RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

TITLE: Music distraction and its influence on anesthetic requirements during elective knee surgery

VCU IRB PROTOCOL NUMBER: HM20010566

INVESTIGATOR: Bryant Tran

Please ask the study doctor or the study staff to explain any information in this consent document that is not clear to you. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

In this consent form, "you" always refers to the research participant. If you are a legally authorized representative, please remember that "you" refers to the study participant.

PURPOSE OF THE STUDY

The purpose of the study is to evaluate how music relates to the amount of sedation used during surgery. Music has been shown to reduce anxiety, reduce pain, and stabilize vital signs outside of the operating room, but has not been used in the operating room for joint replacement surgery.

DESCRIPTION OF THE STUDY

This study will incorporate all the elements of the standard protocol for total knee replacement at VCU. In addition, a music device and noise-cancelling headphones will be given to you once you arrive in the operating room. You will be randomized into one of two groups; one group will receive noise-cancelling headphones with music, and the other group will receive noise-cancelling headphones with no music. If you are in the music group, you will be able to select the music of your choice from the library provided by an internet music service. Music will be chosen for you if you have no preference. The anesthesia provider can help you adjust the music volume to your comfort level; you can approve of the volume by saying "yes, the volume is good" or giving another verbal cue of approval. The music will play for about two hours. You will not be able to adjust the volume or change the music channel during the surgery. If you opt to have the music stopped during the surgery, you will be withdrawn from the study and we will continue standard of care. You will also be given a noise-making instrument (rubber duckie) that you can squeeze if you are uncomfortable and need a dose of sedation through your IV.

Your participation in this study will last up to one day. The study protocol would be implemented during your surgery and no additional time would be necessary. Approximately 32 individuals will participate in this study.

Significant new findings developed during the course of this research study include the implementation of music as a safer and less expensive alternative to intravenous sedation. This finding has not been studied previously. The study will allow you to receive sedation if you feel uncomfortable or nervous during the surgery, regardless of which group you are assigned to.

PROCEDURES

Per VCU standard protocol, you will be evaluated in the pre-operative surgical unit on the day of surgery; if appropriate, a combined spinal-epidural will be offered to you, which will provide complete numbness to your legs during your knee replacement procedure. This allows the procedure to be completed without general anesthesia. A small amount of sedation is normally given in your IV in order for you to remain comfortable.

If you are in the music group, you will be given a music selection as described above during the procedure. Sedation will be given only if you request it; since you will not be able to feel anything in your legs during the surgery, sedation is not essential for successful completion of your knee replacement.

RISKS AND DISCOMFORTS

Safety is a priority, and this study will not interfere or delay any decisions that the anesthesiologist will make in order to ensure the best care possible.

Possible risks associated with the use of music distraction during surgery include:

- Discomfort
- Anxiety
- Need to switch to general anesthesia
- Confidentiality/privacy loss
- Unforeseeable risks due to limited research with music in the operating room

In order to minimize these risks, sedation will be available and will be given in a calculated fashion in order to optimize your comfort during surgery. If general anesthesia is necessary, we can safely do this. The study will not delay this decision if this becomes necessary. The risks associated with undergoing the surgery in the control group, without any music distraction, are not different than the risks associated with undergoing the surgery with music distraction.

USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

Authority to Request Protected Health Information

The following people and/or groups may request my Protected Health Information:

- Principal Investigator and Research Staff
- Research Collaborators
- Data Safety Monitoring Boards
- Others as Required by Law
- Study Sponsor
- Institutional Review Boards
- Government/Health Agencies

Authority to Release Protected Health Information

The VCU Health System (VCUHS) may release the information identified in this authorization from my medical records and provide this information to:

- Health Care Providers at the VCUHS
- Study Sponsor
- Data Coordinators
- Data Safety Monitoring Boards
- Others as Required by Law
- Principal Investigator and Research Staff
- Research Collaborators
- Institutional Review Boards
- Government/Health Agencies

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

Type of Information that may be released

The following types of information may be used for the conduct of this research:

☒ Complete health record
☐ Diagnosis & treatment codes
☐ Discharge summary
☐ History and physical exam
☐ Consultation reports
☐ Progress notes
☐ Laboratory test results
☐ X-ray reports
☐ X-ray films / images
☐ Photographs, videotapes
☐ Complete billing record
☐ Itemized bill
☐ Information about drug or alcohol abuse
☐ Information about Hepatitis B or C tests
☐ Information about psychiatric care
☐ Information about sexually transmitted diseases
☐ Other (specify):

Expiration of This Authorization

☒ This authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research project, whichever is later.

☐ This research study involves the use of a Data or Tissue Repository (bank) and will never expire.

☐ Other (specify):

Right to Revoke Authorization and Re-disclosure
You may change your mind and revoke (take back) the right to use your protected health information at any time. Even if you revoke this Authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you revoke this Authorization you may no longer be allowed to participate in the research study. To revoke this Authorization, you must write to the Principal Investigator.

BENEFITS TO YOU AND OTHERS

There is no guarantee that you will receive any medical benefits from being in this study. This is not a treatment study, and you are not expected to receive any direct medical benefits from your participation in the study. The information from this research study may lead to a better, safer, and less costly experience for people receiving a total knee replacement.

COSTS
There will be no additional costs created by this study.

ALTERNATIVE TREATMENT
Your alternative is not to participate in this study.

CONFIDENTIALITY
Potentially identifiable information about you will consist of data abstracted from your medical record, which will be used to obtain information about medications given in the operating room during your surgery.

Data is being collected only for research purposes.

It will be noted in your protected electronic medical record at VCU Health System that you are in this clinical trial. Information about the study including any medications you may receive will be noted in the record. This information is protected just as any of your other medical records are protected.

Your data will be identified by ID numbers, not names, and stored separately from medical records in a locked research area. All personal identifying information will be kept in password protected files and these files will be deleted after the study is completed. Research data from the study and its analysis will be kept indefinitely but will not contain any identifying information. Access to research data will be limited to study personnel. A data and safety monitoring plan is established.

VCU and the VCU Health System have established secure databases to help with monitoring and oversight of clinical research. Your information may be maintained in these databases but are only accessible to individuals working on this study or

VCU/VCUHS officials who have access for specific research related tasks. Identifiable information in these are not released outside VCU unless stated in this consent or required by law. Personal information about you might be shared with or copied by authorized officials of the Federal Food and Drug Administration or the Department of Health and Human Services.

Although results of this research may be presented at meetings or in publications, identifiable personal information pertaining to participants will not be disclosed.

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 Website will include a summary of the results. You can search this Web site at any time.

COMPENSATION FOR INJURY or ILLNESS

If you are injured by, or become ill, from participating in this study, please contact your study doctor immediately. Medical treatment is available at the Virginia Commonwealth University Health System (VCU Health System). Your study doctor will arrange for short-term emergency care at the VCU Health System or for a referral if it is needed.

Fees for such treatment may be billed to you or to appropriate third party insurance. Your health insurance company may or may not pay for treatment of injuries or illness as a result of your participation in this study.

To help avoid research-related injury or illness it is very important to follow all study directions.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may decide to not participate in this study. Your decision not to take part will involve no penalty or loss of benefits to which you are otherwise entitled. If you do participate, you may freely withdraw from the study at any time. Your decision to with draw will involve no penalty or loss of benefits to which you are otherwise entitled.

Your participation in this study may be stopped at any time by the study doctor (Dr. Bryant Tran, the principal investigator) without your consent. The reasons might include:

- the study doctor thinks it necessary for your health or safety;
- you have not followed study instructions;
- administrative reasons require your withdrawal.

QUESTIONS
If you have any questions, complaints, or concerns about your participation in this research, contact:

Bryant Tran, M.D
Assistant Professor of Anesthesiology
VCU Health System
Email address: Bryant.Tran@vcuhealth.org
Work phone: (804) 663-3589
Mailing address: P.O. Box 980695, Richmond, VA, 23298-0695

The researcher named above is the best person to call for questions about your participation in this study.

If you have general questions about your rights as a participant in this or any other research, you may contact:

Office of Research
Virginia Commonwealth University
800 East Leigh Street, Suite 3000
Box 980568
Richmond, VA 23298
Telephone: (804) 827-2157

Contact this number to ask general questions, to obtain information or offer input, and to express concerns or complaints about research. You may also call this number if you cannot reach the research team or if you wish to talk to someone else. General information about participation in research studies can also be found at http://www.research.vcu.edu/irb/volunteers.htm.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

CONSENT

I have been provided with an opportunity to read this consent form carefully. All of the questions that I wish to raise concerning this study have been answered.

By signing this consent form, I have not waived any of the legal rights or benefits, to which I otherwise would be entitled. My signature indicates that I freely consent to participate in this research study. I will receive a copy of the consent form once I have agreed to participate.

_____
Participant Name, printed

_____ _____
Participant Signature Date

_____
Name of Person Conducting Informed Consent Discussion
(Printed)

_____
Signature of Person Conducting Informed Consent Discussion Date

_____
Principal Investigator Signature (if different from above) Date [3]