Augusta University
Social Behavioral Research Informed Consent Document

The Impact of Meditation on Anxiety and Post-Operative Pain in Pediatric Patients Undergoing Urological Surgery

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If you are a legally authorized representative, or parent, permission from you is required. If the research involves a child, their assent (agreement) may also be required. When we say "you" in this consent form, it means the research subject; "we" means the staff involved with this study.

You are being asked to take part in this research study about anxiety that may occur when someone is going to have surgery. You are being asked to participate because you have been scheduled for urological surgery.

The purpose of this document is to:

- Explain your rights and responsibilities
- Explain the purpose of the study
- Describe what will happen if you decide to take part in this study
- Explain the potential risks and benefits of taking part in the study

Participation in research studies is voluntary. Please read this consent form carefully and take your time making your decision. As the study staff discusses this consent form with you, please ask them to explain any words or information that you do not clearly understand.

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

Why is this study being done?
The purpose of this study is to assess anxiety in patients before and after surgery and to assess whether meditation can reduce that anxiety. There will be up to 60 participants enrolled at Wellstar MCG Health.

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 this website at any time.

How long will I be in this study?
Your active participation in this study is expected to take about one month.
You can choose not to be in the study or stop participating at any time without penalty or loss of any rights or benefits you are entitled to. Please talk to the study staff first before you stop participating in the study.

What will happen to me in the study?
After providing consent, you will be "randomized" into one of the study groups described below. Randomization means that the group you are in is assigned by chance, like the flip of a coin. Neither you nor your doctor can choose the group you will be assigned to. You will have an equal chance of being placed in either group.

If you are assigned to the intervention group, you will be asked to watch a meditation video 3-5 times per week for 5 minutes, beginning 3 weeks before surgery. You will also be asked to complete a questionnaire to assess your anxiety at four different time points before and after surgery.

If you are assigned to the control group, you will be asked to complete the questionnaires only. You will not be asked to watch the video.

The questionnaire will be completed after surgery is scheduled, at the halfway point to the surgery, on the day of surgery, and one week postoperatively.

What are the risks of being in this study?
As a result of your participation in this study, there is a risk of loss of confidentiality of your information that is used in this study. There is some risk that your anxiety may worsen.

There may be more risks that are not known or not expected.

The study staff will tell you about new information that may affect your willingness to stay in this study.

Will I benefit from this study?
The possible benefits of this study are: You may experience a reduction of anxiety related to your surgery.

What are my other choices if I do not take part in this study?
You are not required to take part in this study. The alternative is not to participate.

Who will see my study information?
Study team members, the sponsor of the study, and their representatives will be able to see your study information. Your records may also be reviewed in order to meet federal or state regulations. Reviewers may include the Augusta University Institutional Review Board (the committee who oversees safety of volunteers in research studies), institutional officials, and outside agencies.

How will you keep my study information confidential?
Study records that identify you will be kept confidential except as required by law. You will not be identified in study records or publications disclosed outside Augusta University.

What will happen to my identifiable private information once collected?
Identifiers might be removed from your identifiable private information collected as a part of this research. After such removal, the information could be used for future research studies or be distributed to another investigator for future research studies without getting additional informed consent from you or your legally authorized representative.

What are my costs (what will it cost me) for taking part in the study?
It will not cost you anything to take part in the study.

Will I be paid for participation in this study?
You will not be paid for taking part in this study.

Who can answer my questions about this study?
You can ask questions about this study at any time. Please contact the study staff listed on page 1 of this document if you have questions about:

- Study procedures
- Reporting an illness, injury or other problem
- Leaving the study before it is finished
- Expressing a concern about the study
- Any other questions you may have about the study

Who can I contact to discuss my rights, problems, concerns, questions, or complaints I have as a study participant?
Contact the Augusta University Institutional Review Board at (706) 721-1483.

Can I be removed from the study?

Yes, you may be removed from the study if your surgery is cancelled, or if you are unable to complete the study procedures.

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to Augusta University and AU Affiliates to use or disclose your health information that identifies you for the study described earlier in this document.

The health information Augusta University and AU Affiliates may use or disclose for this study includes information in your medical or dental record, results of physical exams, medical or dental history, lab tests or certain health information indicating or relating to your condition.

The health information listed above may be used by and/or disclosed to the following, as applicable:

- Researchers and their staff;
- The sponsor of the study including its agents such as data storage banks or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Health insurers or payers in order to secure payment for covered treatment;
- Parents/Guardians of children younger than 18 years
- Vendors to facilitate payment or reimbursement for your participation in this study;
- Federal/state agencies and Augusta University and AU Affiliates committees having authority over the study. These may include, but are not limited to:
    - The Institutional Review Board (IRB) overseeing this study;
    - Committees with quality improvement responsibilities;
    - Office of Human Research Protections;
    - Privacy and Security staff for oversight and investigations;
    - Food and Drug Administration;
    - National Institutes of Health;
    - Other governmental offices as required by law.

Augusta University and AU Affiliates are required by law to protect your health information. By signing this document, you authorize Augusta University and AU Affiliates to use and/or disclose your health information for this research.

Once your information has been disclosed outside Augusta University and AU Affiliates, it may no longer be protected by federal laws and regulations and might be further disclosed by the persons or institutions receiving the information.

Please note that you cannot receive the research-related treatment (meditation video) if you do not sign this authorization.

Augusta University and AU Affiliates may not withhold treatment whether or not you sign this Authorization.

You may change your mind and take back (revoke) this Authorization at any time. If you revoke this Authorization, Augusta University and AU Affiliates may still use or release health information and any data and/or specimens already obtained about you as necessary for this study. If you revoke this Authorization, you cannot continue to participate in this study. To revoke this Authorization, you must write to the Principal Investigator listed at the top of this document.

You may not be allowed to see or copy the study information described on this Authorization as long as the study is in progress. When the study is complete, you have a right to request a copy of your personal health information collected for the study.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the study will reveal your identity without another signed authorization from you.

You will be given a copy of this Authorization. This Authorization does not have an expiration date. If you have questions or concerns about this Authorization or your privacy rights, please contact the Augusta University and AU Affiliates Enterprise Privacy Officer at 706-721-0900 or the toll-free compliance and ethics hotline at 1-800-576-6623.

Regulations require that you be given a copy of the Augusta University and AU Affiliates Notice of Privacy Practices describing the practices of Augusta University and AU Affiliates regarding your health information.

STATEMENT OF CONSENT

I have read this form and the information in it was explained to me. My taking part in the study is voluntary. All of my questions were answered. I will receive a copy of this form for my records. I agree to take part in this study. **I am not giving up my legal rights by signing this form.**

_____
Participant's Name (print)

_____ _____
Participant's Signature Date /Time (00:00)

PARENTAL STATEMENT OF CONSENT

I have read this form and the information in it was explained to me and my child. My taking part in the study is voluntary. All of my questions were answered. I will receive a copy of this form for my records. I agree to take part in this study. **My child is not giving up their legal rights by my signing this form.**

_____
Child's Name (print)

_____
Parent or Child's Legally Authorized Representative Name (print)

_____ _____
Signature of Parent or Child's Legally Authorized Representative Date /Time (00:00)

Participant's Name: _____

Participant's Medical Record Number:_____

INVESTIGATOR STATEMENT

I acknowledge that I have discussed the above study with this participant and answered all of his/her questions. They have voluntarily agreed to participate. I have documented this action in the participant's medical record source documents or research chart source documents, as applicable. A copy of this signed document will be placed in the participant's medical record or research chart, as applicable. A copy of this document will be given to the participant or the participant's legally authorized representative.

_____

Printed name of Investigator obtaining consent

_____ _____

Signature of Investigator obtaining consent Date /Time (00:00)