SLEEP COHORT STUDY - CONSENT FORM TO PARTICIPATE IN RESEARCH

Invitation: You are invited to participate in the Sleep Cohort Study of breathing disorders and other problems during sleep. Your decision to participate in this research is entirely voluntary. Your participation in this research will help us identify risk factors for sleep disordered breathing, describe its physical progression, and determine what, if any, contribution sleep disordered breathing may have on other health outcomes, such as hypertension. Each of the tests you take part in is done at no cost to you.

What will I be asked to do for this research study? During this overnight study at the University of Wisconsin Clinical Res Center, you will be asked to participate in the test listed below. All tests will be fully explained and you can refuse any part the study.

- Health Questionnaire -- includes about 20 minutes of questions on health and sleep, family history of sleep problems; "paper and pencil" memory tests; and some basic measures of height, weight, girth, and blood pressure, which take about 40 minutes.

- 12-Lead Electrocardiogram (ECG)

- Standard polysomnography -- This test measures your breathing, heartbeat, blood pressure, chest movement and sleep stages throughout the night. A sleep technologist will tape or paste small wires on the surface of your skin to record the measurements. In addition, a finger cuff will record your oxygen level. A video camera will film changes in body position during your night of sleep.

- A blood sample will be obtained in the morning. The sample will be analyzed for standard chemistry, lipids, and hormones (FSH and LH) for women. A report on the results of these tests will be provided. The results are checked by our project physician and we will tell you if any of the tests are outside of the normal limits.

A portion of the sample, identified by only your identification number, will be sent to Stanford University for analysis. Genetic material (DNA) will be extracted from the sample and analyzed for new sleep genes or markers for sleep that may be important in the regulation of sleep. Stanford will store the frozen sample for 5 years, after which the sample will be returned to us.

Along with your other sleep study tests and information, we will use the genetic information for research on whether these markers are related to sleep characteristics such as ease of falling asleep, sleepiness, amount of rapid-eye movement sleep (REM), sleep problems such as difficulty getting to sleep, and other sleep-related factors. As new discoveries are made on sleep genes, we will be able to re-analyze your blood sample.
No other genetic analysis will be performed on your sample and we will not be identifying any genes for diseases. We will not be reporting results of the genetic analysis to you; this is a very new research area and very little is known about the meaning of any genetic markers or genes for sleep in humans.

As with all information from your participation, your name will never be attached to the sample sent to Stanford University or to the genetic information, and the confidentiality of the identifying code is strictly protected.

Please continue to the back page.....

You may decline either the standard analysis or the DNA analysis or both by signing and dating below:

1. I do not want to have my blood sample analyzed for genetic markers that may be related to sleep: _____ Signature & date

2. I do not want to have my blood sample analyzed for the standard tests listed above: _____ Signature & date

What are the benefits of participating? We will send you a summary of your sleep evaluation, which is beneficial health information. We will provide a form for you to complete if you would like a copy of the sleep summary to be sent to your doctor. If the study results are of possible clinical significance, our project physician will contact you.

Keep in mind, however, that this is not a clinical research study and the test results from this study are not the same as those used for diagnosis and treatment of sleep disorders. If you want to know for certain that you have a sleep disorder or other health problem, you would need to see your physician and not rely on the study results.

What are the risks of participating? There are no risks associated with polysomnography, however you may not sleep as well as you do at home, and so you might not feel as rested the next day. None of the recording monitors cause any pain, but you may have some minor, temporary skin irritation from the adhesive that attaches the recording wires. There might be some bruising and the usual discomfort of a needle-stick as the result of the blood sample. We know of no risk whatsoever that could occur as the result of your participation in the genetic analysis. It is possible, of course, that an unforeseen risk could occur in the future.

Will I be paid for participating? You will also receive $150 for your participation in this study.

How will my confidentiality be protected? All data is identified by code number only. Your file will be completely confidential and will not be shared with anyone. We will keep in touch with you and we may invite you to participate in other studies.

What if I change my mind? You are free to withdraw at any time and there is no obligation to take part in any further studies. We encourage you to ask any questions you may have before you decide.

What if I am injured during this study? In the event that you are physically injured as a result of participating in the research, emergency care will be available. You will, however, be responsible for the charges for the emergency care. There is no commitment to provide any compensation for research-related injury. You should realize, however, that you have not released this institution from liability for negligence. Please contact Kathryn Pluff at 265-3045 if you are injured or for further information. If you have questions about the rights of research subjects, please contact the University of Wisconsin Hospital and Clinics patient relations representative at 608-263-8009.

I would like to participate in the sleep study research project described above. My signature indicates that I have read the information in this consent form and have received a copy.

_____

Signature Date