INFORMED CONSENT DOCUMENT

Project Title: **Epicenters for the Prevention of Healthcare Associated Infections (HAIs) -- Volume of Contamination and Nosocomial Infection Control: Specific Aim II.1**

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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 healthcare worker at University of Iowa Hospitals and Clinics.

The purpose of this research study is to assess whether applying Provodine™ to hands protects against self-contamination during personal protective equipment (PPE) removal.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 40 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 about 30 minutes,

WHAT WILL HAPPEN DURING THIS STUDY?

- You will perform hand hygiene with an alcohol-based hand rub as you normally would in clinical practice then put on a gown and gloves (personal protective equipment [PPE]).
- The research assistant will apply either the bacteriophage MS2 or *S. marcescens* ATCC 14756, which are not harmful to people, to the palms of each gloved hand.

- You will then remove the PPE.
- The research assistant will have you rinse your hands for 60 seconds in a sterile baggie that contains liquid culture medium.
- You will then rinse and dry your hands to remove the culture medium and then rinse your hands with 70% ethanol.
- You will then apply the Provodine™ – an FDA approved hand hygiene product -- to your hands and then put on fresh PPE.
- The research assistant will apply the same organism to your PPE.
- You will remove this PPE and repeat the hand rinsing in the baggie containing culture medium. The study will take place in the Molecular Epidemiology and Fungus Testing Laboratory, 273 MRC.
- *HIPAA INFORMATION*: Your health information will not be used

WHAT ARE THE RISKS OF THIS STUDY?

You may experience the risks indicated below from being in this study. In addition to this, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

There is a risk the Provodine™ may cause mild skin irritation consisting of redness, pain, swelling, or itching where the Provodine was applied. Very rare side effects requiring immediate medical attention include severe itching, hives, swelling in the hands or face, swelling or tingling in the mouth or throat, chest tightness, or trouble breathing.

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit from being in this study. However, we hope that, in the future, other people might benefit from this study because this study may help us identify ways to decrease self-contamination while removing personal protective equipment and, thereby, possibly decrease the risk of transmission of infectious diseases from patient to healthcare worker.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

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

WILL I BE PAID FOR PARTICIPATING?

You will receive compensation for participating in this study.

You will receive a $30 gift card after you complete both sets of hand cultures. You will be able to choose between gift cards from several merchants.

WHO IS FUNDING THIS STUDY?

The US Department of Health & Human Services, Centers for Disease Control & Prevention is funding this research study. This means that the University of Iowa is receiving payments from US Department

of Health & Human Services, Centers for Disease Control & Prevention 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 US Department of Health & Human Services, Centers for Disease Control & Prevention 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,
- 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 not link healthcare workers' identities to specimens collected. We will assign each participant a study number but we will not link that to the healthcare workers' names. The hand cultures will be labeled with the healthcare workers' study numbers. Hard copy records will be kept in a locked file cabinet in a locked office in the Molecular Epidemiology and Fungus Testing Laboratory or in SW 54Q GH, which will be accessible only to the investigators. Electronic data will be stored on password protected computers in a folder that only the investigators can access. The cultures and the culture results will be labeled with a study number not with your name. There will be no link from your name to the study number. 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 in the medical record 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.

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: **Dr. Loreen Herwaldt, 319-356-8150, or Ms. Melissa Ward, 319-384-8284 (melissa-ward@uiowa.edu).** If you experience a research-related injury, please contact: **Dr. Loreen Herwaldt, 319-356-8150, or Ms. Melissa Ward, 319-384-8284 (melissa-ward@uiowa.edu).**

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: 01/04/20.

_____ _____

(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)