Feasibility of Povidone Iodine Decolonization among Orthopedic Trauma Surgery Patients

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INFORMED CONSENT DOCUMENT

Project Title: **Feasibility of Povidone Iodine Decolonization among Orthopedic Trauma Surgery Patients**

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This consent form describes the research study to help you decide if you want to participate. This form 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 as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- 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 are inviting you to participate in this research study because you are a patient at the University of Iowa Hospitals and Clinics and will be having surgery to fix your bones or joints (orthopedic trauma).

The purpose of this research study is to evaluate whether PROFEND (an over-the-counter povidone iodine antiseptic) can be used to prevent infections among orthopedic trauma patients and patients' opinions about using PROFEND.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 60 people will take part in this study conducted by investigators at the University of Iowa.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for approximately 24 hours on the day of your surgery or until you are discharged from the University of Iowa Hospitals and Clinics, if discharge occurs before 24 hours from surgery.

WHAT WILL HAPPEN DURING THIS STUDY?

1. The research assistant will use a cotton swab to swab the inside of your nostril before your surgery. This swab will be tested in the laboratory for *Staphylococcus aureus* bacteria, which is commonly found in people's noses.
2. Your nurse will apply PROFEND, a yellow antiseptic ointment, to the inside of your nose in the hour before your surgery.

3. After your surgery, in the evening, the research assistant will again use a cotton swab to swab the inside of your nose. This swab will be tested for *Staphylococcus aureus* bacteria.
4. After your surgery, your nurse will apply a second dose of PROFEND to the inside of your nose, timed approximately 12 hours after your first dose.
5. Approximately 24 hours after your first dose of PROFEND, the research assistant will come to your bedside and swab the inside of your nose with a cotton swab. This swab will also be tested for *Staphylococcus aureus* bacteria. This is the last nasal swab we will collect.
6. The research assistant will ask you to fill out a short questionnaire to tell us about how you felt when PROFEND was applied to your nose. You may skip any questions you prefer not to answer.
7. If you are discharged from the University of Iowa Hospitals and Clinics before the research assistant comes to see you approximately 24 hours after your first dose of PROFEND, the research assistant will attempt to call you at home by telephone. The research assistant will read the questionnaire over the phone to you. You may skip any questions you prefer not to answer or decline to participate in the questionnaire.
8. A research assistant will review your medical record for the following information: medical record number, age, date of admission, date of procedure, type and location of procedure, procedure codes, a description of your operative site, *S. aureus* found in nose, other nasal ointments given, antibiotics received, date of discharge, where the patient was discharged to, whether the patient developed a surgical site infection within 90 days of the procedure, details about the surgical site infection, and death within 90 days. This information will be used to determine whether the application of PROFEND has been beneficial.

Your information and biospecimens collected as part of the research, even if identifiers will be removed, will not be used or distributed for future research studies. Specimens will not be used for commercial profit or to complete whole genome sequencing.

WILL I BE NOTIFIED IF MY BIOSPECIMENS RESULT(S) IN AN UNEXPECTED FINDING?

The results from the nasal swab we collect in this research study are not the same quality as what you would receive as part of your routine health care. The nasal swab culture results will not be reviewed by a physician who normally reads such results. Due to this, you will not be informed of any unexpected findings. The results of your nasal swab culture will not be placed in your medical record with your primary care physician or otherwise. If you believe you are having symptoms that may require care, you should contact your primary care physician.

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.

Rare (less than 10%) – 1 to 2% of people who have used PROFEND reported the following side effects:

- Itching (pruritus)
- Slight burning feeling in the nose
- Cough
- Runny nose (rhinorrhea)
- Skin rash

Profend has a mild medicinal/iodine scent.

There is also a risk of loss of confidentiality of data. Measures in place to protect confidentiality are indicated in the 'What About Confidentiality' section below.

WHAT ARE THE BENEFITS OF THIS STUDY?

We don't know if you will benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because use of PROFEND may help prevent infections after the surgical repair of broken bones.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

Before you decide whether or not to be in this study, other options may be available to you. Instead of being in this study, you could request that your physician order a *Staphyloccocus aureus* nasal screening swab and, if that result is positive, prescribe mupirocin, a different ointment that can treat *S. aureus* nasal colonization. The PROFEND product used in this study is only available through participation in this study because the product has been donated by the manufacturer.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any additional costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will not be paid for being in this research study.

WHO IS FUNDING THIS STUDY?

PDI Healthcare is funding this research study. This means that the University of Iowa is receiving payments from PDI Healthcare 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 PDI Healthcare for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

- If you are injured or become ill from taking part in this study, medical treatment is available at the University of Iowa Hospitals and Clinics.
- The University of Iowa does not plan to provide free medical care or payment for treatment of any illness or injury resulting from this study unless it is the direct result of proven negligence by a University employee.
- If you experience a research-related illness or injury, you and/or your medical or hospital insurance carrier will be responsible for the cost of treatment.

WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that 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.

- federal government regulatory agencies,
- the U.S. Food and Drug Administration and the sponsor, PDI Healthcare,
- auditing departments of the University of Iowa, and

- the University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

In the future, PDI Healthcare may continue to use your health information that is collected as part of this study. For example, PDI Healthcare may combine information from this study with the results of other studies to re-analyze the safety and effectiveness of the study medication, to evaluate other products or therapies, to develop a better understanding of a disease, or to improve the design of future research studies. PDI Healthcare may also share information from the study with regulatory agencies in foreign countries.

To help protect your confidentiality, we will use a descriptor such as "P01-MMDD" (MM: numerical month, DD: numerical day) to label any data, documents, or specimens. Your name or other identifying information will not be used. The hard copy records (the survey and consent form) will be a locked cabinet inside a locked office. The medical record collected will be stored in a password-protected, access-restricted shared network drive that is only accessible by members of the research team. The nasal swabs will be destroyed after any cultures grow and the results will be stored with in the network drive as well. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

The University of Iowa Hospitals and Clinics generally requires that we document your participation in research occurring in a University of Iowa Health Care facility. This documentation will be in either your medical record or a database maintained on behalf of the institution reflecting that you are participating in this study. The information included will provide contact information for the research team as well as information about the risks associated with this study. We will keep this Informed Consent Document in our research files; it will not be placed in your medical record chart.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WILL MY HEALTH INFORMATION BE USED DURING THIS STUDY?

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires your health care provider to obtain your permission for the research team to access or create "protected health information" about you for purposes of this research study. Protected health information is information that personally identifies you and relates to your past, present, or future physical or mental health condition or care. We will access or create health information about you, as described in this document, for purposes of this research study and for your treatment. Once your health care provider has disclosed your protected health information to us, it may no longer be protected by the Federal HIPAA privacy regulations, but we will continue to protect your confidentiality as described under "Confidentiality."

We may share your health information related to this study with other parties including federal government regulatory agencies, the University of Iowa Institutional Review Boards and support staff, or the study sponsor PDI Healthcare.

You cannot participate in this study unless you permit us to use your protected health information. If you choose *not* to allow us to use your protected health information, we will discuss any non-research

alternatives available to you. Your decision will not affect your right to medical care that is not research-related. Your signature on this Consent Document authorizes your health care provider to give us permission to use or create health information about you.

Although you may not be allowed to see study information until after this study is over, you may be given access to your health care records by contacting your health care provider. Your permission for us to access or create protected health information about you for purposes of this study has no expiration date. You may withdraw your permission for us to use your health information for this research study by sending a written notice to **Dr. Marin Schweizer, Institute for Clinical and Translational Science, 200 Hawkins Dr, Iowa City, IA, 52242.** However, we may still use your health information that was collected before withdrawing your permission. Also, if we have sent your health information to a third party, such as the study sponsor, or we have removed your identifying information, it may not be possible to prevent its future use. You will receive a copy of this signed document.

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. 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 HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: **Sandra Cobb (319) 353-6247.** If you experience a research-related injury, please contact: **Loreen Herwaldt (319) 356-8150.**

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://hso.research.uiowa.edu/. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

This Informed Consent Document 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 signing this Informed Consent Document. 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 copy of this form.

Subject's Name (printed): _____

_____ _____
(Signature of Subject) (Date)

Statement of Person Who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

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