# The Ohio State University Consent to Participate in Research

**Study Title: The Effects of Bright White Light Therapy on Fatigue, Sleep, Distress, Depression and Anxiety in the Hospitalized Leukemia Patient**

**Principal Investigator: Shelly L. Brown MS, APRN-CNS, OCN, AOCNS**

**Sponsor: None**

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

## Key Information About This Study

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

The purpose of this study is to determine if using Bright White Light Therapy (BWLT) during a patient's hospitalization can decrease adverse side effects that are often experienced during an intense leukemia treatment regimen. Those participants randomized to the treatment arm

will receive bright white light therapy which will consist of a light therapy unit designed to emit 10,000 LUX of bright white light, similar to a cloudless sky, without the UV exposure. The unit will be placed in front of the patient for 30 minutes each day at the time when the patient first awakens or at 12:00pm, whichever occurs first. There will not be activity restrictions during the 30 minutes of light therapy, as long as the light therapy unit remains on and within 16-24 inches of the participant's face.

Bright white light therapy has been shown to provide improvement in chemotherapy related fatigue when used in the home setting following treatment. This study will help to determine if some chemotherapy related symptoms can be minimized if bright white light therapy is used during treatment and a lengthy hospital stay.

Side effects reported when using bright white light therapy are rare and include nausea, headache, eyestrain and agitation. These side effects are common with patients receiving chemotherapy for acute leukemia and will be managed with standard of care medications. If these side effects do not resolve with standard of care medications and you are randomized to the treatment arm of this study, the light therapy will be discontinued.

## 1. Why is this study being done?

We are inviting you to join this study because patients receiving intensive treatment for a leukemia diagnosis may experience side effects during their treatment including fatigue, sleep alteration, distress, depression and anxiety. The main goal of this study is to learn if the addition of bright white light therapy to standard treatments will improve these symptoms. We also want to know if you saw your experience with bright white light therapy as a positive one.

The symptoms listed above are treated when necessary with medications. Bright white light therapy may offer improvement of these symptoms during hospitalization without the need for additional medication

## 2. How many people will take part in this study?

This study will include 110 patients.

## 3. What will happen if I take part in this study?

If you join this study, we will randomly assign you to one of two groups. The first group will receive our current standard of care, which includes all medications as needed to support you through your lengthy hospital stay. The second group will receive our current standard of care, which includes all medications as needed to support you through your lengthy hospital stay and will additionally receive bright white light therapy for thirty minutes each morning upon awakening. For those in the

second group, the bright white light therapy will be provided by a light therapy unit, often called a "happy light", which will stay in your hospital room until you are discharged from the hospital.

In order to determine whether the bright white light therapy provides a benefit, participants in both groups will be asked to complete five surveys which will be given pre-study and then weekly for three weeks and prior to discharge. There will be one additional survey provided at discharge for those who are in the group that receives the bright white light therapy. The surveys will also be provided at one month after your hospital discharge. The time to complete all 5 surveys is approximately less than ten minutes.

## 4. How long will I be in the study?

The study will be conducted during your initial hospitalization for leukemia treatment and include surveys 1 month after hospital discharge.

## 5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

## 6. What risks, side effects or discomforts can I expect from being in the study?

Some people who have used bright white light therapy have reported nausea, headache, eyestrain and agitation. During this study, you will also be receiving chemotherapy and may experience these same side effects during or following intensive treatment for leukemia. Management of these side effects will be the same for both groups which include standard medication treatment, depending on the symptom. For this research study, if you are in the group receiving bright white light therapy and you experience any of these listed side effects and they are not controlled with standard treatment, the use of the bright white light therapy will be discontinued.

## 7. What benefits can I expect from being in the study?

Your participation in this study allows us to collect more information about the use of bright white light therapy to control symptoms common to patients who receive chemotherapy during a lengthy hospital stay. Information from this study will help doctors and nurses learn more about methods for decreasing symptoms. Your symptoms may be lessened or stay the same during the study.

## 8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

## 9. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office records. Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information.

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

You may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form if the study involves the use of your protected health information.

## 10. Will my de-identified information (and bio-specimens) be used or shared for future research?

No.

## 11. What are the costs of taking part in this study?

There is no cost associated with this study.

## 12. Will I be paid for taking part in this study?

There will be no payment for participation.

## 13. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

## 14. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

## 15. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact Shelly Brown at 614-293-2598.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Shelly Brown at 614-293-2598 or contact the Office of Responsible Research Practices at 1-800-678-6251.

## Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form**.**

| | |
|---|---|
| **Printed name of participant** | **Signature of participant**<br>**AM/PM**<br>**Date and time** |
| **Printed name of person authorized to consent for participant (when applicable)** | **Signature of person authorized to consent for participant (when applicable)**<br>**AM/PM** |
| **Relationship to the participant** | **Date and time** |

## Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

| | |
|---|---|
| **Printed name of person obtaining consent** | **Signature of person obtaining consent**<br>**AM/PM**<br>**Date and time** |

**Witness(es)** - *May be left blank if not required by the IRB*

| | |
|---|---|
| **Printed name of witness** | **Signature of witness**<br>**AM/PM**<br>**Date and time** |
| **Printed name of witness** | **Signature of witness**<br>**AM/PM**<br>**Date and time** |