Boston Children's Hospital

RESEARCH CONSENT FORM

Use Plate or Print:

MRN#:

DOB:

Subject's Name:

Gender:

Protocol Title: Bacterial Wound Contamination Prior to Closure: Povidone-Iodine versus Saline Irrigation in Pediatric Spine Fusion Surgery

Principal Investigator: Michael Glotzbecker MD

Please check one of the following:

_____ You are an adult participant in this study.

_____ You are the parent or guardian granting permission for a child in this study.

If the participant is a child the use of "you" refers to "your child".

This consent form gives you important information about a research study. A research study helps scientists and doctors learn new information to improve medical practice and patient care.

Participation in this research study is voluntary. You are free to say yes or no and your decision will not impact the care you receive at Boston Children's Hospital. You can withdraw from the study at any time. A description of the study and its risks, potential benefits and other important information are in this consent form. Please read this consent form carefully and take your time making a decision. The form may contain words that you do not understand. Please ask questions about anything you do not understand. We encourage you to talk to others (for example, your friends, family, or other doctors) before you decide to participate in this research study.

How are individuals selected for this research study? How many will participate?

We are inviting you to participate in this study because you are between the ages of 3 to 18, have a diagnosis of spinal deformity and are undergoing elective posterior spine instrumentation surgery.

Why is this research study being conducted?

In this research study, we want to learn more about how effectively povidone-iodine (disinfectant that has been shown to reduce the number of bacteria present on human tissue) can reduce the number of bacteria in a surgical wound compared to the sterile saline solution (sterile salt water).

For many years, povidone-iodine has been used to disinfect the outer surface of the skin, and disinfect the wounds of heart, chest, lung, genital, and urinary surgeries. We want to know if povidone-iodine is more effective than sterile saline at lowering the number of bacteria in spine fusion surgery.

Who is conducting this research study, and where is it being conducted?

You are being asked to participate in a multi-center research study conducted in Boston, Philadelphia, and Kansas City. At Boston Children's Hospital, the principal investigator of the study is Dr. Michael Glotzbecker of the Division of Spine Surgery in the Department of Orthopedics. The study is sponsored by a Shore Foundation grant provided by Boston Children's Hospital.

Your health care provider may be a research investigator for this research and as an investigator, is interested in both your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another health care provider who is in no way associated with this project. You are not under any obligation to participate in any research project offered by your health care provider. If you choose not to participate or not to allow your child to participate, your care at Boston Children's Hospital and/or with your health care provider will not be affected in any way at all.

How many people will participate in this research study?

Approximately 150 people will take part in this study at the three different hospitals, and approximately 100 people will take part at Boston Children's Hospital.

What do I have to do if I am in this research study?

As part of your clinical care, you have agreed to undergo an elective posterior spine instrumentation surgery.

Once the surgery has been performed, we will collect a first sample by swabbing the wound, or removing a small piece of tissue, according to the hospital's routine surgical pathology guidelines, before it is washed out and closed, in order to find out how much bacteria is present.

A spine fusion wound is typically washed out with sterile saline (sterile salt water) or povidone-iodine (disinfectant that has been shown to reduce the number of bacteria present on human tissue). If you participate in the study, your wound will be washed out with 1) povidone-iodine or 2) sterile saline.

Because no one knows whether povidone-iodine or sterile saline is best, you will be "randomized" into one of the two study groups. Randomization means that you are put into a group by chance. It is like flipping a coin. You will have an equal chance of being placed in either group. One group will receive povidone-iodine, and one group will receive sterile saline. Neither you nor the research investigator can choose what group you will be in.

Since the expectations of patients can influence the results of a study, you will not know which type of wash-out you get until the study is over. But, if there is an emergency, your doctor will be able to get this information.

After the wound is washed out with povidone-iodine or sterile saline, we will collect another sample by swabbing the wound, or removing a small piece of tissue, according to the hospital's routine surgical pathology guidelines. This sample will be done in order to compare how well the povidone-iodine and saline, or sterile saline reduced the number of bacteria. The clinical treatment after the second sample is considered standard practice.

In addition, the research study will collect demographic, antibiotic usage, medical history, and surgical data, including but not limited to: gender, race, diagnosis, height, weight, surgical time, and blood loss. The outcome of your spine fusion surgery will be followed for up to two years, and any complications you have will be noted.

The assignment of the wash-out (povidone-iodine and saline, or sterile saline) and swabbing or tissue collection are considered research. The spine instrumentation surgery and treatment is considered standard of care, and

the data that we are collecting for the research study are from your medical record. No other procedures will be necessary for the research.

Study Protocol Summary:

	Surgery
Surgical wound wash with povidone-iodine, or sterile saline	X
Bacteria Swab or Tissue Collection	X

What are the risks of this research study? What could go wrong?

If your surgical wound is washed with povidone-iodine and saline, it is possible that trace amounts of iodine could remain in the wound and increase the amount of iodine in your blood.

We will swab or collect tissue from your surgical wound before and after it is washed with your assigned solution. As part of clinical care, all patients are given antibiotics for the first 24 hours following surgery. These antibiotics treat most types of bacteria and, for this reason, even if any of your wound samples test positive for bacteria, we will note it in your medical record but we will not treat you. This is standard practice and you would only be treated by your surgeon if there were clinical signs of an infection.

All research study data will remain private and secured at all times; however, you should be aware that despite all safeguarding efforts a breach of confidentiality is possible.

In addition you should be aware that participating in a research study may have risks that are currently unforeseeable and that additional costs could result from participation (eg. extended hospitalization).

What are the benefits of this research study?

Being in this research may not help you **right now.** In the future, this research study may benefit children who undergo surgical procedures. If povidone-iodine is found to be more effective at reducing the number of bacteria in a wound, then fewer patients' wounds will become infected.

Are there costs associated with this research study? Will I receive any payments?

Patients who participate in this study will receive no monetary compensation or reimbursement.

Although research funds will pay for the testing of the swabs or tissues during your elective posterior spine instrumentation surgery, we may bill your health insurer for routine items and services you would have received even if you did not take part in this research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. If you have any questions about costs to you that may result from taking part in the research, please speak with the research staff.

In the event of an injury resulting directly from your participation in this research study, medical treatment will be provided if the injury is reported in a timely manner. Provision of such medical care does not imply any negligence or other wrongdoing on the part of the Hospital or any of the physicians or other personnel involved in the study. Where applicable, the Hospital reserves the right to seek payment from third-party payers for any

medical care or services rendered. The Hospital has no program to provide you with any additional compensation as a result of any such injuries.

If I do not want to take part in this research study, what are the other choices?

Participation in this study is voluntary. If you do not want to take part in this research study, your wound will be washed out according to your doctor's clinical judgment before it is closed up.

At Boston Children's Hospital, washing out wounds with povidone-iodine or sterile saline is standard care. Surgeons at other institutions use sterile saline, povidone-iodine, chlorhexidine gluconate, soap, or bacitracin. Since no method has yet been proven best, this study will compare the effectiveness of two options.

Note that your refusal to participate will not interfere with current or future care received at Boston Children's Hospital.

What are my rights as a research participant?

Study participation is voluntary. Refusal to participate or withdrawal from the study will in no way affect the medical care patients receive at Boston Children's Hospital. Participants will be able to know the results of the study once they have been published.

Why would I be taken off the study early?

Anticipated circumstances under which your participation will be terminated by the investigator without regard to your consent include:

- The study loses funding.
- You fail to follow the study requirements.
- You need a treatment or medication that may not be taken while on the study or the Principal Investigator feels it is in your best interest to be taken out of this study.
- Withdrawal of parent/guardian permission.

Other information that may help you

Boston Children's Hospital has recently developed a web-based, interactive educational program for parents called "A Parent's Guide to Medical Research." To find out more about research at Children's Hospital, please visit the program at www.researchchildren.org.

Boston Children's Hospital is interested in hearing your comments, answering your questions and responding to any concerns regarding clinical research at Children's Hospital. If you would like further information about the type of clinical research performed at the hospital or have suggestions, questions or concerns regarding clinical research you may send an email to cci@childrens.harvard.edu or call 617 355-7052 between the hours of 8:30 and 5:00.

Who may see, use or share your health information?

A copy of this consent form will be placed in your medical record. If you do not have a medical record at Boston Children's Hospital, one will be created for you.

Medical information collected during this study will become part of your hospital record, including: bacteria present before and after washout with povidone-iodine or sterile saline (presence and type, if applicable)

Medical records are considered permanent records; therefore, materials cannot be deleted from the record. Medical records are available to health care professionals at Children's Hospital and may be reviewed by Hospital staff in their course of carrying out their responsibilities; however, they are required to maintain confidentiality in accordance with applicable laws and Hospital policies. Information contained in your/your child's medical record may not be given to anyone unaffiliated with Children's Hospital in a way that could identify you/your child without written consent, except as required or permitted by law. Information collected during the study that does not become part of your/your child's medical record will be stored in separate research files maintained by the investigator. These research records will not be made available to any individuals who are not part of the research team unless you so request or as required by law. If you/your child withdraw from the research study, information that has already been collected will become part of the research data; however, you/your child will not be identified.

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.

What should you know about HIPAA and confidentiality?

You/your child's health information is protected by a law called the Health Information Portability and Accountability act (HIPAA). In general, anyone who is involved in this research including those funding and regulating the study may see the data, including information about you. For example, the following people might see information about you:

- Research staff at Boston Children's Hospital involved in this study.
- Medical staff at Boston Children's Hospital directly involved in your care that is related to the research or arises from it.
- Other researchers and centers that are a part of this study, including people who oversee research at that hospital.
- People at Boston Children's Hospital who oversee, advise, and evaluate research and care. This includes the ethics board and quality improvement program.
- People from agencies and organizations that provide accreditation and oversight of research.
- People that oversee the study information such as data safety monitoring boards, clinical research organizations, data coordinating centers, and others.
- Sponsors or others who fund the research, including the government or private sponsors.
- Companies that manufacture drugs or devices used in this research.
- Federal and state agencies that oversee or review research information, such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and public health and safety authorities.
- People or groups that are hired to provide services related to this research or research at Boston Children's Hospital, including services providers, such as laboratories, and others.
- Your health insurer for portions of the research and related care that are considered billable.

If some law or court requires us to share the information, we would have to follow that law or final ruling.

Some people or groups who get your health information might not have to follow the same privacy rules. Once your information is shared outside of Boston Children's Hospital, we cannot promise that it will remain private. If you/your child decide to share private information with anyone not involved in the study, the federal law designed to protect privacy may no longer apply to this information. Other laws may or may not protect sharing of private health information. If you have a question about this you may contact the Boston Children's Hospital Privacy Office at 857-218-4680 which is set up to help you understand privacy and confidentiality.

Because research is ongoing we cannot give you an exact time when we will destroy this information. Researchers continue to use data for many years so it is not possible to know when they will be done.

We will also create a code for the research information we collect about you so identifying information will not remain with the data and will be kept separately. The results of this research may be published in a medical book or journal or be used for teaching purposes. However your name or identifying information will not be used without your specific permission.

Your privacy rights

If you or your child do not want to participate in this study, you do not have to. If you do want to participate, however, you must sign this form.

If you do not sign this form, it will not affect your care or your child's care at Boston Children's Hospital now or in the future and there will be no penalty or loss of benefits. You/your child can withdraw from the study and end your permission for Boston Children's Hospital to use or share the protected information that was collected as part of the research; however you cannot get back information that was already shared with others. Once you remove your permission, no more private health information will be collected. If you wish to withdraw your health information will need to do so in writing.

You/your child may have the right to get some the information that was shared with others for research, treatment or payment. This information is available after the study analysis is done. To request the information, please contact the Hospital's Privacy Officer at 857-218-4680.

Contact Information

I understand that I may use the following contact information to reach the appropriate person/office to address any questions or concerns I may have about this study. I know:

I can call…	At	If I have questions or concerns about
Investigator **Michael Glotzbecker**	Phone: **(617) 355-4847** Pager: **4583**	▪ General questions about the study ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints
Research Coordinator	Phone: **(617) 919-1633** Pager: **8351**	▪ General questions about the study ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints
Office of Clinical Investigations	Phone: **617-355-7052**	▪ Rights of a research subject ▪ Use of protected health information. ▪ Compensation in event of research-related injury ▪ Any research-related concerns or complaints. ▪ If investigator/study contact cannot be reached. ▪ If I want to speak with someone other than the Investigator, Study Contact or research staff.

Documentation of Informed Consent and Authorization

- I have read this consent form and was given enough time to consider the decision to participate in this study.
- This research study has been satisfactorily explained to me, including possible risks and benefits.
- All my questions were satisfactorily answered.
- I understand that participation in this research study is voluntary and that I can withdraw at any time.
- I am signing this consent form prior to participation in any research activities.
- I give permission for my/my child's participation in this research study and for the use of associated protected health information as described above (HIPAA).

Parent/Legal Guardian Permission (if applicable)

If the child to be involved in this research study is a foster child *or a* ward of the state *please notify the researcher or their staff who is obtaining your consent.*

■ _____ _____ _____

Date (MM/DD/YEAR) Signature of **Parent #1** or **Legal Guardian** Relationship to child

Child Assent (if applicable)

■ _____ _____

Date (MM/DD/YEAR) Signature of **Child/Adolescent Subject**

■ If child/adolescent's assent is **not** obtained above, please indicate reason below (check one):

☐ Assent is documented on a separate IRB-approved assent form

☐ Child is too young
☐ Other reason (e.g. sedated), please specify: _____

Adult Subject (if applicable)

■ _____ _____
Date (MM/DD/YEAR) Signature of **Adult Subject** *(18+ years)*

ADULT SUBJECT - if decisionally impaired (if applicable)

Legal Authorized Representative/Guardian

I give permission for the person I am authorized to represent to participate in this research study and for the use of associated protected health information as described above (HIPAA).

■ _____ _____ _____
Date (MM/DD/YEAR) Signature of **Legal Guardian** Print Name

■ Relationship to Subject * (*This order must be followed. If there is a court appointed guardian, this is who needs to provide consent. If not, a health care proxy, followed by durable power of attorney and lastly, family members)*

☐ Court-Appointed Guardian
☐ Health Care Proxy (Attach Proxy and ensure there is express authority to make health care decisions inclusive of research.)
☐ Durable Power of Attorney (POA) (Durable POA may be limited to specific areas. Attach Durable POA and ensure it covers research.)
☐ Family Member/Next of Kin, (*in order of preference: spouses, parents and adult children)*
Specify relationship_____

Adult Assent (if applicable)

■ _____ _____
Date (MM/DD/YEAR) Signature of **Adult Subject**

☐ CHECK if Adult Subject's assent **not** obtained above, and specify reason below:

_____

Investigator or Associate's Statement & Signature

- I have fully explained the research study described above, including the possible risks and benefits, to all involved parties (subject/parents/legal guardian as applicable).
- I have answered and will answer all questions to the best of my ability.
- I will inform all involved parties of any changes (if applicable) to the research procedures or the risks and benefits during or after the course of the study.

- I have provided a copy of the consent form sign by the subject/ parent / guardian and a copy of the hospital's privacy notification (if requested)

■ _____ _____

Date (MM/DD/YEAR) Signature of **Investigator or Associate**

Witness Statement & Signature

A witness must be present for the entire consent process in the following situations (please check the appropriate box)

☐ The individual cannot read and this consent document was read to the subject or legal representative, **or**

☐ The individual has certain communication impairments that limit the subject's ability to clearly express consent **or**

☐: Situations where the IRB requests a witness be present: please specify _____

I confirm that the information in this consent form was accurately explained to the subject, parent or legally authorized representative, the individual appeared to understand the information and had the opportunity to ask questions, and that informed consent was given freely.

☐ _____ _____

Date (MM/DD/YEAR) Signature of Witness

Or

☐ The individual is not English speaking and, through an interpreter, a short form consent document was presented orally to the subject or legal representative and this consent document serves as the summary for such consent.

I confirm that the information in this consent form was presented orally to the subject, parent or legally authorized representative, in a language they could understand and the individual had the opportunity to ask questions.

☐ _____ _____

Date (MM/DD/YEAR) Signature of Witness and Interpreter