Center for Human Phenomic Science
Sleep Core Protocol and IRB Language

Polysomnogram/Sleep Study

Protocol Description

Overnight polysomnography will be performed in the pediatric sleep laboratory. The following parameters will be recorded using sleep diagnostic software (Polysmith, Tokyo, Japan): electroencephalogram, electro-oculogram, submental and tibial electromyograms, chest and abdominal wall movement by inductance plethysmography (Respitrace, Ambulatory Monitoring Inc., Ardsley, NY); ECG; airflow by nasal pressure (Pro-Tech, Mukilteo, WA), and three-pronged thermistor (Pro-Tech), end-tidal PCO_2 (Novametrix 7000; Novametrix, Wallingford, CT); arterial oxygen saturation, and digital, infra-red video. The infra-red video is a component of any sleep study that is crucial for polysomnography interpretation as it provides information on breathing patterns, parasomnias, movements, and seizures. The following parameters will be determined using standard pediatric techniques and the latest American Academy of Sleep Medicine pediatric scoring guidelines: sleep architecture, apneas and hypopneas, arterial oxygen saturation (S_pO_2) and end-tidal carbon dioxide tension ($ETCO_2$).

Consent Description

A sleep study is a standard clinical test that is not experimental. It will tell us if you have obstructive sleep apnea or not. The sleep study is done overnight in the sleep lab at Children's Hospital of Philadelphia. Small patches will be placed on your skin on your head, face, chest, and legs. These patches will be connected by wires to machines in a separate monitoring room to monitor your breathing, heart rate, and sleep stage. You will wear stretchy belts around your chest and abdomen and a tube under your nose to measure your breathing. You will also be videotaped, so that the doctor can see your breathing pattern during sleep. Your mom or dad or other designated adult caregiver will sleep in the same room as you.

Consent Risks

Minor skin irritation is possible from the patches put on the skin similar to other adhesives. Sleeping away from home may make you feel uncomfortable. However, another family member will sleep in the same room with you.

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Actigraphy

Protocol Description

days of actigraphy will be obtained, using a n antigraphy watch (Actiwatch 2, Philips Respironics, Murrysville, PA). Actigraphs are small activity meters that are the size and shape of a wristwatch. It will be worn on the non-dominant wrist. The actigraph has an internal sensor that detects movement and translates this information to digital counts across pre-designed epoch intervals (e.g., 1 minute) which are stored in the internal memory. (*Discuss when the actigraph will be given to the family and how it will be returned to the lab to be downloaded*). Caregivers will complete a simultaneous sleep diary. Discrepancies between the actigraphic data and the sleep diary will be identified, and the actigraphy record annotated for periods when the device was off or where the actigraphy record was not congruent with behavior. The data will be analyzed to estimate sleep continuity variables using the Actiware software (Philips Respironics, Murrysville, PA). The primary outcome variable will be the total sleep time (defined as the number of minutes between bedtime and wake time, minus the nocturnal wake time in minutes) averaged over all nights of measurement for the subject. Secondary variables of interest will include time of sleep onset, wake time, sleep efficiency, and number of minutes of wake after sleep onset.

Consent Description

You will be asked to wear a device similar to a wristwatch, called an actigraph, for 7 days. This device records movements and will show us when you get up and when you go to sleep, so we can know your sleep habits. You will fill out a diary about your sleep habits during this time.

Consent Risks

Actigraphy could cause mild discomfort similar to a wristwatch.

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