Landstuhl Regional Medical Center
CONSENT TO PARTICIPATE IN RESEARCH
Title: *Using Human Centric Lighting to Improve Inpatient Sleep: A Feasibility Study*
Principal Investigator: Pauline A. Swiger, PhD

You may be eligible to take part in this research study. This form gives you important information about the study.

Please take time to carefully review this information. You should talk to the researchers about the research study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or your personal physician) about your potential participation in this research study. You do not have to take part in this study. Participation is voluntary. You may also leave the research study at any time without penalization.

1. KEY INFORMATION:

Voluntary Participation	Your participation is voluntary. You do not have to take part in this research or you can also choose to stop participating at any time.
Purpose	The purpose of this research study is to learn about the effect of light on sleep and to learn how to improve the study process so that a larger study can be conducted at a later date.
Duration	You will be in this study until discharge from hospital or no more than 5 days, whichever comes first.

Procedures	You will be assigned to one of two rooms during your inpatient hospital stay: the Human Centric Lighting (HCL) room where the lights in your room have been modified or the Standard Lighting (SL) room where no changes are made to the lights in the room. You will be asked to complete a short 2-5 minute demographic questionnaire. You will also wear an Actigraphy device (similar to a watch) for the duration of your participation in the study. Each morning after you wake, you will be asked to complete a 2-5 minute sleep diary about the previous night's sleep. Each evening, a member of the research team will also collect saliva samples hourly between 1900 and 2300 to test your melatonin level. For this test, you will place a small cotton swab inside your mouth for 1-2 minutes to collect saliva and then place it in a tube. At discharge, you will complete a short 2-5 minute interview aimed to better understand your experience during the study.
Why might you want to participate in this research (benefits)?	The possible benefit to participating in this research study is contributing to scientific knowledge of the effect of light on sleep.
Why might you choose not to participate in this research (risks)?	The **main** risks from being in this study are minimal. Although efforts are made to protect your research study records, there is always a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.
What are the alternatives to participating?	Choosing not to take part in this research study is an alternative. If you choose to not participate in this study, your care will continue as planned.

Your decision will not affect your future care at Landstuhl Regional Medical Center (LRMC). If you decide to take part in this research study, you will be asked to sign this document. Before you sign this document, be sure you understand what the research study is about in all sections of the consent form, including the risks and possible benefits to you.

Please tell the researchers if you are taking part in another research study.

2. WHAT IS THE PURPOSE AND DURATION OF THIS RESEARCH AND WHO WILL TAKE PART?

You are being asked to take part in this research study because you will be admitted as a patient to the medical surgical unit. The purpose of this research study is to learn about the effect of light on sleep and how to improve the study process so that a larger study can be conducted at a later date.

This study is looking at special lights to help our bodies realign with the natural light and dark cycles of the sun. These lights ensure that bright light is emitted during the day and filtered light is used in the evening and at night. Human Centric Lighting (HCL) has not been well-studied before. This means that Human Centric Lighting (HCL) is considered experimental for inpatient sleep.

There will be about 76 people taking part in the study at Landstuhl Regional Medical Center.

The duration of your participation in the research is through discharge from the hospital or no more than 5 days, whichever comes first. During the study, you will complete a demographic questionnaire, daily sleep diaries and a short semi-structured interview at discharge. Each of these questionnaires will take 2-5 minutes to complete. Saliva cotton swabs will be collected hourly between 1900-2300 while you are awake. The study team will not attempt to wake you to collect the saliva sample. Each saliva swab collection will take 1-2 minutes of your time.

At the end of this research study, the clinical results, including research results about you, will not be shared with you.

3. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

Your information was screened and you were found eligible to participate in this study based on your admittance to the medical-surgical unit. Before you can take part in this study, you will need to provide additional information so that the Investigator can confirm your eligibility. This is called the "Screening Process." This information is collected as a part of your regular medical care.

4. WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH?

You will be assigned to a patient room on 8D based on your needs. The charge nurse will assign the patient room according to their standard bed assignment criteria.

If you are assigned to the Human Centric Lighting (HCL) room, there will be special lights in your room. Commercially available HCL light sources are installed on the ceiling and wall, over your bed space. The overhead wall light has two light components: An upward projecting 'mood' light that emits HCL and a downward projecting reading light that emits only standard lighting. For the HCL light sources, bright blue human centric light will be used during the day (approximately 0600-1900) and depleted blue (dimmed) human centric light will be used at night (approximately 1900-0600). The transition of the ceiling and upward overhead wall light from

the daytime light to the nighttime light will be controlled by the research team and/or nursing staff.

You will be free to use any of these lights as you want or need.

A removable blue light filter will be placed on each downward wall reading light and on each non-shared hospital television screen. These are the modifications that will be maintained until study completion.

You will also be provided with a Blue Light Filter Information Sheet, which will have information about blue-light filters. You will also be encouraged to install the blue light filter on your personal electronic devices for the duration of the study to mitigate the effects of blue light in the evening/night time hours from device use.

If you are in the Standard Lighting (SL) room, no changes will be made to the lights in the room and no filter will be placed over your reading light television set. You will still be provided the information sheet about blue-light filters, but not until the day of your hospital discharge.

Whether you are in the HCL or SL room, you will be asked to complete a short 2-5 minute demographic questionnaire. A member of the research team will also place an Actigraphy device (similar to a watch) on your wrist and provide instructions for wear. The Actigraphy device should be worn while you shower and it should be worn all day and throughout the night. You may move the Actigraphy device from one wrist to the other, if needed for comfort. You will be asked to wear the Actigraphy device for the duration of your stay in the hospital, but not longer than 5 days.

Each morning after you wake, you will complete a short 2-5 minute sleep diary about the previous night's sleep. After completion, the sleep diaries will be stored in a study folder inside your night stand drawer.

Each evening, a research team member will collect saliva samples hourly between 1900 and 2300 to test your melatonin level. For this test, you will place a small cotton swab inside your mouth for 1-2 minutes to collect saliva and then place it in a tube. This sample will be stored at the LRMC laboratory and batch shipped to Saliva Lab Trier for analysis. Each evening, the research team member will also collect your sleep diaries and review for completeness as well as answer additional questions or concerns you may have.

Once you are aware that you are being discharged, you will be asked to call a research team member at the Center for Nursing Science and Clinical Inquiry (CNSCI) research office phone number provided, to notify them of your discharge. The CNSCI research office phone number is +49-6371-9464-4059 or DSN 314-590-4059.

If possible, a member of the team will come, on the day of discharge, to collect the Actigraphy device, sleep diaries, and complete a 2-5 minute interview aimed to better understand your experience during the study. The interview will be completed in your patient room. If a research team member is not available, you will place the Actigraphy device and sleep diary folder in the

secured box in your room before you leave the hospital. The research team member will contact you by phone to conduct a phone interview, or if the Actigraphy equipment is not returned, or if there are any other missing information on your questionnaires.

If we learn new information during the study that could affect your decision to remain in this study, we will tell you this information. For example, if we learn about new side effects of the special lights, we will tell you about these side effects.

5. WHAT ARE THE RISKS OR DISCOMFORTS FROM BEING IN THIS RESEARCH?

There may be discomforts from being in this study. If you are in the HCL room, you may find that the application of the blue-light filter to your television changes the color slightly. You may find that the day or night HCL light does not seem as bright or it may seem brighter than standard lighting.

If you are in either HCL or SL room, you may also find that wearing the Actigraphy device requires adjustment, especially if you are not accustomed to wearing a watch when you sleep or when you shower. Also, you will be visited every evening, once per hour from 1900-2300 and may find that the cotton swab saliva samples interrupt your evening or is uncomfortable. The research team will only stay in your room long enough to obtain your saliva swabs, collect questionnaires, and answer any questions you may have.

The risks associated with this study are minimal. Although efforts are made to protect your research study records, there is always a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.

There may also be other risks of taking part in this study that we do not yet know about.

6. WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?

The possible benefit to you as a research participant in this research study is improved sleep during your hospital stay. However, there is no guarantee that you will benefit from being in this research study.

7. WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS RESEARCH?

Choosing not to take part in this research study is also an option. If you choose to not participate in this study, your care will continue as planned.

8. IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?

No, you will not receive any compensation for participating in this study.

9. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

No, there are no costs to you for taking part in this research study.

10. PRINCIPAL INVESTIGATOR (the person(s) responsible for the scientific and technical direction of the study):

This research study is being conducted by Pauline A. Swiger, PhD.

11. STUDY SPONSOR (the organizations or persons who oversee the study and are responsible for analyzing the study data):

Landstuhl Regional Medical Center, Center for Nursing Science and Clinical Inquiry.

As the sponsor of this research, the Department of Defense may have access to your research data in accordance with DoDI 3216.02.

12. SOURCE OF FUNDING:

TriService Nursing Research Program (TSNRP)

13. LOCATION OF THE RESEARCH:

Landstuhl Regional Medical Center

14. DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS:

There are no financial interests or other personal arrangements to disclose.

15. WHO WILL SEE MY INFORMATION (PRIVACY) AND HOW WILL IT BE PROTECTED (CONFIDENTIALITY)?

Records of your participation in this research study may only be disclosed in accordance with state and federal law, including the Federal Privacy Act, 5 U.S.C.552a, and its implementing regulations. DD Form 2005, Privacy Act Statement - Military Health Records, contains the Privacy Act Statement for the records. A copy of DD Form 2005 can be given to you upon

request, or you can read on-line at:
https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd2005.pdf.

The research team will keep your research records for a minimum of 6 years. These records may be looked at by staff from the Landstuhl Regional Medical Center, the Institutional Review Board (IRB), and the other DoD/federal organizations as part of their duties. These duties include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed.

The medical surgical nursing staff may be made aware of your participation in the research study. Also, the rooms used for this research are shared with other individuals who may or may not be participating in the study.

Procedures to protect the confidentiality of the data in this study include but are not limited to the following:

You will be assigned a unique number code, or study identification, which will be used in place of personally identifiable information on your questionnaires, sleep diaries and saliva specimen. Any research record that contain personally identifiable information will be kept in a locked file cabinet in the research office and/or a password-protected file on a secured computer server.

Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss.

Complete confidentiality cannot be promised for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty.

Pauline A. Swiger, PhD and study team

Those listed above will have access to your records and agree to safeguard your protected health information by using and disclosing it only as permitted by you in this consent or as directed by state and federal law.

Information gained from your participation in this research study may be published in literature, discussed for educational purposes, and used generally to further science. You will not be personally identified when your information is shared in these ways; all information will de-identified.

16. USE OF INFORMATION AND SPECIMENS

During this research study, you will be asked to provide the following types of samples (biological specimens): Saliva Cotton Swab Sample

The information and/or biospecimens collected as part of this research will not be used or distributed for future research studies. Identifiers on the sample you provided will be removed. The de-identified sample will be stored at the LRMC laboratory then batch shipped to and processed by an outside laboratory.

While this study is on-going, your samples will be handled in accordance with this study's protocol and applicable regulations at the following laboratory: Saliva Lab Trier, Wissenschaftspark Trier, Max-Planck-Str-22, D-54296, Trier, Germany

Your samples will be disposed two months after the lab results have been delivered to the research team, in accordance to the laboratory policy. This laboratory is outside the military health system but is under contract. This outside laboratory will not have permission to conduct any additional research on your samples beyond the scope of this study.

17. VOLUNTARY PARTICIPATION

The decision to take part in this research study is completely voluntary on your part which means you do not have to take part if you do not want to. You may also leave the research study at any time. If you choose not to take part in this research study or if you leave the study before it is finished, there will be no penalty or loss of benefits to which you are otherwise entitled.

You will be informed if significant new findings develop during the course of this research study that may relate to your decision to continue participation.

18. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

You may withdraw your consent at any time and stop participating in this research study without affecting your eligibility for care or any other benefits to which you are entitled.

Should you choose to withdraw, you must contact the principal investigator or a research team member. If you decide to no longer participate in this research study, the researcher will still analyze your research data, collected prior to your withdrawal.

You have the option to request your research data be removed from the study by a written requested to Pauline A. Swiger, Landstuhl Regional Medical Center, Center for Nursing Science and Clinical Inquiry, Unit 33100, APO AE, 09180.

Please note that withdrawing your consent to participate in this research does not fully revoke your HIPAA Authorization Form to use/disclose your protected health information. To make that revocation, please send a letter to the principal investigator as discussed in the HIPAA Authorization Form.

The principal investigator of this research study may terminate your participation in this research study at any time if she determines this to be in your best interest, if you are unable to comply with the procedures required, if you no longer meet eligibility criteria, or if the study room is unavailable.

A maximum of four study participants can be enrolled at a given time. Upon your admission, space in the study room may be unavailable because the rooms have reached capacity or due to other bed management reasons. Under these conditions, your participation in the research program will be withdrawn but your medical care in the medical surgical unit will continue as planned.

19. CONTACT INFORMATION:

Principal Investigator (PI)
The Principal Investigator or a member of the research staff will be available to answer any questions throughout this study.

Principal Investigator: Pauline A. Swiger
Phone: 49-6371-9464-4832
Mailing Address: Landstuhl Regional Medical Center, Center for Nursing Science and Clinical Inquiry, Unit 33100, APO, AE, 09180

Landstuhl Regional Medical Center Human Research Protection Office (HRPO)
The Human Research Protection Office Point of Contact and/or Human Protections Director (HPD) will be available to answer questions or discuss concerns you may have about this research study.

Human Protections Director: Silvija Salai, PhD
Phone: 49-6371-9464-4771

Institutional Review Board (IRB) Office
If you have any questions about your rights as a research participant or if you have concerns or complaints about the research study, please contact the IRB Office or the Human Protections Director at the Department of Research Programs by: Phone: (301) 295-8239 or at: Walter Reed National Military Medical Center, 8901 Wisconsin Ave. Building 17B, Floor: 3C, Bethesda, MD 20889.

IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE SIGNING. YOU MAY CONSULT WITH YOUR PERSONAL PHYSICIAN OR LEGAL ADVISOR, IF YOU WISH.

A signed and dated copy of this document will be given to you.

SIGNATURE OF PARTICIPANT

By signing below, I agree that I have been provided time to read the information describing the research study in the consent form. The content and meaning of this information has been explained to me. I have been provided with the opportunity to ask questions. I voluntarily consent to participate in this study.

By signing this form, I have not given up any of my legal rights as a research participant.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT
(Can only be signed by an investigator or staff approved to administer consent)

_____
Printed Name of Administering Individual

_____ _____
Signature of Administering Individual Date