The UNIVERSITY OF CHICAGO
The Division of the Biological Sciences • The University of Chicago Medical Center

CONSENT/AUTHORIZATION BY SUBJECT FOR PARTICIPATION IN A RESEARCH PROTOCOL

Protocol Number: IRB 14-0528

Name of Subject: _____

Medical History Number: _____

STUDY TITLE: Home Sleep and Metabolism

Doctor Directing Research: Dr. Esra Tasali
Address: The University of Chicago, 5841. S. Maryland Ave, MC6026, Chicago, IL, 60637
Telephone Number: 773-702-1497

You are being asked to participate in a research study. A member of the research team will explain what is involved in this study and how it will affect you. This consent form describes the study procedures, the risks and benefits of participation, as well as how your confidentiality will be maintained. Please take your time to ask questions and feel comfortable making a decision whether to participate or not. This process is called informed consent. If you decide to participate in this study, you will be asked to sign this form.

WHY IS THIS STUDY BEING DONE?

Bedtimes and wake-up times vary from person to person. This research will examine the associations between sleep habits and metabolism in healthy people. In this study, we will collect information on your sleep-wake habits and how your body metabolizes energy. Your body gets the energy it needs from food through a process called metabolism.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 250 people will take part in this study at the University of Chicago

WHAT IS INVOLVED IN THE STUDY?

The entire study lasts approximately 5 weeks and involves screening procedures and study phase including a total of 8 visits to University of Chicago as follows:

SCREENING PROCEDURES:

Visit 1 (one night of stay in the sleep laboratory):

Your sleep will be recorded overnight in the sleep laboratory to determine if you have any sleep disorders. Sensors will be pasted on your head to measure your brain waves and on your legs to measure your leg movements; a small sensor will be taped on your finger to measure your blood oxygen level (without collecting any blood). You will also be wearing sensors that will be put in front

of your nose, around your chest and belly to measure your breathing. If you pass this screening step then you will qualify for further screening procedures and come for Visit 2 (described below). Prior to coming to the sleep laboratory for overnight sleep study, you will start wearing a small wristwatch-like monitor (called actiwatch), which will measure the movements of your wrist and help us determine your sleep-wake schedule. You will wear the actiwatch on your wrist continuously for one week while you follow your usual bedtimes and wake-up times at home. You will be asked to press a button on the actiwatch when you go to bed to sleep each night and when you get out of bed each morning. You will give the Actiwatch to sleep technicians and the investigators will review the data to determine your eligibility.

Visit 2 (one morning for approximately 2.5 hours in the clinical research unit):

You will arrive in the morning after an overnight fasting at home. You will undergo blood tests and physical exam. About 2 tablespoons of blood will be drawn for complete blood count, liver, kidney and a pregnancy test for women. You will also have a morning oral glucose tolerance test (OGTT) to determine if you have diabetes. A small flexible needle will be inserted into a vein of your arm to allow for blood samples to be drawn. You will be given a drink (about 1 1/3 cups), which contains 75 grams of glucose (sugar). You will be asked to drink this sugar mix over 5 minutes. Once before taking the drink and then once after 2 hours, approximately 1/3 of a teaspoon of blood will be drawn for measurement of glucose (sugar) and insulin levels.

STUDY PHASE:

The study phase will last 28 days (Day 1 through Day 28).

Measurements at home (28 consecutive days):

You will continuously wear the actiwatch. You will measure your weight on a digital scale every morning.

Visit 3 (approximately half-day in the clinical research unit):

On Day 1, you will arrive in the morning to the research unit after an overnight fasting at home. You will undergo a dual-energy X-ray absorptiometry (DXA) scan in the morning. DXA scan involves lying on a scanner table for approximately 15-20 minutes. During that time your whole body will be scanned to measure the bone, muscle and fat amount. We will ask you to drink a cup of doubly labeled water (DLW). DLW is used to measure how many calories your body burns. DLW is water containing two tracers, 2H (deuterium) and 18O. These two tracers are not radioactive and do not expose people to any ionizing radiation. The doubly labeled water is used to measure total energy expenditure and body water in similar experiments to this one and has been used in thousands of people including babies, pregnant and lactating women, children, and adults. To measure this, we will collect urine before and after you drink the DLW. During this visit, you will also fill out questionnaires about your sleep and eating habits and mood, which will take approximately 15-20 minutes.

Visit 4 (approximately half-day in the clinical research unit):

On Day 14, you will arrive in the morning to the research unit after an overnight fasting at home. You will rate your sleepiness and appetite, which will take about 30 seconds. We will measure the rate of

your metabolism for 40 minutes before breakfast and for 4 hours afterwards. During this time you will remain at bed rest and a clear plastic canopy will be placed over your head for 4 hours to measure the amount of oxygen consumed and the amount of carbon dioxide produced by your body. During this time, we will also simultaneously collect frequent blood samples called mixed meal tolerance test (in total less than 2 tablespoons) for glucose (sugar) and insulin measurements.

Visit 5 (approximately half-day in the clinical research unit):

On Day 15, you will arrive in the morning to the research unit after an overnight fasting at home. You will rate your sleepiness and appetite, which will take about 30 seconds. The same testing procedures (DXA and DLW with urine collections) described under Visit 3 will be repeated.

Visit 6 (approximately 1-hour in clinical research unit):

On Day 22, you will meet with the research staff to review your sleep patterns from the actiwatch.

Visit7 (approximately half-day in the clinical research unit):

On Day 28, you will arrive in the morning to the research unit after an overnight fasting at home. You will rate your sleepiness and appetite, which will take about 30 seconds. The same testing procedures described under Visit 4 will be repeated.

Visit8 (Final visit; approximately 1.5 hour):

On the morning following the Day 28, you will arrive to the research unit after an overnight fasting at home. You will rate your sleepiness and appetite, which will take about 30 seconds. You will undergo a DXA scan as described under Visit 4. You will be asked to return the actiwatch and the scale provided by the investigators.

INFORMATION TO BE COLLECTED

During this entire study, Dr. Tasali and her research team will collect information about you for the purposes of this research. You will be asked questions about your medical history including your sleep history, some personal health habits, medications that you currently take, and contact information, including name, home address, e-mail address, telephone number. For payment purposes only, your mailing address and social security number will be needed.

HOW LONG WILL I BE IN THE STUDY?

We think you will be in the study for about 5 weeks. Dr. Tasali may decide to take you off of the study without your consent if:

- The initial screening results indicate that you do not qualify for the rest of the study;
- You are unable to meet the requirements of the study;
- Your medical condition changes;
- If the study is stopped.

WHAT ARE THE RISKS OF THE STUDY?

- Blood draw risks, which include temporary pain, slight bruising, possible inflammation that may occur from IV insertion. Every care will be taken to avoid these complications. An experienced research nurse will insert the IV under sterile conditions.
- Minor temporary skin irritation could occur with the surface electrodes or sensors used for screening sleep recording and with activity monitors.
- Measurement of your metabolism may be associated with some discomfort, since you will be asked to move as little as possible and remain completely relaxed while breathing comfortably under the plastic canopy.
- It is possible that the information that we collect about you may be accessible to individuals that are not part of the research team. Every care will be taken to assure that this does not happen. This is described in the Confidentiality section of this consent form.
- The DXA scan involves X-ray to measure your body composition. Your body's exposure to radiation from this test is very low, approximately 10 times less than you would receive from a standard chest X-ray, or less than that from an airline flight between New York to California and back.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

There is no direct medical benefit to being in the study. You will have physical examination and screening medical testing during the study and we will tell you if we find any problems in these screening tests. You will receive copies of the screening test results.

WHAT OTHER OPTIONS ARE THERE?

Instead of being in this study, you may choose not to participate; it is entirely voluntary. The decision whether or not you wish to participate in this study will not affect your care at the University of Chicago Medical Center.

WHAT ARE THE COSTS?

Clinical services provided during a clinical trial are either research-related or related to usual medical care. Research-related services are done to complete the research and the costs are not the responsibility of you or your insurance. The costs that are considered research-related for this study include the following: research-related blood and urine tests, physical exams, glucose tolerance test, DXA scan, actiwatch and digital scale.

If you suffer an unanticipated injury as a direct result of this research and require emergency medical treatment, the University of Chicago Medical Center will provide such treatment at the University of Chicago Medical Center at no cost to you. You must notify Dr. Tasali as promptly as possible after your injury in order to receive this care. An injury is "unanticipated" if it is not one of the known effects of a study drug, medical device or procedure, and is not the result of your disease or condition. The costs of any non-emergency care for such an injury will be billed to you, your insurance company or the study sponsor in the ordinary manner.. If you think that you have suffered a research related injury, you must let Dr. Tasali know right away.

WILL I BE PAID FOR MY PARTICIPATION?

You will receive up to $2300 for successfully completing the study. You will receive $75 for completing the screening procedures $50 for completing Visit 1 and $25 for completing Visit 2 and

$2225 for completing the entire 28-day study phase.

As policies at the University of Chicago require that these payments be given in the form of a check, you will need to complete a tax form. Therefore we will be collecting personal information about you including your name, address, and social security number. In addition, because the process for requesting a check oftentimes takes several weeks, we will mail your check to you when it is ready. Please note that it may take 3-4 weeks after conclusion of your study participation in order for you to receive your payment.

WHAT ABOUT CONFIDENTIALITY?

Study records that identify you will be kept confidential. Study records will be kept in a locked office and are only accessible by members of the research team. Data will be coded as to not identify you and will not contain information that identifies you. The data collected in this study will be used for the purpose described in the form. By signing this form, you are allowing the research team access to your Protected Health Information (PHI), which consists of any health information that is collected about you, which could include your medical history and new information collected as a result of this study. The research team includes the individuals listed on this consent form and other personnel involved in this study at the University of Chicago.

The University of Chicago's Comptroller's office will have access to your name, address and social security number when processing your check payment. Your records may be reviewed by federal agencies whose responsibility is to protect human subjects in research including Office of Human Research Protections (OHRP). In addition, representatives of the University of Chicago, including the Institutional Review Board, a committee that oversees the research at the University of Chicago, may also view the records of the research. If your research record is reviewed by any of these groups, they may also need to review your entire medical record. If health information is shared outside the University of Chicago, the same laws that the University of Chicago must obey may not protect your health information.

During your participation in this study, you will have access to your medical record. Dr. Tasali is not required to release to you research information that is not part of your medical record. The research team will keep this consent form for at least six years. The study results will be kept in your research record and be used by the research team indefinitely. At the time of study completion, either the research information not already in your medical record will be destroyed or information identifying you will be removed from study results. Any research information in your medical record will be kept indefinitely.

Data from this study may be used in medical publications or presentations. Your name and other identifying information will be removed before this data is used. If we wish to use identifying information in publications, we will ask for your approval at that time.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. If you choose not to participate in this study, your care at the University of Chicago/University of Chicago Medical Center will not be affected. You may choose not to participate at any time during the study. Leaving the study will not affect your care at the University of Chicago/University of Chicago Medical Center.

If you choose to no longer be in the study and you do not want any of your future health information to be used, you must inform Dr. Tasali in writing at the address on the first page. Dr. Tasali may still use your information that was collected prior to your written notice. You will be given a signed copy of

this document. This consent form document does not have an expiration date.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

You have talked to _____about this study and you had the opportunity to ask questions concerning any and all aspects of the research. If you have further questions about the study, you may call Dr. Tasali at 773-702-1497.

If you have a research related injury, you should immediately call 773-702-1000 and ask the operator to page Dr.Tasali at #9050.

If you have any questions concerning your rights in this research study you may contact the Institutional Review Board, which is concerned with the protection of subjects in research projects. You may reach the Committee office between 8:30 am and 5:00 pm, Monday through Friday, by calling (773) 702-6505 or by writing: Institutional Review Board, University of Chicago, 5841 S. Maryland Avenue, MC7132, I-625Chicago, Illinois, 60637.

CONSENT

SUBJECT

The research project and the procedures associated with it have been explained to me. The experimental procedures have been identified and no guarantee has been given about the possible results. I will receive a signed copy of this consent form for my records.

I agree to participate in this study. My participation is voluntary and I do not have to sign this form if I do not want to be part of this research study.

Signature of Subject: _____

Date: _____ Time: _____ AM/PM (Circle)

PERSON OBTAINING CONSENT

I have explained to _____ the nature and purpose of the study and the risks involved. I have answered and will answer all questions to the best of my ability. I will give a signed copy of the consent form to the subject.

Signature of Person Obtaining Consent: _____

Date: _____ Time: _____ AM/PM (Circle)

INVESTIGATOR/PHYSICIAN:

Signature of Investigator/Physician _____

Date: _____ Time: _____ AM/PM (Circle