INFORMED CONSENT DOCUMENT

Project Title: **Povidone-iodine to Stop Access-related Infections and Transmission of Staphylococcus aureus (PAINTS)**

Principal Investigator: Loreen Herwaldt (319) 356-8150

Research Team Contact: Melissa Ward (319) 384-8284

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 getting outpatient dialysis treatment at a dialysis center.

The purpose of this research study is to see if applying Povidone-iodine (PVI), on the inside of the nose of people getting dialysis, can reduce the spread of a type of bacteria called *Staphylococcus aureus* (Staph).

About 25% of all people carry the bacteria called Staph in their noses. This usually doesn't hurt you but having Staph in your nose increases your chances of getting a Staph infection while on dialysis. Nasal PVI has already been used to prevent Staph infections after surgery and in the intensive care unit. During this research study, we will ask patients receiving dialysis to use nasal PVI at the beginning of every dialysis session and we will monitor their health to see if they get any infections.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 150 people will take part in this study conducted by investigators at the University of Iowa. Approximately 2000 people will participate in this study at four other locations across the country**.**

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last until the end of the study in April 2023 or until your dialysis treatment is no longer needed. If you agree to participate in this study, we will ask you to use nasal PVI at the beginning of every dialysis session. It will take about 3 minutes to put the nasal PVI in your nose for each hemodialysis session.

WHAT WILL HAPPEN DURING THIS STUDY?

After you give verbal consent to take part in this study:

1. You will be given a bottle of nasal PVI and 4 applicators and directions on how to apply the PVI during each dialysis session. You will also be given the option to bring the PVI home to use before your dialysis session. However, prisoners will not have this option. The research team member will teach you how to apply the nasal PVI using the following steps:
    a. Blow your nose with a tissue (throw away the tissue).

    b. Dip the first applicator into the bottle, place the applicator in the bottom part of your nostril and gently rub the inside of one lower nostril for 15 seconds. Then tilt the applicator toward the inside front tip of your nostril and gently rub the nasal PVI there for another 15 seconds. Don't insert the applicator beyond the flared part of your nostril. Throw away the first applicator.

    c. Dip the second applicator in the bottle and apply the nasal PVI to your other nostril. Gently rub the inside of the lower nostril for 15 seconds then tilt the applicator toward the inside front tip of your nostril and gently rub the nasal PVI there for another 15 seconds. Throw away the second applicator.

    d. Dip the third applicator in the bottle and repeat step b. Throw away the third applicator.

    e. Dip the fourth applicator in the bottle and repeat step c. Throw away the fourth applicator.

    The total time to apply nasal PVI to both nostrils is 2-3 minutes.

2. A member of the research team will also review your medical record to see if you receive treatment for infections while undergoing dialysis. This information will be used to determine if the nasal PVI is preventing bloodstream infections.

3. If you would like help applying the nasal PVI, you can ask the nurse to help you or the nurse can also do it for you. We encourage you to use the nasal PVI before every dialysis session so that we can see if using the nasal PVI works to prevent infections.

4. The inside of your nose may look yellow after using nasal PVI.

WILL I BE NOTIFIED IF MY DATA RESULTS IN AN UNEXPECTED FINDING?

The results from the **data** we collect in this research study are not the same quality as what you would receive as part of your routine health care. The **data** 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 **data** 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 nasal PVI reported the following side effects:

- Itching
- Slight burning feeling in the nose
- Cough
- Runny nose
- Skin rash
- Hives (less than 1% reported)

Nasal PVI has a mild medicinal/iodine scent. You may also experience yellow-colored nasal mucous after using nasal PVI. The yellow color will fade in a few hours.

There is also a risk of loss of confidentiality of data. Measures in place to protect your 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 if nasal PVI is found to help decrease infections in people who receive dialysis treatment.

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 prescribe nasal iodine or a medicine called mupirocin, which is a different ointment that can treat staph in the nose.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study. You and/or your medical/hospital insurance carrier will remain responsible for your regular medical care expenses.

WILL I BE PAID FOR PARTICIPATING?

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

WHO IS FUNDING THIS STUDY?

The Agency for Healthcare Research and Quality (AHRQ) is funding this research study. The company 3M is donating the nasal iodine. This means that the University of Iowa is receiving payments from AHRQ to support the activities that are required to conduct the study. The University of Iowa is not receiving payment from 3M. No one on the research team will receive a direct payment or increase in salary from AHRQ or 3M 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 sponsor AHRQ may also inspect any part of your medical record for the purposes of auditing the conduct of the study.
- auditing departments of the University of Iowa, and
- the University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

To help protect your confidentiality, we will create a Study ID (code number) for you. We will label any data we collect with this Study ID and keep a separate log linking the Study ID to your identifying information. When the research study is complete, this log will be destroyed. 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. A copy of the informed consent document will be available on this website. 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 University of Iowa Healthcare 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. 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, and the sponsor AHRQ may also inspect any part of your medical record for the purposes of auditing the conduct of the study.

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 healthcare 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. Loreen Herwaldt
University of Iowa Healthcare
200 Hawkins Dr.
C 327-1 GH
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.

Before each dialysis session, you may say if you want to use the nasal iodine on that day. If you choose to not use the iodine, you won't be penalized or lose any medical benefits for which you otherwise qualify. If you think that you have an allergy or sensitivity to iodine, you can say no to receiving nasal iodine.

What if I Decide to Drop Out of the Study?
If you decide to leave the study early, we will ask you to fill out a short form explaining your reason for withdrawing from the study. You may decline to fill out the form if you choose.

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 researchers might decide to end your participation in this research study earlier than planned. This might happen because you are or became pregnant. If you discover that

you are pregnant after giving your consent to participate in this research please stop using the nasal PVI during your dialysis sessions. This is because nasal PVI has not been extensively tested in pregnant women.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: **Loreen Herwaldt at 319-356-8150 or loreen-herwaldt@uiowa.edu.** If you experience a research-related injury, please contact: **Loreen Herwaldt at the above information**.

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.

Check the method by which consent is being obtained:

□ Consent is being obtained in person or by mail after a discussion between a research team member and the subject. (Research team member signs below.)

Statement of Person Who Obtained Consent

(This line is only to be signed by a research team member after discussion with subject.)

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)