Informed Consent/Authorization for Participation in Research

Title of Research Study: Implementation of digital vital sign monitoring to decrease sleep interruption and enhance recovery in Phase II of the PROmoting Sleep, Patient Engagement and Recovery (PROSPER) project

Study Number: 2022-0190

Principal Investigator: Vijaya Gottumukkala, MD

_____ _____
Participant's Name Medical Record Number

Key Information

The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

You are invited to take part in a research study because you are being admitted to MD Anderson for further medical care and you are expected to stay in the hospital for at least 3 days.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

This study involves the use of sleep enhancement intervention that may improve sleep quality, which can result in faster recovery during hospitalization. This intervention is made of standard-of-care methods that lower the number of sleep interruptions during the hours of 10pm to 6am, such as: noise monitoring and reduction strategies, limiting

bedtime medication administration, delayed early morning blood collection, and use of red light instead of white light when interacting with the doctor or nursing staff. A digital vital sign motioning device (called ViSi Mobile) is also used to collect vital signs without waking the patient.

The goal of this research study is to learn how sleep enhancement intervention, including the use of ViSi Mobile, affects the quality of life of cancer patients receiving acute care.

ViSi Mobile is an FDA-approved device available for the use of monitoring vital signs. The investigational part of this study is to learn how ViSi Mobile combined with sleep enhancement intervention affects patient outcomes.

How long will the research last and what will I need to do?

You are expected to be in this research study for as long as you are hospitalized at MD Anderson.

During this study, you will be asked to complete questionnaires on the day you are admitted to the hospital and at the time you are discharged. Some participants may also be asked to wear the ViSi Mobile device to monitor vital signs during this study.

More detailed information about the study procedures can be found under ***"What happens if I agree to be in this research?"***

Is there any way being in this study could be bad for me?

The risks in this study are small and mostly related to questionnaires, which may be distressing.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

Taking part in this study may improve your feeling of well-being or quality of life due to fewer interruptions at night during your hospital stay. Future patients may benefit from what is learned. It cannot be promised that there will be any benefits to you or others from your taking part in this research.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate, not participate, or discontinue participation at any time without penalty or loss of your regular benefits.

Your alternative to participating in this research study is to not participate. You may receive sleep enhancement intervention during your hospital stay outside of this study.

Detailed Information

The following is more detailed information about this study in addition to the information listed above.

Who can I talk to if I have questions or concerns?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 713-563-0034.

This research has been reviewed and approved by an Institutional Review Board (IRB – an ethics committee that reviews research studies). You may talk to them at (713) 792-6477 or IRB_Help@mdanderson.org if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be in this study?

It is expected about 700 people will be enrolled in this research study. All will take part at MD Anderson.

What happens if I agree to be in this research?

Study Groups and ViSi Mobile

If you agree to take part in this study, you will be enrolled in either the Intervention study group or the Control study group based on bed availability on the floor unit in the hospital:

- If you are in the **Intervention group**, you will receive sleep enhancement intervention and will wear the ViSi Mobile device.

- If you are in the **Control group**, you will receive sleep enhancement intervention only. You will not wear the ViSi Mobile device.

The study doctor will discuss with you what group you are assigned to.

As part of sleep enhancement intervention, medication administration will be limited to before bedtime, blood collection will be delayed in the early morning, and red light will be used instead of white light if you must interact with a doctor or nursing staff. These are done to lower the number of sleep interruptions during the hours of 10pm to 6am for all participants in the study.

If you are assigned to wear the ViSi Mobile device, you will wear the device on your wrist like a watch, and it will continuously (non-stop) monitor your pulse, blood pressure, temperature, breathing rate, heart rate, and pulse rate. You will be able to see your vital signs on the display screen. Your vital sign data will be recorded at scheduled times and sent directly your electronic medical record.

Study Questionnaires
During this study, you will answer questionnaires using either an iPad given to you by the study staff, via text message or email, or on paper.

At the time that you are admitted to the hospital and then within 24 hours after you leave the hospital, you will complete questionnaires about your quality of life, emotions, and sleep. They will take about 15 minutes total to complete. About 24 hours after you leave the hospital, the study team will call you to check if you have answered the questionnaires.

If you are in the Intervention group, you will answer an additional 3 questionnaires about your experience with the ViSi Mobile device when you are admitted to the hospital and again when you leave. They will take about 15 minutes total to complete.

When you leave the hospital and then 3 more times every 3 months (Months 3, 6, and 9 after you leave the hospital), you will answer 2 questionnaires about how satisfied you are with your inpatient stay. They will take about 10 minutes total to complete.

Medical Information Collection
Your personal health information from your medical records will also be collected as part of this study. The type of information that may be collected includes, but is not limited to, you demographics (such as your age, sex, and race), cancer diagnosis, body mass index (BMI), timing of morning blood draws, other health conditions you may have, how long you stay in the hospital, and if you are re-admitted to the hospital within 30 days after you are discharged.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for completing the questionnaires truthfully and accurately.

What happens if I say yes, but I change my mind later?

You can leave the research at any time; it will not be held against you.

If you decide to leave the research, it will not affect your care. If you decide to leave the research, contact the study doctor. You will be asked to answer the questionnaires 1 last time. The study doctor will discuss this with you. If you withdraw from this study, you can still choose to be treated at MD Anderson.

If you stop being in the research, already collected data may not be removed from the study database. You may be asked whether the study doctor can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

Is there any way being in this study could be bad for me? (Detailed Risks)

Questionnaires may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about completing the questionnaires, you are encouraged to contact your doctor or the study chair.

If you are feeling distressed and the study staff or doctor thinks it is needed, you will be referred to another doctor or therapist for additional help.

Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen, which may result in a **loss of confidentiality**. All study data will be stored in password-protected computers and/or locked file cabinets and will continue to be stored securely after the study.

This study may involve unpredictable risks to the participants.

You will be told about any new information that may affect your health, welfare, or choice to stay in the research.

Will it cost anything to be in this study? Will I be paid to be in this study?

There is no cost to you to take part in this study.

Certain procedures that you may receive as part of this study may be without cost to you because they are for research purposes only. However, your insurance provider and/or you may be financially responsible for the cost of care and treatment of any complications resulting from the research procedures. Standard medical care that you receive under this research study will be billed to your insurance provider and/or you in the ordinary manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your insurance provider may pay for, and which costs may be your responsibility. You may ask that a financial counselor be made available to you to talk about the costs of this study.

You will not receive any compensation for taking part in this study.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who need to review this information. Complete secrecy cannot be promised. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

Any personal information that could identify you will be removed or changed before data are shared with other researchers or results are made public.

Federal law provides additional protections of your medical records and related health information. These are described below.

Will my data be used for future research?

Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson or shared with other researchers and/or institutions for use in future research.

In some cases, all of your identifying information may not be removed before your data is used for future research. If future research is performed at MD Anderson, the researchers must get approval from the MD Anderson IRB before your data can be used. At that time, the IRB will decide whether or not further permission from you is required. If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data.

If identifiers are removed from your identifiable private information that are collected during this research, that information could be used for future research studies or shared with another researcher for future research studies without your additional informed consent.

What else do I need to know?

MD Anderson may benefit from your participation and/or what is learned in this study.

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:
   - Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
   - The IRB and officials of MD Anderson
   - Study monitors and auditors who verify the accuracy of the information
   - Individuals who put all the study information together in report form

   The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible (according to state and federal law). However, in some situations, the FDA could be required to reveal the names of participants.

   Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

E. A description of this clinical trial 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.

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under this protocol.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE

A witness signature is only required for non-English speakers utilizing the short form consent process (VTPS) and patients who are illiterate.

_____
PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT