demonstrate knowledge of the age-appropriate criteria rules for scoring pathologic events, as well as the normal values (AASM Manual for the Scoring of Sleep and Associated Events)?				
	Do the technologists receive sufficient on the job training (minimum 3 months, with primary responsibility for the setting up and scoring of at least 20 pediatric sleep studies) from an experienced technologist (mentor) to provide them with sufficient knowledge and technical expertise?				

INDEPENDENT HEALTH FACILITIES
ASSESSORS PROTOCOL CHECKLIST – SLEEP STUDIES

Note: Please complete only for facilities who provide Pediatric Sleep Studies

PERFORMANCE, DIAGNOSIS AND MANAGEMENT OF PEDIATRIC SLEEP RELATED DISORDERS		Meets	Meets with Recommendations	Does not meet	N/A
7.4	***Sleep Disorder Facility***- Is the facility set up specifically for the age range of children to be studied?				
	Is there a clear system of triage for all referrals made to the facility, with a physician designated specifically triage pediatric referrals?				
	In patients with severe and unambiguous OSAS, is there a clear list of protocols for the use of split night studies available?				
7.5	***Equipment Standards*** Is the following equipment available for infants or young children: CO2 monitor; Oxyhemoglobin saturation; chest and abdominal respiratory bands; bedding and accommodation; resuscitation equipment?				
7.10	Does the facility follow the appropriate indications for a follow-up polysomnography study include: • Monitoring of CPAP therapy due to changes in the following significant change in body weight or body structure due to growth?				
	• Reoccurrence of snoring or gasping in sleep on CPAP?				
	• Development of daytime sleepiness				
	• Failure of response to prescribed treatment or a change in symptoms				
	• Change in compliance				
	Initiation of Bi-Level Positive Airway Pressure Therapy (BiPAP/CPAP)?				
	Titration of ventilator settings (invasive and noninvasive) with disease and symptom progression in patients with respiratory control disorder?				
	Following a surgical procedure of the upper airways (adenotonsillectomy) if there is reason to doubt less than complete success (persisting snoring)?				
	Adjustment of and determining the efficacy of oral appliance therapy for obstructive sleep apnea?				
	A significant change or development of a medical condition including cardio-respiratory, neuro-psychiatric and/or sleep disorder?				

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