Washington University in St. Louis

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INFORMED CONSENT DOCUMENT

Project Title: Intravenous Lidocaine to Reduce Postoperative Opioid Consumption and Improve Recovery After Posterior Spinal Fusion for Adolescent Idiopathic Scoliosis

Principal Investigator: Scott Luhmann, MD
Research Team Contact: Susan Brandon (618-520-0590)

- If you are the parent/guardian of a child under the age of 18 who is being invited to participate in this study, the word "you" in this document refers to your child. As the parent/guardian, you will be asked to read and sign this document to give permission for your child to participate.
- If you are under the age of 18 and reading this document, the word "you" in this document refers to you. You will be asked to read and sign this document to indicate your willingness to participate.

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant. By signing this form you are agreeing to participate in this study.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you are schedule to have spinal fusion to correct your spinal deformity.

The purpose of this research study is to evaluate the effectiveness of systemic intravenous (IV; given through a vein) lidocaine to reduce opioid useafter posterior spinal fusion surgery in patients with Adolescent Idiopathic Scoliosis (AIS). Systemic means that the drug is given in a way so that the entire body is affected. Another purpose of this study is to see if lidocaine will reduce the inflammatory response to surgeryresulting in decreased opiate use and inflammation after surgery, and if it will lead to better long-term outcomes including decreased chronic opiate use and improved physical function.

Currently, opioids are the gold standard for pain management after spinal surgery. However, opioid use is associated with negative effects including long-term dependency and overdose. In the past 20 years, opiate addiction andthe associated risk of drug overdose, has become a crisis of public-health proportions, with overdose deaths exceeding those from both motor-vehicle collisions and firearms. Amongst the current epidemic of opioid use disorders (by prescription opioids and heroin), there is also an alarming growing public health problem in adolescent opioid dependency, which comes with devastating consequences. Early age onset of prescription opioid use has been associated with higher

likelihood of dependency and increasing health problems.

We are studying to see if intravenous lidocaine is an effective non-opioid method of treating pain after surgery. It has been studied most extensively in abdominal surgeries, which has shown it to be effective in reducing pain, opioid consumption, constipation, and hospital length of stay after abdominal surgeries. There has been only limited investigation into systemic lidocaine in orthopedic surgery, and none in orthopedic spinal fusion surgery treating adolescent idiopathic scoliosis (AIS). Thus, a study investigating the efficacy of intravenous lidocaine in the adolescent population after spinal surgery is needed, since this population is at higher risk for long-term use of opioid and drug dependency.

Lidocaine is approved by the U.S. Food and Drug Administration to produce local or regional anesthesia (anesthesia to a specific part of the body). However, the use of systemic lidocaine is considered investigational in this study.

The lidocaine is being compared to a placebo. A placebo is something that looks like the lidocaine, but does not contain any active ingredients. This means that some participants will receive the lidocaine, while others will receive the placebo.

WHAT WILL HAPPEN DURING THIS STUDY?

If you agree to be part of this study, you will first have some tests to see if you may continue. You will have blood (1ml of blood or less than half of a teaspoon) drawn to test how your kidneys and liver are working as a part of standard of care. You will also provide urine sample for a test to confirm you are not pregnant as a part of standard of care. Standard of care means you will have these tests anyway as part of your pre-op assessments and it is not done specifically for research purposes.
If these tests show you are able to continue in the study and you choose to continue, you will be randomly assigned to Group 1 (Study) which will receive intravenous lidocaine during and after posterior spinal fusion for AIS, or to Group 2 (Control) which will receive saline placebo during and after surgery. You have a 50% chance of being in the Study Group and a 50% chance of being in the Control Group. This is similar to the flip of a coin. Neither you nor your doctor can choose which group you are in. Neither you nor the surgeon will know which group you will be assigned to by the pharmacist. If you are assigned to the Study Group (the lidocaine group), you will be given lidocaine intravenously. If you are assigned to the Control Group (the placebo group), you will be given the placebo (saline) intravenously. The lidocaine or placebo will start to be given right when skin incision has been made and it will continue to be given during and after the surgery. It will stop being given once you have been in the Pediatric Intensive Care Unit (PICU) or the Pediatric Acute Care Unit (PACU) for 24 hours after the surgery.

We will also collect around two teaspoons of your blood (10mls) immediately before surgery, 4 hours and 8 hours post incision, day 1 post surgery, and day 2 to 3 post surgery to determine the effect of lidocaine infusion on the immuno-inflammatory response after spinal fusion surgery.

Your doctor and his medical team will monitor your health condition after the surgery twice a day to make sure that in the case there would be complications related to your surgery, they can treat the condition immediately.

You will be asked to complete two questionnaires at pre-op, 6 weeks, 3 months, 6 months, and 12

months after surgery. These questionnaires will ask questions regarding opioid use and your recovery. The questionnaires will be given during your standard of care postoperative visits; however, they may be e-mailed (if you agree later in the consent) or mailed to you if you do not come in for your standard of care visits at these times.
We will collect medical data from your medical record during your surgery and hospital stay and after surgery. We will follow you up to a year after your surgery.

Will you save my samples or research data to use in future research studies?
As part of this study, we are obtaining blood samples and data from you. We would like to use your blood samples and data for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding the immune response before and after surgery in AIS population or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use your blood samples and data you give up any property rights you may have in the blood samples and data.

We will share your blood samples and data with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at Washington University, at other research centers and institutions, or industry sponsors of research. We may also share your research data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual research data is placed in one of these repositories only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.

If you change your mind and do not want us to store and use your blood samples and data for future research you should contact the research team member identified at the top of this document. The blood samples and data will no longer be used for research purposes. However, if some research with your blood samples and data has already been completed, the information from that research may still be used. Also, if the blood samples and data has been shared with other researchers it might not be possible to withdraw the blood samples and data to the extent it has been shared.

Please place your initials in the blank next to Yes or No for each of the questions below:

My blood samples and data may be stored and used for future research as described above.

_____ **Yes** _____ **No**
Initials **Initials**

My blood samples and data may be shared with other researchers and used by these researchers for the future research as described above.

_____ **Yes** _____ **No**
Initials **Initials**

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 50 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for until your 12 month follow-up visit. If you agree to participate, the study procedures will add an additional 15 minutes onto your standard of care.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study. Lidocaine is given routinely as part of surgery and anesthesia. It is a widely used medication with a safe history. All medications may cause unwanted things though, some of the following may occur when we give you the lidocaine.

Some risks described in this consent document, if severe, may cause death.

Lidocaine

Likely

Cold feeling at your IV site with the injection

Less Likely

- Lightheadedness/dizziness
- Metallic taste in mouth

Numbness in fingers/toes

- Numbness in your mouth
- Ringing in ears

Rare

- Nausea/vomiting
- Impaired hearing
- Tremors
- Confusion
- Labile blood pressure (blood pressure that changes suddenly and frequently)
- May affect your heart rhythm (arrhythmias)

Blood Drawing

The blood draw may cause bleeding, bruising, or pain. Some people become dizzy or feel faint. There is also a rare risk of infection.

Breach of Confidentiality

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section

in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?
You may or may not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because this study will provide data for future non-opioid intra-and post-operative pain management for AIS patients.

WHAT OTHER TREATMENT OPTIONS ARE THERE?
Before you decide whether or not to be in this study, your doctor will discuss the other options that are available to you. Instead of being in this study, you could receive standard of care; which mainly only use opioid medication only to treat acute pain after surgery.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?
As part of this study you will receive tests and procedures that are similar to what you would receive during routine clinical care of your condition. Your health plan/insurance company will be billed for some or all of these costs, and you will be responsible for any co-pays and deductibles that are normally required by your health plan/insurance. Not all insurance plans cover the costs associated with being in a study. Even if they do, you may be responsible for more out-of-pocket expenses, such as co-pays and deductibles, when there are more tests and procedures or more expensive tests and procedures involved in the study than if you were to receive routine clinical care outside the study.

If you wish to know whether there are more tests and procedures or more expensive tests and procedures in the study, you should ask your study doctor.

If you wish to know whether your insurance will pay, you should contact them directly, or speak with the study team about obtaining a financial pre-certification prior to enrolling in the study.

WILL I BE PAID FOR PARTICIPATING?
You will not be paid for being in this research study.

WHO IS FUNDING THIS STUDY?
The Robert Jones Research Fund (RJRF) is funding this research study. This means that Washington University is receiving payments from RJRF to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from RJRFfor conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?
Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator at 314-454-4191 and/or the Human Research Protection Office at 1-(800)-438-0445.

Decisions about whether payment for medical treatment for injuries relating to your participation in research will be made by Washington University. If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you. We will keep your participation in this research study confidential to the extent permitted by law.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- The Robert Jones Research Fund
- Hospital or University representatives to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- The last four digits of your social security number may be used in hospital or University systems to track billing information for research procedures.
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.

To help protect your confidentiality, we will de-identify your data (remove identifiers and label the data with a unique ID number) and keep all paperwork in locked cabinets in a locked office. Electronic records will be maintained on a secure network on the secure Washington University system. All specimens will be assigned unique IDs so that they can't be directly linked to the participants, and only research team members will have the master key. Specimens will be stored in the secure facility and only authorized personnel and research team members will have access to enter the facility. Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others. Sharing this information will allow others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

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.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
    - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
        - **If you revoke your authorization:**
            - The research team may only use and share information already collected for the study.
            - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
            - You will not be allowed to continue to participate in the study.

Can we contact you by email?

We would like to contact you by email for the purposes listed below. Some of these emails may contain health information that identifies you.
We may email the questionnaires for you to fill out

Only the research team will have access to your email communications. We will only communicate by email to send you the information listed above. If you have any questions or need to contact us for an urgent or emergent situation, please contact the research team member identified at the top of this document.

You should be aware that there are risks associated with sending your health information via email.

- There is always a risk that the message could be intercepted or sent to the wrong email address. To avoid sending messages to the wrong email address, the first email we send you will be a test message to ensure we have the correct email address.
- When using any computer you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.
- If you share a home computer with other family members, and do not want them to know you are participating in this study make sure you provide an email address that only you can access.
- Your employer will have access to any email communications sent or received on any electronic devices used for work or through a work server.

Do you agree to allow us to send your health information via email?

_____ Yes **_____ No**
Initials **Initials**

IS BEING IN THIS STUDY VOLUNTARY?
Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?
You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ under Withdrawing from a Research Study.

If you decide to leave the study early before the surgery, we will ask you to contact the research team member and to inform your intention to withdraw from the study prior to your surgery. Some of the study intervention may have been performed if you decide to withdraw your participation after the surgery.

Will I receive new information about the study while participating?
If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?
Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because your medical conditions prior to the surgery altered and may not fit to be in the study.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Susan Brandon at 618-520-0590**.** If you experience a research-related injury, please contact: Scott Luhmann, MD at 314-454-4191.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: 01/17/25.

_____ _____

(Signature of Participant) (Date)

_____

(Participant's name – printed)

Parent/Guardian Name and Relationship to Participant:

Do not sign this form if today's date is after EXPIRATION DATE: 01/17/25.

_____
(Child's name – printed)

_____ _____
(Signature of Parent/Guardian) (Date)

_____ _____
(Name of Parent/Guardian- printed) (Relationship to participant – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)

_____
(Name of Person who Obtained Consent - printed)