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

CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH PROTOCOL

Protocol Number: 19-0169 Name of Subject: _____
Medical History Number: _____

STUDY TITLE: Mentoring Patient Oriented Research: Sleep During and After the Hospital Stay

Doctors Directing Research: Dr. Vineet Arora
Address: 5841 S. Maryland Ave, MC 2007, AMB W216, Chicago IL 60637
Telephone Number: 773-702-8157

KEY INFORMATION

We are asking you to choose whether or not to volunteer for a research study about how healthcare, the environment, and a patient's feelings about their sleep impact the length and quality of their sleep during their hospitalization and after they are discharged from the hospital. This section is to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is above.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

If you enroll in the study, your participation will begin while you are here in the hospital, each encounter lasting less than one hour. During these visits, you will be asked to do things such as, complete surveys and wear a lightweight watch on your wrist. This watch measures your sleep, activity, and the amount of light in the room. You may also receive educational materials about the importance of sleep in the hospital as well as some items such as ear plugs and an eye mask to help you sleep better while you are hospitalized. We will also ask you to take the watch home with you for a period of one week and continue wearing it after your discharge. Three months after your discharge you will also be asked to wear the watch again for one week. By doing this study, we hope to learn how healthcare, the environment, and patient attitudes about sleep impact their sleep during and after their hospitalization. We also hope to learn if educating and empowering patients' about sleep can improve their sleep. Your participation in this research will last about three months. A detailed list of all tasks to be completed and a schedule of these tasks are included in the detailed consent.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

If you agree to take part in this study, there will not be any direct medical benefit to you.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

Participation in this study is of minimal risk, there is no more risk to you in participating in this study than there is to going about your everyday life. There is a risk of breach of confidentiality to you. In this study, you are being asked to answer questions about your sleep experiences in the hospital. You will be given surveys, but no data identifying you, such as your name, will be recorded in the survey. You can choose not to answer any questions that make you uncomfortable. The surveys will be kept in the locked

offices of the study personnel in a locked file cabinet. There are no risks associated with wearing the Actiwatch. Patients wearing the Actiwatch may find it uncomfortable or may not like wearing a watch. If study tasks cause you to feel emotional distress, you can choose to stop participating. For a complete description of risks, refer to the Detailed Consent.

DO YOU HAVE TO TAKE PART IN THE STUDY?
Taking part in this study is voluntary. If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

You may choose not to participate at any time during the study. You will not lose any services, benefits or rights you would normally have if you choose to leave the study. The University of Chicago/University of Chicago Medical Center will not condition (withhold or refuse) treating you on whether you sign this Authorization or revoke your authorization at a later time. If you do not sign this form, you will not receive the research-related intervention(s).

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?
The person in charge of the study is Vineet Arora, MD, MAPP of the University of Chicago. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: email: varora@medicine.bsd.uchicago.edu or office phone 773-702-8157.

For questions about your rights as a research subject, please contact the University of Chicago BSD IRB at 773-702-6505.

DETAILED CONSENT

WHAT IS INVOLVED IN THE STUDY?
About 850 people will take part in this study at the University of Chicago.

On the day of enrollment, while you are at University of Chicago Medicine (Day 1), we will give you 2 surveys and ask you to wear an Actiwatch which measures sleep and daytime physical activity, as well brightness of light. We will also place a Larson Davis sound meter, a device that measure noise levels in your hospital room. We will ask you to wear the Actiwatch and have the Sound Meter in your hospital room for the duration of your hospitalization The first survey is called the Initial Sleep Assessment. This survey asks you questions about your initial sleep duration (how long you sleep) and quality, presence of sleep disorders as well as risk of developing sleep disorders, initial attitudes about sleep, and level of your perceived sleep control. This survey is only given once on Day 1. The second survey, the Daily Sleep Assessment, will be given to you on Day 1 and each day until your discharge from the hospital. This survey measures your potential sleep disruptions, sleep duration, sleep quality, your activity and memory function.

On Day 1, you will also be randomized (like the "flip of a coin") to Group A or Group B. Group A will receive educational materials (a short video and a brochure) about the importance of sleep in the hospital and at home for health and recovery. This education will occur on Day 2 before you are discharged from the hospital. You will also be given some items such as ear plugs and an eye mask that may help you

sleep better while you are hospitalized. You are encouraged but not required to use these items. If you are randomized to Group B, you will complete the protocol outlined above, but you will not receive educational materials or ear plugs or eye mask.

For both members of Group A and Group B, upon your discharge from the hospital, we will ask you to continue wearing the the Actiwatch for one week. If you choose to continue with this equipment, we will retrieve it from you in one of the following ways:

- If you are returning for a follow-up appointment between 7 and 14 days after discharge, we will arrange a meeting with you at the clinic site to retrieve the equipment OR,
- We will provide you with an envelope to return the equipment and also call you 5 days after discharge to remind you to return the equipment OR,
- If you are unable to mail the equipment, we will meet you at your home to pick up the equipment.

We will also call you at your home two weeks after your discharge to perform a two week follow-up questionnaire in order to determine how you feel your sleep quality was for the two weeks after being discharged.

We will ask you to keep a journal of your sleep and wake times and any significant events you may have had so that we may see how well you were able to sleep in your post-hospitalization recovery time.

At 3 months post discharge, we will contact you again by phone to wear the Actiwatch again for a period of one week. We will either meet you at a clinic visit at University of Chicago Medical Center or mail the equipment to you.

If you choose to continue with this equipment, we will retrieve it from you in one of the following ways:

- If you are returning for a follow-up appointment between 7 and 14 days after you receive the Actiwatch, we will arrange a meeting with you at the clinic site to retrieve the equipment OR,
- We will provide you with an envelope to return the equipment and also call you 5 days after discharge to remind you to return the equipment OR,
- If you are unable to mail the equipment, we will meet you at your home to pick up the equipment.

We will call you at your home three months after your discharge to perform a follow-up questionnaire in order to determine how you feel your sleep quality was for the three months after being discharged. We will ask you to keep a journal for the one week you wear the Actiwatch at home at three months post discharge of your sleep and wake times and any significant events you may have had so that we may see how well you were able to sleep in your post-hospitalization recovery time. Measuring your post-discharge activity and post-discharge sleep quality is necessary for our study because this data will allow collection of objective and subjective information on post-discharge sleep and physical activity in your recovery period after hospitalization.

In future, identifiers associated with your data could be removed from the data. The de-identified data could then be used for future research by our research team or other researchers without notifying you or asking your permission for this use.

The results from this study will not be shared with you.

Dr. Arora may decide to take you off of the study without your consent if:

- You are unable to meet the requirements of the study or your medical condition changes;
- New information becomes available that indicates that participation in this study is not in your best interest; or
- If the study is stopped.

WHAT ARE THE RISKS OF THE STUDY?

There is a potential risk of breach of confidentiality to you. You will be given surveys, but no data identifying you, such as your name, will be recorded in the survey. Subjects can chose not to answer any question that makes them feel uncomfortable. The surveys will be kept in the locked offices of the study personnel in a locked file cabinet.

Patients wearing the Actiwatch may find it uncomfortable or may not like wearing a watch.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

Being in this study will not help you directly. We hope that your participation in the study may benefit other people in the future by helping us learn more about the causes of sleep loss in hospitalized older patients in order to improve inpatient sleep duration and sleep quality which leads to improved health outcomes.

WHAT OTHER OPTIONS ARE THERE?

Instead of being in this study, you may choose not to participate. 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?

There will be no costs to you or your insurance company resulting from your participation in this research study. However, you or your insurance company will be responsible for costs related to your usual medical care.

WILL I BE PAID FOR MY PARTICIPATION?

For participation in this study you may receive a total of $75, which will be paid to you in cash before your discharge from the hospital.

WHAT ABOUT CONFIDENTIALITY?

Study records that identify you will be kept confidential. During this study, Dr. Vineet Arora and her research team will collect protected health information (PHI) about you for the purposes of this research. The research team includes the individuals listed on this consent form and other personnel involved in this study at the University of Chicago. Protected Health Information (PHI) 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. Some of this information will come from your medical record. The information to be used on this study includes names, medical record numbers, dates of birth, addresses, ages, and telephone number. . These identifiers will be stored separately from the other data (responses to surveys or data collected from the Actiwatch) collected as a part of this study. In order to do this, we will assign you a unique Subject ID number. The only place that this Subject ID will be linked with your identifiers is on a spreadsheet stored in a HIPAA compliant, password-protected computer to which only the Principal Investigator and primary contact of this study have access.

Your records may be reviewed by federal agencies whose responsibility is to protect human subjects in research including Office of Human Research Protections (OHRP). Representatives of the University of Chicago, including the Institutional Review Board (a committee that oversees the research) and the Office of Clinical Research 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.

Once information is shared outside the University of Chicago, please note that your identifiable health information may be shared with someone else. 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. Arora is not required to release to you research information that is not part of your medical record.

This consent form will be kept by the research team for at least six years. The study results will be kept in your research record and be used by the research team until study completion**.** 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.

Data from this study may be used in medical publications or presentations. Your name and any 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.

A description of this study will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

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. Vineet Arora in writing at the address on the first page. Dr. Vineet Arora may still use your information that was collected prior to your written notice.

You will be given a signed copy of this document. Your authorization to use and disclose your health information does not have an expiration date.

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)