VUMC Institutional Review Board
Informed Consent Document for Research

Study Title: Enhanced Recovery After Surgery in Extremity Sarcoma
Version Date: 12/19/2022 NCT04461171
PI: Joshua M. Lawrenz, MD

Name of participant:_____Age:_____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:
You are being asked to take part in this research study because you are being treated for sarcoma, including having surgery.

The purpose of this study is to learn more about pain control regimens given to sarcoma patients before, during, and after their surgery. This study will last from the time you are diagnosed until 3 months after your surgery, or approximately 6 months. During this study, you will receive a pain management regimen prescribed by your surgeon.

We will give you pain/mental health/functional outcome questionnaires to fill out at the time of your preoperative visit, during your hospital stay, and at the time of your postoperative visits. These questionnaires will be made available to you electronically via a link sent by email. Your physician will also fill out an assessment of your status called the MSTS Extremity Functional Outcome Score at the time of your initial clinic visit, day of discharge, and 3 week and 3 month post-operative visits.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to take part in this research study because you are being treated for sarcoma, including having surgery.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study

at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Side effects and risks that you can expect if you take part in this study:
All of the pain medications you will be taking as part of your treatment are standard of care. The only possible risk of study participation is a potential loss of privacy, and all relevant rules and regulations will be followed to protect the confidentiality of your information. This is described below in the sections about Confidentiality and Privacy.

Good effects that might result from this study:
The benefits to science and humankind that might result from this study are a better understanding of how different pain management plans affect sarcoma patients, which will allow us learn more about how best to treat patients like you for the pain associated with their sarcoma treatment.

Procedures to be followed:
You will be given the opportunity to enroll in this clinical trial during your first clinic visit. We will use four questionnaires to measure your pain and function. These will be given to you during the course of your treatment and after your operation. During your hospitalization, a pain management plan specific to you will be planned by your doctor. The pain management anesthesia team will be officially consulted throughout your hospital stay and managing your pain medications. After discharge, you will be seen at 2-3 weeks after surgery for wound check, and then again at 3 months after surgery. This will serve as final follow up for the purposes of this study. All pain management medications are standard of care and not experimental in themselves. The only research related activity you are participating in during this study is the completion of the questionnaires.

Payments for your time spent taking part in this study or expenses:
There are no payments to participants for taking part in this study.

Costs to you if you take part in this study:
If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research. However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the

costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury.

There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Research Coordinator [redacted]. If you cannot reach the research staff, please call the office of the lead primary investigator [redacted]

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:
If study personnel are unable to contact you after multiple attempts, you will be considered lost to follow-up.

What will happen if you decide to stop being in this study?
If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

Confidentiality:
Confidentiality will be assured by entering patient information directly into a secure database called REDCap. Vanderbilt REDCap is a secure program for building and managing online data collection. Only key study personnel will have access to the REDCap database. When the data are used for research, no patient identifying health information including date of birth, specific dates, name or medical record number will be included. Study ID numbers will be assigned to each patient to protect their identity.

Privacy:
Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Study Title: Enhanced Recovery After Surgery in Extremity Sarcoma
Version Date: 12/19/2022
PI: Joshua M. Lawrenz, MD

Study Results:
After study completion, a one-page summary sheet of your questionnaire scores will be given to you at your follow up visit, if you would like. To ensure the scientific quality of the research study, you will not be able to review your research data until after the research study is finished.

Authorization to Use/Disclose Protected Health Information

What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

Study Title: Enhanced Recovery After Surgery in Extremity Sarcoma
Version Date: 12/19/2022
PI: Joshua M. Lawrenz, MD

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date _____ Signature of patient/volunteer _____

Consent obtained by:

Date _____ Signature _____

Printed Name and Title _____