Akron Children's Hospital

# Consent to Participate in a Research Study and HIPAA Authorization to Release Medical Information

Study Title: Title: Subdermal Betadine to Reduce Microbacterial Bioburden During Posterior Spinal Fusion

Principal Investigator: Lorena Floccari, MD
Co-Investigators: Todd Ritzman, MD
Richard Steiner, PhD
Alexandria Rundell, BS
Xiaotian Zheng, PhD

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PARTICIPANT'S NAME: _____ DATE OF BIRTH: _____

## Introduction

You are being asked to participate in a research study. This document has important information about what will happen if you decide to be in the study. Someone from the study team will use this document to explain the study to you.

In this document, "you" generally refers to the person who takes part in the research. If you are being asked as a parent, guardian, or legally authorized representative to allow someone else to take part, "you" in the rest of this document generally means that person.

## Key Information

You are being invited to participate in this research study because you have scoliosis and are undergoing a primary posterior spinal fusion.

Please make sure that you ask any questions that you have before you make your decision. Participating in research is voluntary, and completely up to you. You may say no or stop participating at any time. There will be no penalties or changes in the quality of health care you receive.

The main purpose of this study is to evaluate the effect of the antiseptic medication povidone-iodine applied underneath the skin. We hypothesize it will significantly reduce microbial growth.

If you join the study, all participants will follow the normal spine pathway, including standard antibiotics and skin preparation. Some participants will be randomized to receive an additional application of povidone-iodine underneath the skin after making the incision. The surgeon will apply 10% povidone-iodine via swab stick onto their subdermal layer (below the skin) after incision has been made. Bacterial cultures will be obtained with the use of a swab on the skin and in several wound layers and sent to the microbiology lab for cultures to assess bacterial

growth. Routine postoperative care of patients will not change according to culture results unless indicated by the care providers.

If you are not comfortable with any of the following, you may not want to join this study:

- You may or may not receive an application of povidone-iodine.
- Your health information will be shared with researchers and investigators.

There may be risks to you from participating. The most significant risk is allergic reaction to the medication, which occurs in up to 0.4% of patients. This could be minor skin irritation or more rarely a serious life-threatening allergic reaction. There is more information in the Study Details section of this form. There may be other risks that we don't know about yet.

We will take steps to protect your private information. However, we cannot guarantee that no one will see or access information collected about you.

There is potential benefit to participating in this research. It is possible that the application of povidone-iodine will reduce the bacteria present in your surgical wound, which could decrease the risk of post-operative infection.

You do not have to participate in this research. The other choice is to follow the standardized spine pathway. This research is not designed to diagnose or treat any disease. Your alternative is to not take part in the research.

**Please take a moment to think about this information and ask any questions that you have. If you think you might like to participate in this study, please continue to the Study Details section to learn more about the study.**

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**Study Details:**

**WHY ARE WE DOING THIS RESEARCH STUDY?**

We want to evaluate the effect of the povidone-iodine application in the dermal layer, located beneath the skin, where there are sweat glands and hair follicles that may contain bacteria. We hypothesize it will help reduce bacteria in the wound and decrease risk of post-operative infection.

**WHERE WILL THE STUDY BE DONE AND HOW MANY SUBJECTS WILL TAKE PART?**

This single site study will be completed at Akron Children's Hospital. Our goal is to enroll 60 patients in this study.

**WHAT WILL HAPPEN DURING THE STUDY AND HOW LONG WILL IT LAST?**

After enrollment, you will be randomly placed in the povidone-iodine group or the control group to follow the standardized spine pathway. The method of study treatment assignment for this study is performed by a biostatistician utilizing computer software that performs randomization. Your chance of receiving the povidone-iodine application is 50%. A sealed envelope will be provided, which will only be opened in the operating room after the surgery has started. Neither you, your parents/guardian, nor your study doctor will know which study treatment you will receive prior to the incision.

All patients will follow the spine pathway, including standard prophylactic antibiotics, skin preparation with isopropyl alcohol followed by 2% chlorhexidine gluconate (CHG) and 70% isopropyl alcohol (IPA) solution (ChloraPrep™), and sterile draping. A bacterial culture will be obtained from the skin with the use of a swab wiped along the planned incision. The surgeon will then make the incision and take another bacterial culture in the subdermal layer underneath the skin.

A nurse in the operating room then will open the sealed envelope that will state whether you are randomized to receive povidone-iodine or in the control group to receive saline. The only deviation from standard of care will be application of 10% povidone-iodine or saline via swab stick by the surgeon onto your subdermal layer of skin after incision has been made. Another bacterial culture will be obtained in the subdermal layer following povidone-iodine application. All patients will then have standard spine exposure, and then an additional bacterial culture will be obtained in the deep wound, and a final culture will be obtained prior to wound closure. All specimens will be labeled and sent to the microbiology lab for standard processing.

Routine postoperative care will not change according to culture results; postoperative antibiotics will not be extended or changed from standard protocol unless there is otherwise a clinical indication by the care providers. The duration of participation for patients will be only on the surgical day, though we will prospectively follow patients clinically to report postoperative course, including bacterial growth from cultures and occurrence of any complications, such as surgical site infection. There will be no secondary use of data/specimens. Clinically relevant research results will be given to participants.

## WHAT BAD THINGS CAN POSSIBLY HAPPEN DURING THIS STUDY?

1. **Risks of Povidone-iodine**
    a. Povidone-iodine is an over-the-counter topical antiseptic that is FDA approved in pediatric and adult patients. It is considered safe and effective to reduce the number of bacteria on the skin prior to surgery. Therefore, it is widely utilized in the healthcare setting as an antiseptic with low risks. This specific use of povidone-iodine in the subdermis after skin incision has not been previously reported. However, it is widely considered the standard of care for surgical skin preparation in the setting of open wounds and is therefore considered safe to use on the skin, in the subdermal and subcutaneous layers, and deeper within the wound. In addition to use as a topical surgical skin antiseptic, povidone-iodine can also be utilized directly within spinal wounds, with prior studies

demonstrating safety in pediatric deformity surgery when used to irrigate the wound.

b. Allergic or hypersensitivity reaction can rarely occur. Allergic contact dermatitis (type-IV hypersensitivity reaction) is poorly described despite widespread use of this product, with prior studies demonstrating a low prevalence of 0.04% - 0.4%. If this occurs, the povidone-iodine will be washed away with saline. Type-1 allergic reactions leading to anaphylaxis resulting from povidone-iodine exposure is exceedingly rare, though could result in anaphylactic shock which can be life-threatening. Patients will be asked about allergy to povidone-iodine at time of consent. While the risk of previously undiagnosed allergy cannot be completely avoided, it is exceedingly rare. Povidone-iodine should be avoided in the setting of true allergy confirmed by patch testing.
c. While povidone-iodine is an antiseptic/antibacterial medication, there is a small risk of contamination that could introduce infection. The FDA has recommended that single-use packages are used to minimize this risk, so single-use packages of 3 swabs will be used for this study.
d. Other contraindications to povidone-iodine use includes pregnancy or comorbidity such as hyperthyroidism or other thyroid disease after treatment with radioiodine.

2. **Risks of Bacterial Cultures**
   a. The culture swabs used for this study are single-use swabs used routinely for obtaining intraoperative cultures. Sterile technique will be followed. However, like all surgical equipment, there is theoretic risk of contamination that could introduce infection.
3. **Other Risks Associated with This Study**
   **a.** Participation in this surgery may slightly prolong your surgery. We anticipate that obtaining each culture and the application of the povidone-iodine will each take about 10-20 seconds, so the total duration for study participation should be less than 2 minutes of additional time under anesthesia.
   **b.** A potential risk is loss of patient confidentiality through your data being accessed and included as part of this study. All precautions will be taken to keep your data

secure.

**WHAT GOOD THINGS CAN POSSIBLY HAPPEN DURING THIS STUDY?**

We hope to learn more about the most effective skin preparation option for spine surgery. Povidone-iodine has the potential benefit as an antiseptic in the subdermal layer that could reduce bacteria and help avoid surgical site infection, which is one of the most common risks of spinal fusion surgery. This study also has the potential for widespread benefit to others by improving methods of reducing the burden of surgical site infection in all surgical wounds.

**WHAT IF BEING IN THIS STUDY CAUSES INJURIES?**

In the event that any injury as a result of this study requires additional medical care, care will be available at Akron Children's Hospital. If you seek emergency care elsewhere, please let your study investigator or someone on their team know as soon as you can. Medical care will be offered at the usual charge. Akron Children's Hospital is not able to provide free medical care or payment for any injuries resulting from participating in this study. However, this does not mean that you give up any of your rights under state or federal laws to seek compensation from those involved in the research, including the Sponsor and Akron Children's Hospital.

**WHAT WILL HAPPEN IF NEW INFORMATION IS FOUND OUT ABOUT THE MEDICATION OR TREATMENT?**

If any significant new findings develop during this research, which may affect your willingness to continue participation, you will be provided this information.

**WHAT OTHER TREATMENTS ARE THERE?**

The alternative to participation in this study would be choosing to not participate. You will then receive the standard of care skin preparation according to the standard spine pathway.

**WHAT WILL HAPPEN IF I DO NOT FINISH THIS STUDY?**

You can change your mind and choose to not participate at any time. You will then receive the standard of care skin preparation according to the standard spine pathway. Please discuss any concerns with the surgeon and/or research team.

**WILL I RECEIVE ANY COMPENSATION FOR PARTICIPATING IN THIS STUDY?**

You will not receive any compensation for participating in this study.

**WILL THERE BE ANY COST TO ME?**

There will be no cost to participate in this study. All materials, including the povidone-iodine, culture swabs, and the bacterial cultures, will be provided through the study at no charge to you.

**HOW WILL MY STUDY INFORMATION BE KEPT PRIVATE?**

All electronic data will be kept on a secure password-protected electronic folder on a secure network drive. All paper records will be secured in a locked cabinet in the principal investigator's office. The Eswabs will be managed according to standard microbacterial lab protocols: they will be stored and refrigerated for 3 days after receiving the specimen. Following this time frame the specimen will be discarded. Disposal of all specimens and isolates is done as regulated medical waste to ensure proper control of biohazards and secure destruction of health information that may be on labels. Any organism reported to the patient's chart is held at room temperature for 5 days for aerobic organisms, and up to 2 years for anerobic organisms before disposal according to standard microbiology laboratory protocols. Following study completion, all patient identifiers will be removed.

We will keep all research records that identify you private to the extent allowed by law. Results of the study may be published; however, your name and other identifying information will be kept private.

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## HIPAA Authorization

**WHY IS MY/MY CHILD'S INFORMATION BEING USED?**

In order to perform the study, the researchers need to use and share some of your/your child's protected health information. Federal and state privacy laws require that the study doctor explain to you/your child in detail, what information will be obtained during the study, how that information will be used and with whom it will be shared. By signing this form, you provide your permission for Akron Children's Hospital to use and disclose your information to the individuals and entities described below for the purpose of conducting and managing the study. This may include research databases or repositories and future research. You have the right to review and/or copy records of your protected health information. However, you do **not** have the right to review and/or copy records kept by the researchers or sponsor associated with this research study.

**WHAT INFORMATION DO THE RESEARCHERS WANT TO USE?**

The study researchers or staff will collect information for the study from medical records, examinations, observations and forms or questionnaires that you/your child may have completed. This information may identify you/your child by name, social security number, date of birth or other identifying information. The information used for the study may include:

- History and diagnosis of the condition to be studied
- Current and previous treatments that you/your child received
- Other medical conditions that may affect the management of the condition to be studied
- Laboratory, radiology and any other test results that have been used to determine if you/your child may participate in the study
- Results used to assess response to and the safety of the study
- Physical findings, vital signs and clinical notes from your/your child's care during the study
- Follow-up information about your/your child's health, course of the condition and any late effects from the study
- Other information from your child's medical record as needed.

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**WHO WILL RECEIVE MY/MY CHILD'S INFORMATION?**

The following is a list of the individuals and entities that Akron Children's Hospital may disclose your information to:

- Akron Children's Hospital and its representatives
- Institutional Review Board and government regulatory agencies such as the US Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), the European Medicines Evaluation Agency (EMEA), or other regulatory agencies within and outside the United States

The researchers will keep all patient information private as required by law. Akron Children's Hospital will use and disclose your information only as described in this form and in our Notice of Privacy Practices.

**WHAT IF I DECIDE NOT TO SIGN THIS AUTHORIZATION?**

We must have your authorization to use and disclose your protected health information for the study. You do not have to give us this authorization. If you do not give us this authorization, you/your child may not join this study.

**HOW LONG WILL THIS AUTHORIZATION LAST? CAN I CHANGE MY MIND ABOUT GIVING THIS AUTHORIZATION?**

This authorization does not expire. However, you can change your mind about the study at any time and revoke (take back) your authorization. If you change your mind, you must revoke your authorization in writing. Beginning on the date that you revoke your authorization, no new protected health information will be used for research, and you will be removed from the research at that time. However, researchers may continue to use the health information that was provided before you revoked your authorization.

To revoke your authorization, please write to the person below. She will make sure your written request to revoke your authorization is processed correctly.

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Name of Contact Person: Lorena Floccari, MD

Address: Akron Children's Hospital
One Perkins Square
Akron, Ohio 44308-1062
Phone: (330) 543-3500 Fax: (330) 543-3166

**WHOM SHOULD I CALL IF I HAVE QUESTIONS OR PROBLEMS?**

If you have questions about anything while you are in this study, you have 24-hour access to talk to the principal investigator Lorena Floccari, MD and/or the Akron Children's Hospital orthopedic surgeon on call for urgent issues. Please call 330-543-3500 during business hours or paged through the hospital operator at 330-543-1000 (24 hours a day, 7 days a week).

If you have questions or are worried about your child's rights as a research participant, please call the Akron Children's Hospital Institutional Review Board (IRB), a committee that reviews all human research, at 330-543-3691.

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## SUBJECT'S LEGAL REPRESENTATIVE STATEMENT

I have read this consent and HIPAA authorization form and have had a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have more questions about my participation in this study or a research-related injury, I may contact Lorena Floccari, MD at 330-543-3500 or through the hospital page operator at 330-543-1000 (24 hours a day, 7 days a week).

I voluntarily agree to participate in this research study. I will be given a copy of this form, with all the signatures and dates, for my own records.

PARTICIPANT'S NAME: _____ DATE OF BIRTH: _____

## CONSENT SIGNATURES

_____ _____
Printed name of Subject/Parent/Legal Guardian Relationship to subject

_____ _____
Parent or Legal Guardian signature (if applicable) Date

_____ _____
Adult subject signature Date

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_____ _____
**Person Obtaining Consent** Date
*I certify that I have explained the research, its purposes, and the procedures to the subject before requesting their signature.*

_____ _____
Person obtaining consent signature Date

If consent was **not** obtained by the Principal Investigator:

_____ _____
Principal Investigator Signature Date