

RESEARCH VS. CLINICAL: A COMPARISON OF THE TWO WORLDS OF SLEEP

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The time is 2015 at the research sleep lab as I wait anxiously for my eight-o'clock subject to arrive. The subject is participating in a Phase II, Double Blind, Multi-center, investigational drug study for the treatment of chronic insomnia. A research study is performed by following clinical procedures according to the study's "protocol;" the so-called Bible for the research sleep technologist. Process-oriented information is found within the protocol's study binder. Prior to the subject's arrival, I have prepared for my nightly routine. The room is setup and the subject's information is entered into the computer.

While waiting, I review the "check list" of evening's procedures and notice that it is time to begin the data collection. The procedures performed are called inclusion/exclusion criteria. The criteria may vary depending on the research study; though the subject is essentially required to pass specific criteria in order to continue. Once the inclusion criteria have been satisfied I, the

sleep technologist, can now proceed with electrode placement and administer study drug medication to the subject under the direction of the principle investigator. The research technologist starts recording, and biocalibrations are performed prior to the subject going to sleep.

This is a brief scenario that of what a research technologist may encounter. Having experience in both worlds of sleep, by comparison, I would like to introduce some of the differences between my job and the role of a clinical sleep technologist.

To distinguish the role differences between a polysomnographic technologist involved in research or clinical practice one needs to see the big picture.

The research tech collects data and follows the protocol, while the tech in a clinical environment actively interprets the data and adjusts medical treatment on the fly. For the research tech, strict timing of data collection adds a dimension of "stress" to the polysomnographic technologist's role; especially if subjects arrive late or if a technologist has several subjects with the same sleep appointment. In research, all procedures and decision-making are guided by the "protocol" of the study. As one follows the protocol, the technologist discerns how to implement the objectives and tasks. Forms and questionnaires for the subject and technologist are included to be filled-out. Research participants, or "subjects," are assigned by number, initials, and date of birth to secure confidentiality.

In clinical sleep labs, the sleep technologist follows the policy procedure manual of the institution or sleep lab. The manual is usually designed by the lab's manager or medical director; who is board-certified in sleep medicine. Clinical participants, or "patients," are identified by their full name and date of birth.

Before Arrival

A subject's participation in a research study is purely voluntary. Television, newspaper, radio, or even by word-of-mouth are means of advertisement that a research facility may use to obtain qualified subjects. The future subject may initiate contact with the research site, and undergo a brief telephone interview to screen whether they meet criteria for the study. Upon passing the initial phone screening interview, an appointment is made for a Clinical Research Coordinator ("CRC") to conduct a more comprehensive interview. The coordinator discloses and educates the subject about the objectives of the study. If study medication is to be given, the coordinator will explain the drug and obtain informed consent from the subject. Subjects are encouraged to ask questions

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and the CRC does not proceed until all questions have been answered to their satisfaction. Until informed consent is signed, the subject cannot move forward with the study. Upon consent, a physical exam is then performed by a physician, which may include a blood draw and/or electrocardiogram to ensure that the subject is in good health. Depending on the protocol, willing subjects may be "excluded" from participating in a study based on findings during the screening visit. Once a subject's medical clearance is obtained, a date is established to determine a sleep study appointment for "lights out."

Clinical studies require less patient preparation time. The patient initially presents to their primary physician with clinical symptoms. Their doctor refers them to a sleep physician to be evaluated. Different types of studies a physician may order include polysomnography ("PSG"), CPAP, Split Night, Multiple Sleep Latency Test ("MSLT"), or Mean Wakefulness Test ("MWT"), to be used as a diagnostic tool. Once the physician has explained the sleep study process and the patient consents, office personnel will assign a night at the sleep lab and review the patients' insurance. As with the researcher, unless consent is given, the patient cannot move forward with the study. Insurance is often a concern to patients and physicians, since some clinical studies are regulated by types of insurance. Some insurance plans may dictate what types of studies can be done. Technologists may be required to be "registered" (Medicare/Medicaid) to meet requirements for the sleep study to be covered. No specific bedtime is discussed, just a date and time range for the patient to arrive.

At the Sleep Lab

Upon the arrival at the sleep lab there are evening procedures for both research and clinical. For research, procedures to determine inclusion/exclusion in the study will be performed. These typically include urine collection for drug screen, obtaining of subject's vital signs (consisting of blood pressure, heart rate and temperature), breathalyzer for alcohol consumption, discussion of any napping during the day, or use of contraindicated medications (conmeds) previously discussed with the research coordinator. Questionnaires are given to the subjects. Questions may include experience about the previous night's sleep or sometimes the subject's "sleep diary" may be reviewed to ensure that bedtime is consistent. Adverse events ("AE's") from any medication are evaluated by the sleep technologist. AE's are defined as any unwanted medical occurrences or changes from the subject's first visit with the physician. This is to avoid any potential drug interference within the study.

Clinical patients arrive at the sleep lab in a more informal environment. On occasion a patient may arrive earlier for a particular study such as a split-night study where technologist will start the study as if performing a PSG, then convert to CPAP (if the patient has a sufficient number of respiratory events). This criteria, which are sometimes guided by health insurance, are found in the policy and procedures manual of each clinical sleep lab. The evening procedures for clinical are minimal. A few examples include: asking the patient of any changes in their medical history; asking about their previous night's sleep; identifying use of any caffeinated products; and obtaining a list of current medications. Any physical symptoms are evaluated as a pre-assessment at the time of arrival.

Electrode Placement

Once the evening assessments are performed, both the researcher and clinician place electrodes and start PSG monitoring. The research tech follows the "PSG manual" found within the specific protocol. Although electrode place-

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ment, or "hook-up," is specific to each study, the standard four EEG (O1, O2, C3, C4), two reference (A1 and A2) leads, and EKG leads are used. Preparing the subjects for a PSG hook-up is dependent upon what visit number the subject may be assigned. A "screening night" is the initial one or two visits of a subject. Screening nights are to ensure the subject meets the PSG inclusion criteria for what is specifically being investigated (for example "chronic insomnia"). The use of leg leads and thermistor are commonly used on screening nights, subsequent visits (once in the study) are generally referred to as "head hookups" and consist of an EEG, an EOG, two reference leads and an EKG.

Clinical hook-up consists of the traditional use of two belts; thoracic and abdominal, snore microphone, EEG leads (C3, C4, O1, O2), EOG, two reference leads (A1, A2), thermistor, EKG leads, two leg leads and pulseoximeter. Before the patient is allowed to sleep, clinical patients may watch TV, read or even snack. As the patient surrenders to sleep, biocalibrations are performed. For most research studies, subjects are not allowed to watch TV nor snack prior to lights out. Study medication is given 30 minutes prior to bedtime, start of recording and biocalibrations are also specified by timing restrictions. Whether the subjects are ready to sleep or not, they are put to bed at their assigned bedtime.

Lights Out

Monitoring for both clinical and research are at the individual lab's discretion. At my research lab we hourly monitor any symptom changes noticed throughout the evening. According to protocol, there are guidelines that the research tech must follow in order to "troubleshoot." In general, the only time a research tech can troubleshoot and enter the room is if all EEG or EOG leads have accidentally been removed. The goal in research is to not interrupt the subject's sleep, at least until latency to persistent sleep ("LPS") has been achieved. LPS (the first 20 epochs of consecutive sleep) is one of the main criteria research labs use for a subject to be included into a specific study. For example, LPS greater than 15 minutes is typical for chronic insomnia; however, this number may vary from study to study per the protocol.

Clinical patients may be monitored every 30 minutes to an hour, sometimes more frequently depending on the type of study. For example, CPAP or split night studies require more attention by the technologist. Concentration is needed while titrating a CPAP study and monitoring respiratory events to increase pressure accordingly. For a split night, apnea hypopnea index ("AHI"), must be calculated to determine whether one should convert the PSG to CPAP. The criteria are designed within the labs policy manual. Clinical technologists should not enter the patients' room regard-

ing accidental lead removal, unless the leads cannot be rereferenced.

There are times a research tech may enter a subject's room that are similar to that of a tech in a clinical lab. For example if a patient calls to use the restroom or sweat artifact is noticed (to turn on a fan) one can enter the room and interrupt the study. Recording time for research is usually for the duration of eight hours from lights out to lights on. If a research subject cannot sleep, they must stay in bed and attempt to fall asleep on their own. Clinical recording time is directed by the patient or sometimes by type of health insurance. For split night studies a clinical technologist may need more time to titrate their patient to optimal pressure. Further examples on how clinical recording time may vary include a patient not being able to tolerate CPAP, or insurance companies requiring at least six hours of recording time.

Lights On

For the research subject, eight hours after lights out, the participant is awakened regardless of their sleep stage. Morning procedures may consist of neurological and physical assessments performed by the sleep technologist, or by a physician. For screening nights, a certified scorer quantifies the study's results on site; at the research sleep lab. This determines if the subject meets the criteria set by the protocol to either continue with the study to the next stage, or to compensate the subject for their time invested thus far. Research studies are scored by distinguishing "wake" and "sleep" (no staging) LPS, WASO, WTDS, PLMA, and AHI, which are some of the criteria specific for research. Once the subject meets the criteria and passes screening evaluation, they are officially accepted into the study. Data from subsequent visits are not scored on site. The data is converted to European Data Format ("EDF") and sent to a central scorer designated by the protocol. The benefits to the research subject are financial, as well as any benefits received from medication administered throughout the study.

As morning approaches the clinical patient is often eager to rise and the study is ended. Once the leads are removed, the patient may be surveyed on their sleep and be released from the lab. The patient will be notified by the physician later with their results. Typically, the patient only experiences the one visit at the sleep lab, unless the physician orders further studies. At most labs the recorded data from a clinical study will be scored by a registered sleep technologist; where AHI, PLM's, sleep efficiency, arousals, and all respiratory events will be calculated. The information obtained will hopefully provide insight and better understanding of the patient's initial signs and symptoms. This information is used to improve their quality of sleep and promote good health and wellness long term.

Summary

In summation, research subjects volunteer to participate. Some subjects find it satisfying as they contribute to the outcome of a new investigational drug, as some may find the benefits as a way to cope with a present condition. Because the volunteers are compensated for their time and travel, it costs them nothing to take part in the study. Often research benefits are only temporary, whereas clinical patients can benefit for the rest of their lives. Regardless of the discipline a polysomnographic technologist may choose, both the research and clinical technologist are key players in the field of Sleep Medicine.



**"And when my paycheck didn't bounce,
I knew this hospital was the right place for me."**