UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT
INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title:	To Serenade or To Sedate? That is still the question – a follow-up trial on anxiolytic options before peripheral nerve blocks
Principal Investigator:	*Veena Graff MD, MS* Department of Anesthesiology & Critical Care Penn Pain Medicine Center 51 North 39th Street, 223 Wright-Saunders Philadelphia, PA 19104
Emergency Contact:	***Ask for the Anesthesia Resident On Call Be sure to tell the resident you are participating in this study. **215 908-0400**

Research Study Summary for Potential Subjects

You are being invited to participate in a research study. Your participation is voluntary, and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

You are scheduled to receive peripheral nerve block procedure as your primary type of anesthesia for the surgery you have been scheduled for and/or for the purposes of pain control after the surgery is complete. When you get this peripheral nerve block, it is done before you enter the operating room, in the preoperative area. This procedure typically takes approximately 10 minutes. In several cases, you may not need any form of anxiety relieving methods while receiving this peripheral nerve block, as it is not all that different than getting your IV placed. However, in times of needing anxiety relieving techniques, we routinely offer a variety of methods – either medication assisted methods by giving small dose, intravenous anxiety relieving sedation medications such as midazolam (also known as Versed) or non-medication methods such as listening to music to help relax you. Both methods (music of your choice or small dose sedation medication) have been shown in numerous studies to reduce anxiety and relax you

when this procedure is done for you. This research study that is being conducted is to simply evaluate any differences in anxiety scores, heart rate, blood pressure, and oxygen status when using sedation medication versus your choice of listening to music while undergoing this peripheral nerve block before your surgery.

If you agree to join the study, you will be asked to complete the following research procedures:

- Before undergoing the peripheral nerve block, you will either receive the sedative medication midazolam by intravenous injection or you will receive a pair of disposable, non-noise canceling headphones and select your choice of music to help ease any anxiety during the procedure.
- You will be asked to complete questionnaires that will assess your anxiety level before the procedure and after the procedure and how satisfied you were with your experience while receiving the nerve block.

Your participation will last for approximately 30-60 minutes from the time you agree in taking part of the study to after the procedure is done. Before and after the surgery, we will conduct an anxiety scoring test which includes six questions to answer and takes only a few minutes.

You are not expected to benefit directly from the study. Risks of using sedative medications include slowing your breathing, stopping breathing, variations in your blood pressure and/or heart rate, or reactions opposite of relaxing you such as making you potentially agitated or paranoid. There are virtually no side effects of listening to music.

Please note that there are other factors to consider before agreeing to participate such as additional procedures, use of your personal information, costs, and other possible risks not discussed here. If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

Why am I being asked to volunteer?

You are being invited to participate in a research study because you will be having surgery to repair a portion of your upper extremity or lower extremity, and you will receive a nerve block containing numbing medication for your pain control protocol after surgery. Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the study doctor and/or the research team about this form. If you decide to participate, you will be asked to sign this form.

What is the purpose of this research study?

You are scheduled to undergo surgery that involves your upper extremity or lower extremity. To help you with your pain control after surgery, you will receive a nerve block containing numbing medication that will numb the specific region your surgeon will be working on for pain control after your surgery. This method of pain control is known as a peripheral nerve block which is categorized under regional anesthesia as it numbs a region of your body. This nerve block involves injecting numbing medication around the nerve that provides feeling to the extremity your surgeon will be performing surgeon on.

The nerve block begins to work about 20 minutes after the needle injection. The extremity remains numb anywhere from 12 to 24 hours after the surgery.

When conducting this nerve block, your anesthesia team will use ultrasound image guidance to visualize the nerve to be numbed. They will numb up your skin with numbing medication prior to inserting a needle to inject the numbing medication around the nerve. Your heart rate, blood pressure, and oxygen status are routinely recorded while this procedure is being done.

During this procedure, patients may or may not get sedative medication. Sedation medication is not absolutely required as your skin is numb before injecting the medication. Sedation medication is used usually if a patient may experience some anxiety before the procedure. Listening to music of your choice has also been used in place of sedation medication to help reduce anxiety before surgery and while a procedure is being done.

The purpose of this study is to determine if there are differences in anxiety scores, heart rate, blood pressure, and oxygen status when using sedation medication versus your choice of listening to music while undergoing a peripheral nerve block before your surgery.

How long will I be in the study? How many other people will be in the study?

Your expected length of participation in this study is approximately 30-60 minutes from the time you agree in taking part of the study to after the procedure is done. Before and after the surgery, we will conduct an anxiety scoring test which includes six questions to answer and takes only a few minutes.

We plan to enroll 160 subjects who are scheduled to undergo surgery that involves their upper or lower extremity in which a peripheral nerve block is done.

What am I being asked to do?

If you sign the consent and agree to participate in this study, you will either receive a pair of disposable, non-noise canceling headphones and select your choice of music or medication to help ease any anxiety during the procedure.

All medications used are approved by the Food and Drug Administration (FDA).

If you agree to participate:
You will be randomized to receive either midazolam, which is a sedation medication, or music of your choice. This is a process of chance, similar to being assigned by the flip of a coin. The doses of midazolam will be administered according to the standard dosing regimen for an adult. The “dosage” or minimum time of listening to music is approximately 10-20 minutes.

By chance you will be assigned to receive one of the following:

- Midazolam
- Music of your own choice

You will be asked to complete questionnaires that will assess your anxiety level before the procedure and after the procedure and how satisfied you were with your experience while receiving the nerve block.

The research assistant will assist you with completing the questionnaires described here:

State Trait Anxiety Inventory – 6 (STAI-6) Anxiety Scale:

You will be asked to complete this survey a total of two times before and after your procedure. These time points will be before the start of your nerve block procedure and after the nerve block has been completed which will be a minimum of 20 minutes afterwards. This questionnaire will ask you questions about how you are feeling currently. This will take about 5 minutes to complete.

Visual Analogue Scale of your experience
You will be asked to complete this survey a total of one time at the end of the nerve block procedure after you do the anxiety inventory. This survey asks one question about how your overall experience was and will take less than 1 minute to complete.

What are the possible risks or discomforts?

A risk which is common to all studies which include randomization of patients to different treatment groups is the removal of the physician’s choice of anxiety preventing options. Since both anxiety control options are safe for the patients enrolled in this study, we do not foresee this to be a major risk to patients enrolling in this study. There is a possibility that outcome measures (like anxiety levels and patient satisfaction) might differ between the two nerve types.

Most patients receive sedation medication like midazolam to control for anxiety before surgery and before doing nerve blocks. However, some patients may not need it and some patients may have significant side effects to this medication. Music is a non-medication type of intervention that has been shown to reduce anxiety before surgery and during procedures. Any medications used in this study are FDA-approved.

You will have been screened by both your surgical and anesthesia team for allergies to any medications including those commonly used for anesthesia and post-surgery pain control. If you have any previous history of allergies to any of the medications used for the block or the standard of care post-surgery and discharge medications, you will not be able to participate in this study.

Common risks of sedation with midazolam include a decrease in your respiratory rate (slowing down your breathing). There is virtually no risk to listening to music of your choice.

You will receive care and be monitored throughout and following your nerve block per hospital standards as would any other non-study subject. (Standard protocol is the rules and regulations that must be followed for patient safety and quality of care).

Risks of breaches of confidentiality are small but nonetheless possible. However, we have taken several measures to protect your identity. All study data will be stored in confidential research files of the research investigator. Records will not contain your name or any other personal identifiers.

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?

Benefits can include minimizing or avoiding medications to reduce anxiety.

What other choices do I have if I do not participate?

If you do not participate in this study, your sedation regimen during your nerve block procedure will be determined by your anesthesia provider. You may ask the study team for more information about clinical options available if you do not participate in the study.

Will I be paid for being in this study?

You will not be paid for participating in this study.

Will I have to pay for anything?

There is no fee for participating in this study. You and/or your health insurance will be billed for the costs of medical care during this study given these expenses would have happened even if you were not in the study, or if your insurance agrees in advance to pay.

What happens if I am injured from being in the study?

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed in the consent form.

When is the study over? Can I leave the study before it ends?

This study is expected to end after all information has been collected. If you enroll in this study and later decide to withdraw your consent, whether before or after your procedure, you will be asked to notify a member of the study team. Their information can be found on page 1 of this consent form.

If you are unable to complete the procedure with music or midazolam, the anesthesiologist will withdraw you from the study and make sure you are able to complete your procedure.

If the primary investigator feels it is necessary for your health or safety, such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.

Who can see or use my information? How will my personal information be protected?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Electronic Medical Records and Research Results

What is an Electronic Medical Record and/or a Clinical Trial Management System?

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

A clinical trial management system (CTMS) is used to register your information as a participant in a study and to allow for your research data to be entered/stored for the purposes of data analysis and any other required activity for the purpose of the conduct of the research.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, information related to your participation in the research (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS. Information related to your participation in clinical research will also be contained in the CTMS.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any information produced from your participation in this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Information related to your participation in the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR.

Once placed in your EMR or in the CTMS, your information may be accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. Health Insurance Company, disability provider, etc.).

What information about me may be collected, used or shared with others?

The following personal health information will be collected, used for research, and may be disclosed during your involvement with this research study:

- Name, gender, ethnic background, date of birth
- Current and past medications or therapies
- Medical record number
- All information in the Medical Record

Why is my information being used?

Your personal contact information is important for the research team to contact you during the study. Your personal health information and results of tests and procedures are being collected as part of this research study. In some situations, your personal health information might be used to help guide your medical treatment.

Who may use and share information about me?

The following individuals may use or share your information for this research study:

- The investigator for the study and the study team
- Other authorized personnel at Penn, including offices that support research operations
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

Which of our personnel may use or disclose your personal health information?

The following individuals may use or disclose your personal health information for this research study:

- The Principal Investigator and the Investigator's study team
- Authorized members of the workforce of the UPHS and the School of Medicine, and University of Pennsylvania support offices, who may need to access your information in the performance of their duties (for example: for research oversight and monitoring, to provide treatment, to manage accounting or billing matters, etc.).

Who, outside of UPHS and the School of Medicine, might receive your personal health information?

As part of the study, the Principal Investigator, the study team and others listed above, may disclose your personal health information, including the results of the research study tests and procedures. This information may be disclosed to those listed below:

Regulatory and safety oversight organizations

- The Office of Human Research Protections
- The University of Pennsylvania Institutional Review Board

If your personal health information is disclosed to others outside of UPHS or the School of Medicine, it may no longer be covered by federal privacy protection regulations. The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

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.

How long may the School of Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire. Your information may be held in a research repository (database). However, UPHS and the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization to do so
- The University of Pennsylvania's Institutional Review Board grants permission after ensuring that appropriate privacy safeguards are in place
- As permitted by law

Can I change my mind about giving permission for use of my information?

Participation in this study is voluntary. You may withdraw your approval to allow the use and disclosure of your personal health information as described here. You must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, your personal health information that was collected before we received your written request may still be used and disclosed, as necessary for the study. If you withdraw your permission to use your personal health information, you will also be withdrawn from the research study.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document, you are permitting the School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

_____	_____	
Name of Subject (Please Print)	Signature of Subject	Date

_____	_____	
Name of Person Obtaining Consent (Please Print)	Signature	Date