INFORMED CONSENT DOCUMENT

Project Title: **Reducing Perioperative S. aureus Transmission via use of an Evidence-Based, Multimodal Program Driven by an Innovative Software Platform (OR PathTrac)**

Principal Investigator: Randy Loftus

Research Team Contact: Dr. Randy Loftus
Telephone: (319) 356-3849 or (603) 306-6475

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 having surgery with regional/general anesthesia.

The purpose of this research study is to evaluate an investigational approach to preventing the spread of bacteria between patients having surgery so that infections can be prevented.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 2800 patient subjects 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 include up to 10 days before surgery through 90 days after your surgery.

WHAT WILL HAPPEN DURING THIS STUDY?

Your care will not be changed due to participation in this study, and you will undergo regional/general anesthesia and surgery according to usual practice.

You will receive a home kit via the mail for the purpose of sampling your nose, armpits, and groin (bikini lines). We will ask that you use the kit to sample your nose, armpits, and groin (bikini lines) at home according to the instructions provided. Sampling of your nose will involve use of a sterile nasal swab to gently sample the front part of each nostril. The swab will be gently inserted into your nostril and rotated ten times. A sterile swab will also be placed gently onto each of your armpits and groin creases (bikini line) and rotated ten times. A sample from your skin outside of your surgical dressing will also be taken with a sterile swab.

You may or may not be provided with disinfection agents (povidone iodine and chlorhexidine) for your nose and surgical site on the day of surgery in the Day of Surgery Admissions(DOSA) area, depending on which group you are assigned to. The surgical team will approve and guide the application of the povidone iodine to the likely surgical incision site(s) or it will not be placed. The application of the povidone iodine to the inside of the nose will be guided by a member of the research team. The chlorhexidine cloths will be used by the patient to sanitize their body after receiving education on how to use the wipes from a member of the research team.

On the day of surgery and within the first 48 hours of your recovery prior to discharge, specimens from various places in your hospital environment will be sampled. When you are under anesthesia, another three samples, just like the home kit, will be obtained, and those samples will be repeated once again when you are in your recovery area.

Your medical record will be reviewed for 90 days after the surgery, for occurrence of infection.

Information from your medical record that will be collected by the study team includes your name with your assigned case-log ID and swab kit, your medical record number, date and time of surgery, your diagnosis, ASA status (a system for assessing the fitness of patients before surgery), age, comorbidities (the presence of one or more additional diseases or disorders co-occurring with (that is, concomitant or concurrent with) a primary disease or disorder), surgery type and duration, type of anesthesia provided, operating room number, gender, dirty or infected surgery (yes/no), preoperative location, postoperative location, and duration of anesthesia.

We will not be giving subjects results of the swabs or cultures.

Specimen Storage for Future Use

As part of this study, we are obtaining culture bacterial specimens from you. We would like to study your bacterial specimens in the future, after this study is over.

The tests we might want to use to study your specimens may not even exist at this time. Therefore, we are asking for your permission to store your specimens so that we can study them in the future. These future studies may provide additional information that will be helpful in understanding infection pathogens but it is unlikely that what we learn from these studies will have a direct benefit to you. It is possible that your specimens might be used to develop products or tests that could be patented and

licensed. There are no plans to provide financial compensation to you should this occur.
Your specimen will be stored *without* your name or any other kind of link that would enable us to identify which sample(s) are yours. Therefore, if you give permission to store your specimen, it will be available for use in future research studies indefinitely and cannot be removed.

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

My bacterial specimen may be used for future infection research.

_____ Yes _____ No

My bacterial specimen may be stored/shared for future research studies

_____ Yes _____ No

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.

- If you receive a povidone-iodine antiseptic to clean your nose or chlorhexidine wipes to clean your body, there is a small chance you could experience redness and burning or itching in the area where the medicine is applied. There is a very rare, but possible chance, that you could have an allergic reaction which could involve itching or hives, swelling in your face or hands, swelling or tingling in your mouth or throat, chest tightness or trouble breathing.
- Your information will be accessed for the purpose of this study; however, this is not expected to have any financial, legal, or social impact on you. We do not expect that this study will not have a negative emotional and psychological impact on you.
- There is a very small risk of unintended disclosure of personal information. Our protocol for maintaining confidentiality of records will be strictly adhered to.

WHAT ARE THE BENEFITS OF THIS STUDY?

We do not know if you will benefit from being in this study.

The results of this study could possibly benefit society by changing healthcare practice. This research could eventually lead to a decrease in the transmission of pathogens during the perioperative period resulting in decreased patient morbidity and mortality, and decreased healthcare costs.

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?

The Anesthesia Patient Safety Foundation and the Department of Anesthesia at the University of Iowa Hospitals and Clinics are funding this study.

This research study will test software created by RBD Bioinformatics. Dr. Loftus, the person running this medical research study, started the company and has equity in the company. The amount of money the company is worth could be affected by the results of this study. This means that Dr. Loftus could gain or lose money depending on the results of this research study.

The University's Conflict of Interest in Research Committee has reviewed the financial interest related to this study and developed a plan to manage it. The plan requires that you be informed of the financial interest in this consent form. If you would like more information, please ask the researchers or the study coordinator.

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

To help protect your confidentiality, we will only view medical information specifically need for this project. No information will be shared within the research team other than for study purposes. No information will be discussed outside the study team. Paper forms will not be labeled with directly

identifying information. The material will be in the possession of a study team member unless securely stored in the principal investigator's office. Electronic files will be maintained on a password protected desktop computer which stays within the principal investigator's locked office. The file linking your information will be kept in a separate file from other subject data. Specimens will be labeled with a study ID and not with a patient name or hospital ID. Specimens will be in the possession of a study team member. The Research Team will review subjects' charts for positive specimens. At no point will personal identification information be attached to the specimen. 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.

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. 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.

You cannot participate in this study unless you permit us to use your protected health information and use bacteria collected for infection control advancements in knowledge, procedures, and/or devices designed to reduce risk of bacterial spread and infection. 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. Randy Loftus, University of Iowa Hospital & Clinics, Department of Anesthesia.
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 Institutional Review Board, 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.

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.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Dr. Randy Loftus (319) 356-3849. If you experience a research-related injury, please contact: Dr. Randy Loftus (319) 356-8349 or (603) 306-6475.

If you experience a research related injury, please contact the main operator at the University of Iowa: 1-800-777-8442 & ask to speak to Anesthesia Resident on Call.

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): _____

Do not sign this form if today's date is on or after EXPIRATION DATE: 07/24/20.

_____ _____

(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)