Consent to Participate in a Research Study
ADULT
Opioid Sparing Potential of Light-Induced Analgesia:
A Pilot Trial of a Novel, Non-Pharmacological Treatment for Pain

CONCISE SUMMARY

This is a research study to find out if non-pharmacological treatment is effective in controlling pain in patients with acute pain.

You will be randomly assigned to one of three groups: The Clear Group, the Green Glasses Group or the Blue Glasses Group. The Clear Group will receive clear lensed glasses to wear for four hours per day during your hospitalization. The Green Glasses Group will receive green lensed glasses to wear for four hours per day during your hospitalization. The Blue Glasses Group will receive blue lensed glasses to wear for four hours per day during your hospitalization. When you are dispensed your glasses, you will also receive a log book to report the time/duration of wearing your glasses. You will be able to share any comments you may have regarding the study and use of these glasses in this log. You will also be asked to complete a profile (PROMIS-57) on how you are feeling today. At the end of the study, the study team will collect your glasses and ask you to, once again, complete a PROMIS-57 profile.

The greatest risk of this study is the possibility of loss of confidentiality.

If you are interested in learning more about this study, please continue reading below.

You are being asked to take part in the research study because you are using opioids to help control your pain. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.
A grant from the National Institutes of Health will sponsor this study. Portions of Dr. Gulur's research team's salaries will be paid by this grant.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, your regular health care provider will continue to be your doctor throughout the time that you are in the study and afterwards.

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WHY IS THIS STUDY BEING DONE?
The purpose of this research study is to evaluate the use of non-pharmacological treatments for pain in patients whose medication regimen includes the use of opioids . We will compare the use of green colored lenses as part of pain management to see if it will lead to a reduction in pain medication usage for the duration of your hospital stay. Group one (Clear Group), involves the use of clear lensed glasses, group 2, (the Green Glasses Group) involves the use of green lensed glasses, and group 3, (the Blue Glasses Group) involves the use of blue lensed glasses.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 120 people will take part in this study within Duke University Health Systems.

WHAT IS INVOLVED IN THE STUDY?
If you agree to be in this study, you will be asked to sign and date this consent form. Participation is completely voluntary. If you decide not to participate, there is no penalty or loss of benefits to which you are otherwise entitled. If you do not sign this consent form, you will continue to receive care, but not as a part of this study.

You will be randomly assigned (by chance, like the flip of a coin) to one of two study groups. You have a 1 in 3 chance of receiving the clear glasses group, a 1 in 3 chance of receiving the green glasses group, and 1 in 3 chance of receiving the blue glasses group for pain management.

Group 1: Clear Glasses Group
Group 2: Green Glasses Group
Group 3: Blue Glasses Group

Although neither you nor the study team can choose which study group you will be assigned to, the study doctor and you will know the group to which you are assigned after you have signed this consent form.

Clear Glasses Group (Group 1): If you are assigned to the clar glasses Group, you will receive a pair of clear lensed glasses to wear for four (4) hours per day.

Green Group (Group 2): If you are assigned this Group, you will receive a pair of green lensed glasses to wear for four (4) hours per day.

Blue Group (Group 3): If you are assigned this Group, you will receive a pair of blue lensed glasses to wear for four (4) hours per day.

All groups will be asked to wear the glasses for four hours per day and record the time and duration of use in a glasses log. This log may also be used to write any concerns or comments you wish to tell the study team. You will also be asked to complete a profile (PROMIS-57) on how you are feeling today.

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On the day of your discharge or 48 hours postoperative, whichever comes first, you will be seen by the study team, again. At that time, the study team will ask you to complete the PROMIS-57 profile again and will collect both your glasses and log book.

HOW LONG WILL I BE IN THIS STUDY?
The study will last for the duration of your hospital stay.

You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

WHAT ARE THE RISKS OF THE STUDY?
There are no physical risks associated with this study other than those involved in standard care procedures. There is, however, the potential of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Also, you will be assigned to a study group by chance (like a coin flip) rather than by a medical decision made by the researchers.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
Participant Benefits
Taking part in this study may be direct benefit to you. If you are in the group that receives green glasses and it proves to improve your pain, you may benefit from participating in the study. However, this cannot be guaranteed. While researchers hope that the study group will be more effective than the usual treatment, there is no proof of this yet.

Benefits to Others or Society
This study will help researchers learn more about optimizing care for pain management in patients using opioids and it is hoped that this information will help in the treatment of future patients with opioid use and acute pain symptoms.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include the Duke University Health System Institutional Review Board and others as appropriate.

If any of these groups review your research record, they may also need to review your entire medical record.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by the federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed. Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1. There is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
2. You have consented to the disclosure, including for your medical treatment; or
3. The research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the

researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

WHAT ARE THE COSTS?
You or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study. Not all services are covered by insurance. Some procedures or scans may require pre-authorization by your insurance plan. We will notify you if we learn that a service is not covered by your insurance plan as part of the pre-authorization process. If it is not covered, you will be responsible for paying for it. The amount of your out-of-pocket expense will depend on your insurance plan. For beneficiaries with Medicare Advantage Plans, traditional Medicare is billed for the routine cost of a research study. You may have more or higher co-pays than with a Medicare Advantage plan. Please discuss the costs of the study with Dr. Gulur**.** At your request, a Financial Counselor in the clinic may provide you with an estimate of costs for routine services.

WHAT ABOUT COMPENSATION?
You will not be compensated for participating in this study.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Gulur at [redacted] or [redacted] at any time.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record. Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke.

If you do decide to withdraw, we ask that you contact Dr. Gulur in writing and let her know that you are withdrawing from the study. Her mailing address is Padma Gulur, MD; Duke University Medical Center; Department of Anesthesiology; [redacted]; Durham, NC 27710.
We will tell you about new information that may affect your health, welfare, or willingness to stay in this study. Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. Regulatory agencies may stop this study at any time without your consent. If this occurs, you will be notified and your study doctor will discuss other options with you.

Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your data, we will no longer be able to identify and destroy them.

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.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Gulur at [redacted] or [redacted] at any time.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

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STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time